

[Health Canada And FDA Issue Adverse Reaction Updates In Second Half Of 2010 Which Involve Popular Drug Zocor \(Simvastatin\)](#)

Cases Of Interstitial Lung Disease (ILD) And Rhabdomyolysis / Myopathy Associated With Cholesterol Drugs Known As Statins, Including

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 5, 2010; see <http://bit.ly/d1qULL>)

The [October 2010 issue of the Canadian Adverse Reaction Newsletter \(CARN\)](#) included an article "Statins and interstitial lung disease" which began with these two "Key points":

During the last 15 years, 29 cases of interstitial lung disease (ILD) suspected of being associated with statins have been published.

Health Canada has received 8 adverse reaction (AR) reports of ILD, or pathologies associated with ILD, suspected of being associated with statins.

As background, drugs in the statin "class" include Zocor (simvastatin), Pravachol (pravastatin), Lescol (fluvastatin), and Lipitor (atorvastatin).

As for "what is" interstitial lung disease, also known as parenchymal lung disease, we return to the October 2010 CARN issue:

Interstitial lung disease (ILD) is a heterogeneous group of disorders that could be acute or chronic and, if left untreated, could lead to pulmonary fibrosis and pulmonary insufficiency. Signs and symptoms include difficulty breathing, nonproductive cough and diffuse crackles heard on auscultation. [footnotes omitted]

As pointed out by this Health Canada CARN publication, a systematic review of the suspected association between ILD and statins was published in a CHEST medical journal from 2008, "[Statins and interstitial lung disease: a systematic review of the literature and of food and drug administration adverse event reports.](#)"

About a month earlier, the FDA included Zocor on its latest list of possible drug safety concerns, "[Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System \(AERS\) between April - June 2010](#)" (Page Last Updated: 08/27/2010).

Specifically, the 80mg dose of Zocor (simvastatin) is listed for muscle injury, with this status: "FDA is continuing to evaluate this issue to determine the need for any regulatory action."

As you may recall, it was a March 2010 FDA Drug Safety Communication, "Ongoing Safety Review of High-dose Zocor (simvastatin) and Increased Risk of Muscle Injury", that initially indicated [the FDA is concerned about an increased risk myopathy and rhabdomyolysis -- which is sometimes called "rhabdo" as its short name -- in patients using the highest dose of Zocor, 80mg.](#)

We will continue to monitor the safety profiles of the statin drugs, and Zocor in particular, and report any significant developments, here.

Meanwhile, if you or someone you know has developed interstitial lung disease (ILD) while using a cholesterol drug in the statin class or suffered rhabdomyolysis (rhabdo) while using Zocor 80mg daily, you may want to share your experience or information by submitting a Comment, below.

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>