



LATEST NEWS ISRAEL BACKS LARGER DEPLOYMENT OF PALESTINIAN FORCES



### Top News

Reuters top ten news stories delivered to your inbox each day.

[Subscribe](#)

Broker Center sponsored links

**FREE \$50,000**

¥ € \$ - Learn. Practice. Trade.



Learn to Trade with a FREE Guide.



\$0 stock tra

You are here: [Home](#) > [News](#) > [Health](#) > Article

[HOME](#)

[BUSINESS & FINANCE](#)

[NEWS](#)

[U.S.](#)

[Politics](#)

[International](#)

[Technology](#)

[Entertainment](#)

[Sports](#)

[Lifestyle](#)

[Oddly Enough](#)

[Environment](#)

[Health](#)

[Science](#)

[Special Coverage](#)

[Video](#)

[Pictures](#)

[You Witness](#)

[Blogs](#)

[Reader Feedback](#)

**Do More With Reuters**

[RSS](#)

[Widgets](#)

[Mobile](#)

[Podcasts](#)

[Newsletters](#)

[You Witness News](#)

**Partner Services**

[CareerBuilder](#)

[Affiliate Network](#)

**Professional Products**

[Support \(Customer Zone\)](#)

[Reuters Media](#)

[Financial Products](#)

## More Information About Reports Of Byetta Use Being Linked To Acute Pancreatitis

powered by BlogBurst

POSTED: Tuesday, March 18, 2008

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

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

### March 2008 Article In FDA's *Drug Safety Newsletter* Discusses Two Cases In Detail

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

The quarterly issue of the FDA's online *Drug Safety Newsletter* [DSN] which was published on March 18, 2008 includes [an article about a postmarket safety review of Byetta \(Exenatide\) that associates this diabetes drug with acute pancreatitis.](#)

As background, one may recall that in October 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, which was approved by the FDA on April 28, 2005 to treat adults with type 2 diabetes.

As seen here, this March 2008 DSN article about Byetta builds upon those 30 reports of acute pancreatitis:

FDA has been monitoring cases of acute pancreatitis in its postmarketing review of adverse event reports associated with the use of [Byetta] exenatide. Spontaneous adverse event reports of acute pancreatitis were described in the Adverse Reactions section of product labeling. Further postmarketing review of [Byetta] exenatide identified additional cases of acute pancreatitis associated with use of the drug. The product labeling has been updated to include information about acute pancreatitis in the Precautions section of the label, and information for healthcare professionals has been posted on FDA's Web site. [Text of footnote 1: [Exenatide \(Byetta\) product labeling.](#)] This article, based on the review of 30 reports of acute pancreatitis, describes the postmarketing data that prompted the revision to product labeling and provides recommendations to healthcare professionals regarding this serious adverse event.

As an aside, one part of this FDA article about the suspected Byetta - pancreatitis link caused a double-take:

[Find a financial adviser](#)

[About Reuters](#)

Exenatide was originally identified in the saliva of the poisonous Gila monster lizard. Pancreatitis has been reported with envenomation with Gila monster saliva due to overstimulation of the pancreas. [Text of footnote 2: Sherman M. Therapeutic Venoms. US Pharm. 2005;12:33-36.]

Here are some of the details about these 30 postmarket reports of serious side effects in patients taking Byetta:

- From April 28, 2005, to December 31, 2006, FDA received 30 domestic reports of acute pancreatitis in patients who received [Byetta] treatment.
- In 21 of the 30 cases (70%), the patients were hospitalized.
- There were no fatalities and no cases describing a hemorrhagic or necrotizing pancreatitis event.
- Nineteen (63%) patients were female.
- The median age of patients described in the case reports was 60 years (range: 43-72 years).
- The median time to onset of symptoms of acute pancreatitis from the start of [Byetta] therapy was 34 days (range: 4-300 days).
- Twenty-seven cases (90%) reported one or more possible contributory factors, including concomitant use of medications that list pancreatitis among reported adverse events in product labeling, or confounding conditions such as obesity, gallstones, severe hypertriglyceridemia, and alcohol use.
- A dose-response relationship was observed in six patients who reported the onset or worsening of symptoms associated with acute pancreatitis soon after the dose of [Byetta] was increased from 5 mcg twice daily to 10 mcg twice daily.
- Twenty-two patients improved after [Byetta] therapy was discontinued, and 15 reports described the event as resolved at the time of the report.
- These findings suggested a strong temporal association between [Byetta] and acute pancreatitis.

In this March 2008 *Drug Safety Newsletter* article about Byetta one finds two reported cases discussed in some detail. Both of these selected case reports in this part of the article serve to show the temporal relationship between initiation of Byetta treatment or dose escalation and the onset of symptoms associated with acute pancreatitis. (Note: The first case has been presented previously in a medical journal article -- Denker PS, Dimarco PE. Exenatide (exendin-4)-induced pancreatitis: a case report. *Diabetes Care*. 2006;29(2):471.)

We will continue to watch the medical journals for reports of acute pancreatitis in association with the use of Byetta.

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

**Reuters.com:** [Help and Contact Us](#) | [Advertise With Us](#) | [Mobile](#) | [Newsletters](#) | [RSS](#)  | [Interactive TV](#) | [Labs](#) | [Reuters in SE](#)  
**Reuters Corporate:** [Copyright](#) | [Disclaimer](#) | [Privacy](#) | [Professional Products](#) | [Professional Products Support](#) | [About Reuters](#) |

**International Editions:** [Africa](#) | [Arabic](#) | [Argentina](#) | [Brazil](#) | [Canada](#) | [Chinese Simplified](#) | [Chinese Traditional](#) | [France](#) | [Germany](#)  
[Russia](#) | [Spain](#) | [United Kingdom](#) | [United States](#)

Reuters is the world's largest international multimedia news agency, providing investing news, world news, business news, technology news, headline market, and mutual funds information available on Reuters.com, video, mobile, and interactive television platforms. Reuters journalists are subject to disclosure of relevant interests.

NYSE and AMEX quotes delayed by at least 20 minutes. Nasdaq delayed by at least 15 minutes. For a complete list of exchanges and delays, please