June 2010 Update On Several Possible Zocor (Simivastatin) Side Effects

From Myopathy And Rhabdomyolysis To Tendon Ruptures And Interstitial Lung Disease

(Posted by Tom Lamb at www.DruglnjuryWatch.com on June 7, 2010; see http://bit.ly/a0mGO4)

The June 2010 FDA Patient Safety News (PSN) includes a video report, "Muscle Injury from High Doses of Zocor", that informs us about a clinical trial which showed the risk of myopathy and rhabdomyolysis is much higher in patients taking 80 mg of Zocor (simvastatin) -- the highest approved dose -- than in those taking a 20 mg Zocor pill.

This FDA PSN video report is a follow-up to a mid-March 2010 FDA MedWatch Safety Alert regarding higher doses of Zocor being associated with an increased risk of serious side effects involving muscle injury. Further, the earlier MedWatch Alert about Zocor pointed out that its active ingredient, simvastatin, is also found in Vytorin, with Zetia, and Simcor, with Niacin.

Moving on, a May 29, 2010 article, "Researchers assess effects of statins on tendon rupture", describes an on-going medical study about whether Zocor and other statin drugs may be causing tendon ruptures:

Francesca Dwamena, an associate professor in the College of Human Medicine's Department of Medicine [at Michigan State University], is leading the study, which will analyze more than 100,000 Blue Care Network enrollees. The study is funded by a grant from the Blue Cross Blue Shield of Michigan Foundation....

While lowering cholesterol, statins [like Zocor] also inhibit certain proteins that are required for remodeling of tendons, she said. Without remodeling, tendons become very prone to injury and potential rupture.

Dwamena and her team seek to confirm the findings from a pilot study that found increased tendon ruptures in women. Before that study, statin-induced tendon rupture was only described in case reports and post-marketing studies. With a large population-based outlook, the researchers also will assess the effects of dose, duration and type of statin on tendon rupture.

Lastly, going back a couple of years, in August 2008 the medical journal *Chest* published an article, "Statins and Interstitial Lung Disease: A Systematic Review of the Literature and of Food and Drug Administration Adverse Event Reports", which discussed a possible relationship between statin drugs such as Zocor and interstitial lung disease. From the Abstract for this 2008 *Chest* article:

Conclusions Statin-induced interstitial lung disease is a possible newly recognized side effect of statin therapy. The mechanism of lung injury is not defined. The current review provides novel information from the FDA-AER that supports a possible, although unusual, pulmonary class effect of statins.

We will continue to watch for reports of myopathy and rhabdomyolysis as well as tendon ruptures and interstitial lung disease in patient using statins like Zocor or simvastatin.

If you have developed any of these possible Zocor side effects, or know about such a situation, you can submit a Comment, below, or <u>send me an email</u>.