Reclast "Dear Doctor" Letter For Kidney Problems Should Be Sent By Novartis In U.S.

Public Citizen March 2011 Letter To FDA Points To Aclasta Safety Alert Material Sent In Canada During October 2010

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 11, 2011; see http://bit.ly/hLxFAY)

To start, Reclast is the U.S. name for the zoledronic acid medication sold by Novartis; it is identical to Aclasta, which Novartis sells in Canada.

By means of a March 10, 2011 letter, the consumer advocacy group Public Citizen is asking the FDA to require that Novartis warn doctors and patients in the U.S. about an apparent association between the osteoporosis drug Reclast and potentially serious kidney problems, "including acute renal failure requiring dialysis which in some cases resulted in death."

In more detail, Public Citizen wants Novartis to send a so-called "Dear Doctor" letter to physicians in the U.S., now, similar to the one the drug company sent out in Canada back on October 12, 2010.

From that October 2010 letter about Aclasta which Novartis sent to healthcare professionals in Canada:

> The ACLASTA Product Monograph, has been revised to further emphasize precautions that should be taken into account to minimize the risk of renal adverse reactions:
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> • ACLASTA has been associated with renal dysfunction manifested as deterioration in renal function and in rare cases, acute renal failure.
> • Renal impairment has been observed following the administration of ACLASTA*, occasionally after a single administration.
> • Renal failure requiring dialysis or with a fatal outcome has occurred especially in patients with history of renal impairment or other risk factors. Risk factors include advanced age, concomitant nephrotoxic medicinal products, concomitant diuretic therapy or dehydration occurring after ACLASTA administration.
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> As of April 30, 2010 Novartis has received 265 spontaneous reports of renal impairment following administration of ACLASTA, corresponding to a reporting rate of approximately 20 cases per 100,000 patient-years of exposure.

Returning to the March 2011 Public Citizen letter about Reclast to the FDA:

> Clearly, the current warnings and precautions in the FDA-approved label for Reclast [accessed March 10, 2011] about the risk of renal impairment are not sufficient for making physicians adequately aware of this serious, life-threatening renal toxicity associated with Reclast, the very reason that the Canadian government convinced the company to initiate the additional warnings. Many physicians in the U.S. fail to read the labels for drugs and thus are unaware of the renal toxic effects of Reclast and the precautions that must be taken to avoid such toxicity.

Public Citizen also suggested that the FDA should require Novartis to issue in the U.S. an item similar to its October 14, 2011 Public Communication, "Association of ACLASTA(zoledronic acid 5 mg/100 mL) solution for intravenous infusion with kidney dysfunction", which has been issued in Canada, only, thus far.

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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