FDA Finds It Unlikely That Vytorin Or Zetia Increases Risk Of Cancer, But Such A Link Is Possible

December 2009 Update From FDA For Its August 2008 Early Communication About Safety Review of Ezetimibe / Simvastatin (Vytorin) And Ezetimibe (Zetia)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on December 22, 2009; see http://bit.ly/5LTwki)

On December 22, 2009 the FDA issued an update about its August 2008 Early Communication which described a possible association between the use of Vytorin – a combination of simvastatin (Zocor) and ezetimibe (Zetia) – and an increased risk of cancer and cancer-related death compared to placebo.

As you may recall, that August 2008 Early Communication was based on preliminary results from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial.

From the December 2009 safety update about Vytorin and Zetia, which is titled "Follow-Up to the August 2008 Early Communication About an Ongoing Safety Review of Ezetimibe/Simvastatin (marketed as Vytorin), Simvastatin (marketed as Zocor) and Ezetimibe (marketed as Zetia) - FDA Investigates a Report from the SEAS Trial":

> FDA has now completed its review of the data from the SEAS trial as well as a review of interim data from two large-scale ongoing cardiovascular trials with Vytorin - the SHARP and IMPROVE-IT trials. Based on the currently available information, FDA believes it is unlikely that Vytorin or Zetia increase the risk of cancer or cancer-related death, but at this time an association cannot be definitively ruled out.... [footnotes omitted]
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> The SHARP trial is placebo-controlled, but uses a lower dose of Vytorin (10/20 mg) than was used in the SEAS trial. The IMPROVE-IT trial compares Vytorin 10/40 mg to simvastatin 40 mg. An interim analysis of the cancer data from these two trials, which includes a total of 20,617 patients, did not show an increased risk of cancer with Vytorin. There was an increase in the number of cancer-related deaths, with 97 deaths in the Vytorin groups compared to 72 deaths in the control groups, but this finding was not statistically significant.
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> When completed, the SHARP and IMPROVE-IT trials will provide additional data to further assess cancer risk with simvastatin and ezetimibe. The SHARP trial is expected to be completed in 2010 and IMPROVE-IT in 2012.

As for other serious side effects which have been associated with Vytorin and Zetia, back in September 2008 we reported about two medical journal articles which described a case of liver disease involving Zeita and a case of liver failure possibly linked to Vytorin.

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