Zocor Label Change: Interstitial Lung Disease (ILD) Added As Possible Adverse Reaction

November 2010 FDA Approval Of Merck Action Raises Profile Of This Emerging Drug Safety Issue

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 15, 2010; see http://bit.ly/92yiAn)

As we reported recently, the October 2010 issue of the Canadian Adverse Reaction Newsletter (CARN) included an article titled "Statins and interstitial lung disease".

Now, in November 2010, the FDA has approved a Supplemental New Drug Application (sNDA) submitted June 16, 2010 by Merck & Co., Inc. -- under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) -- adding interstitial lung disease (ILD) to the "**ADVERSE REACTIONS, Post-Marketing Experience**, subsection of the Zocor package insert", or label.

As some of you may recall, we first wrote about this ILD lung disease side effect for Zocor in June 2010, when we pointed out an August 2008 article published by the *Chest* medical journal, "Statins and Interstitial Lung Disease: A Systematic Review of the Literature and of Food and Drug Administration Adverse Event Reports".

We will continue to monitor this emerging drug safety issue for Zocor (simvastatin) as well as the other statin drugs such as Pravachol (pravastatin), Lescol (fluvastatin), and Lipitor (atorvastatin).

If you or someone you know has developed interstitial lung disease (ILD) while using using Zocor or one of the other cholesterol drugs in the statin class, you may want to share your information by submitting a MedWatch report to the FDA.

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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