Diabetes Drug Byetta Linked To Kidney Problems And Cases Of Renal Failure

October 2009 Byetta Label Change Follows Earlier Alert From U.K. About Kidney-Related Side Effects

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 3, 2009; see http://bit.ly/2AoN5P)

In March 2009 the Drug Safety Update Newsletter alerted us about reports of kidney-related side effects associated with the use of the diabetes drug Byetta (exenatide) from the U.K.

About eight months later, in early November 2009, the FDA informed doctors and other healthcare providers in the U.S. that it had approved revisions to the Byetta package insert, or label, so that it will now include information about numerous post-marketing reports of altered kidney function, including acute renal failure and insufficiency.

This move seemingly was prompted by reports of 78 cases of altered kidney function (62 cases of acute renal failure and 16 cases of renal insufficiency) in patients using Byetta that were received by the FDA from April 2005 through October 2008.

From the Information for Healthcare Professionals: Reports of Altered Kidney Function in patients using Exenatide (Marketed as Byetta) issued by the FDA on November 2, 2009, and the Data Summary part of that document in particular, we get these details:

> FDA has completed a review of 78 cases of altered kidney function reported in patients with diabetes using Byetta. The cases were reported to FDA's Adverse Event Reporting System (AERS) between April 28, 2005 and October 29, 2008. Sixty-two of the cases were classified as acute renal failure and 16 cases were classified as renal insufficiency. Cases of acute renal failure or insufficiency occurred as soon as 3 days and up to 2 years after initiation of Byetta. The patient ages ranged from 23 to 83 years, with an average age of 60 years.
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> The majority of patients, 74/78 (95%), had at least one contributory risk factor for altered kidney function, such as cardiac insufficiency, hypertension, pancreatitis, rhabdomyolysis, and urinary tract infection, as well as concomitant medications such as antiretrovirals, antihypertensives, diuretics, and non-steroidal anti-inflammatory drugs (NSAIDs)....
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> Hospitalization was required in 71 of 78 (91%) patients and there were 4 deaths reported in the cases reviewed. Eighteen patients required dialysis and two patients required kidney transplantation after initiation of Byetta. Of those patients who required dialysis, six had no prior history of altered kidney function, two had a prior history of altered kidney function, and the remaining 10 patients reported no information regarding prior renal history.
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> Byetta was discontinued in 63 of 78 (80%) patients, with 39 (50%) patients reporting improved signs and symptoms after discontinuation of the drug. One patient experienced recurrent altered kidney function after re-initiation of Byetta....
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> Due to the serious potential consequences of altered kidney function and temporal relationship between the development of renal effects and initiation of Byetta, FDA has approved revisions to the drug label for Byetta to describe this risk.

For the drug-company perspective concerning this Byetta label change about kidney-related side effects, we direct you to the October 2009 "Dear Doctor" letter from Amylin Pharmaceuticals Inc. and Eli Lilly and Co. which includes, as an enclosure, the "BYETTA® (exenatide) injection Full Prescribing Information (October 2009)".

We will continue to monitor and report about this emerging drug safety issue involving the diabetes medication Byetta.

P.S. On November 2, 2009 Amylin Pharmaceuticals, Inc., and Eli Lilly and Company issued their joint statement in response to the FDA on BYETTA® (exenatide) injection. (11/4/09)

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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