FDA Wants Studies Done On Byetta Safety, With Focus On Pancreatitis, Pancreatic Cancer, Thyroid Neoplasm, And Acute Renal Failure

FDA Letter About Byetta Sent To Amilyn In October 2009; Drug Company Tries To Downplay, But Investors React When They Learn About It In December 2009

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 6, 2010; see http://bit.ly/4N2PrE)

On October 30, 2009 Amylin Pharmaceuticals Inc. issued a press release, "BYETTA Approved for Expanded Use as First-Line Treatment for Type 2 Diabetes Prescribing Information Also Includes Updated Safety Information", in which they announced that the FDA had approved an expanded indication for BYETTA® (exenatide) injection:

> BYETTA is now approved for use as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Previously, it was approved for use only in patients who were also taking other common diabetes medications and had not achieved adequate glycemic control.

It was not until the end of December 2009, however, that we got the rest of the picture. From a December 23, 2009 *Bloomberg* article, "Amylin Falls as Analyst Says FDA Wants Byetta Study", by reporter Rob Waters:

> San Diego-based Amylin and Indianapolis-based Eli Lilly & Co., which co-market the drug, announced Oct. 30 that the Food and Drug Administration had cleared the drug for use as standalone therapy for Type 2 diabetics and that prescribing information would warn about the risk of pancreatitis, an inflamed pancreas, in patients with severe kidney disease. That statement didn't say the FDA wanted more studies.
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> Citigroup analyst Yaron Werber said today in a note to investors that he had obtained a copy of the FDA's approval letter and that the agency was requiring animal and human studies aimed at clarifying the risk of pancreatitis posed by the drug. A statement e-mailed by Lilly and Amylin today said most of the requested studies are under way and have shown no increased risk of pancreatitis in patients taking Byetta.
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> "The FDA considers post-marketing reports of acute pancreatitis (fatal and non-fatal hemorrhagic or necrotizing pancreatitis), acute renal failure and thyroid neoplasms as 'new safety information' and is requiring Amylin to conduct additional studies," Werber said in his note.
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> Amylin dropped $1.48, or 9.6 percent, to $13.97 at 4 p.m. in Nasdaq Stock Market composite trading, the most since April 2. The shares have gained 29 percent this year.

From the October 30, 2009 FDA letter to Amilyn sent by Mary Parks, M.D. -- who is the Director of the agency's Division of Metabolism and Endocrinology Products in the Center for Drug Evaluation and Research -- we get these relevant excerpts:

> Since Byetta (exenatide) was approved on April 25, 2005, we have become aware of postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, and postmarketing reports of acute renal failure, sometimes leading to death or transplantation, in patients taking Byetta (exenatide). We have also become aware of postmarketing reports of thyroid neoplasms associated with the use of Byetta (exenatide) and of a signal of thyroid neoplasms observed pre-clinically with other GLP-1 analogues. We consider this information to be "new safety information" as defined in section 505-1(b)(3) of the FDCA.
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> After consideration of this new safety information, we have determined that postmarketing requirements are needed to assess the risk of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, and the risk of thyroid neoplasms, and that a REMS is necessary for Byetta (exenatide) to ensure that the benefits of the drug outweigh the risks of acute pancreatitis and acute renal failure....

> We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to assess the signal of a serious risk of acute pancreatitis, including hemorrhagic or necrotizing pancreatitis, and the signal of a serious risk of thyroid neoplasms.
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> Furthermore, the new pharmacovigilance system that FDA is required to establish under section 505(k)(3) of the FDCA has not yet been established and is not sufficient to assess this serious risk.
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> Therefore, based on appropriate scientific data, FDA has determined that you are required, to conduct [several studies about these possible Byetta 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