March 2010: FDA Warns About Highest Dose Of Zocor Causing Myopathy And Rhabdomyolysis

Active Ingredient Simvastatin Is Found In Vytorin, With Zetia, And Simcor, With Niacin, Also

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 19, 2010; see http://bit.ly/dfXRK2)

On March 19, 2010 the FDA issued a News Release about Zocor (simvastatin) 80 mg pills which starts as follows:

> The U.S. Food and Drug Administration today warned patients and healthcare providers about the potential for increased risk of muscle injury from the cholesterol-lowering medication Zocor (simvastatin) 80 mg. Although muscle injury (called myopathy) is a known side effect with all statins, today's warning highlights the greater risk of developing muscle injury, including rhabdomyolysis, for patients when they are prescribed and use higher doses of this drug. Rhabdomyolysis is the most serious form of myopathy and can lead to severe kidney damage, kidney failure, and sometimes death.
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> Review of simvastatin is part of an ongoing FDA effort to evaluate the risk of statin-associated muscle injury and to provide that information to the public as it becomes available," said Eric Colman, M.D., Deputy Director of FDA's Division of Metabolism and Endocrinology Products (DMEP). "It's important for patients and healthcare professionals to consider all the potential risks and known benefits of any drug before deciding on any one therapy or dose of therapy."

For further information, the agency referred us to an FDA Drug Safety Communication, "Ongoing Safety Review of High-dose Zocor (simvastatin) and Increased Risk of Muscle Injury", also issued on March 19, 2010. From that document we learn the basis for this new Zocor warning from the FDA as well as more about myopathy and rhabdomyolysis -- which is sometimes called "rhabdo" as its short name:

> The clinical trial data being reviewed is from the **S**tudy of the **E**ffectiveness of **A**dditional **R**eductions in **C**holesterol and **H**omocysteine (SEARCH) trial. The agency is also reviewing data from other clinical trials, observational studies, adverse event reports, and data on prescription use of simvastatin to better understand the relationship between high-dose simvastatin use and muscle injury...
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> The muscle injury, also called myopathy, is a known side effect with all statin medications. Patients with myopathy generally have muscle pain, tenderness or weakness, and an elevation of a muscle enzyme in the blood (creatine kinase). The higher the dose of statin used, the greater the risk of developing myopathy....
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> The most serious form of myopathy is called rhabdomyolysis. It occurs when a protein (myoglobin) is released as muscle fibers break down. Myoglobin can damage the kidneys as they filter blood out of the body. Patients with rhabdomyolysis may have dark or red urine and fatigue, in addition to their muscle symptoms. Damage to the kidneys from rhabdomyolysis can be so severe that patients may develop kidney failure, which can be fatal.

Some additional information about the development of myopathy is set forth in an article, "High-Dose Simvastatin Associated With Increased Risk for Myopathy, FDA Warns", published March 19, 2010 by *Medscape Today* (free registration):

> Risk for myopathy may be linked to genetic heterogeneity in statin users. A study published in the October 20, 2009, issue of the Journal of American College of Cardiology found that carriers of the reduced-function single nucleotide polymorphism of the SLCO1B1 gene were at increased risk of

> developing mild statin-induced adverse effects, including myopathy and myalgia. The risk for adverse events was greatest among those treated with simvastatin, but minimal in those receiving pravastatin.

This *Medscape Today* article also points out that the FDA's "Potential Signals of Serious Risks/New Safety Information Identified by AERS, Second Quarter 2009" list of drugs included an item concerning a drug interaction between Zocor (simvastatin) and Cardizem (diltiazem) causing myopathy, included this statement:

> FDA is evaluating this issue to determine if simvastatin labeling, which includes myopathy, is adequate.

Going back to the March 2010 FDA Drug Safety Communication about Zocor, toward the very end, we find their position about the current simvistatin package insert, or label:

> Moreover, FDA has requested that the sponsor of simvastatin change the product labeling to instruct healthcare professionals to avoid prescribing simvastatin doses greater than 40 mg daily when patients are taking the medication diltiazem, due to an increased risk for myopathy.

We remind you that the FDA advises one should not stop taking any prescription drug, including Zocor, without first speaking to the doctor who prescribed it.

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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