June 2011 FDA Warning About 80 mg Dose Of Zocor, Simvastatin, And Vytorin Cholesterol Medications

Highest Simvastatin Dosage Linked To Potentially Fatal Rhabdomyolysis Muscle Injury And Kidney Failure

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 13, 2011; see http://bit.ly/mHapQy)

On June 8, 2011 the FDA announced dosing restrictions for pills containing 80 milligrams (mg) of simvastatin due to the determination these cholesterol drugs are associated, or linked, with an increased risk of developing myopathy and rhabdomyolysis, the latter medical condition a serious muscle injury usually requiring hospitalization, and that could lead to kidney failure, and, possibly, death.

For more information, see "FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury":

> **[06-08-2011]** The U.S. Food and Drug Administration (FDA) is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication, simvastatin (80 mg) because of increased risk of muscle damage....

Simvastatin is sold under the brand-name Zocor and as a single-ingredient generic product. It is also sold in combination with Zetia (ezetimibe) as Vytorin and in combination with Niacin as Simcor.

The FDA has revised the drug labels for Zocor, generic simvastatin pills, and Vytorin to include the new 80 mg dosing restrictions.

According to the FDA, there is a higher risk of developing rhabdomyolysis (sometimes just called "rhabdo") with the 80 mg dose of Zocor or simvastatin in two instances:

1. **during the first year using pill with 80 mg**, and;
2. when a Zocor 80 mg or generic simvastatin pill or Vytorin pill which contains 80 mg dose of simvastatin is **used in combination with patients taking calcium channel blockers, particularly Cardizem or generic diltiazem.**

The FDA also revised the labels for Zocor, generic simvastatin pills, Vytorin, and Simcor to include new dosing recommendations when these drugs are used with certain medications which combine to create a drug-drug interaction which may increase the level of simvastatin in the body, which can increase the risk for rhabdomyolysis, or rhabdo.

Simcor (simvastatin-niacin combination) is **not** available with the 80 mg dose of the simvastatin; its label / package insert / drug prescribing information will add the new simivastatin drug-drug interaction warning, only.

What is rhabdomyolysis?

Rhabdomyolysis is a rare but very serious condition. It occurs when muscles are damaged and muscle cell contents are released into the bloodstream. If not detected early and treated promptly, rhabdomyolysis may result in acute renal failure, kidney damage, or other organ damage which may be fatal.

What are the symptoms of rhabdomyolysis?

Patients who develop rhabdomyolysis can have several different symptoms, but most often complain about muscle aches involving their calves, back, or their entire body. In addition to this type of muscle pain, weakness, fever, nausea, vomiting, and passing of dark urine can occur.

For some important background facts about this June 2011 FDA action concerning Zocor and these several other simvastatin-containing pills, we turn to *Forbes*' pharmaceutical news reporter Matthew Herper and his two recent articles written for his column, The Medicine Show.

First, from his June 8, 2011 report, "FDA Limits High-Dose Zocor, Backing Earlier Concerns For Second-Most Prescribed Drug":

> **Controversy over whether the 80 mg Zocor dose caused more muscle problems** that competitors is ***not new***. In 2004, Cleveland Clinic cardiologist Steven Nissen, who sparred with Merck over the safety of the painkiller Vioxx (since withdrawn) and the efficacy of Zetia, the cholesterol drug that is the other ingredient in Vytorin, wrote an editorial in the Journal of the American Medical Association saying that the 80 mg dose of Zocor "was associated with an unusually high rate of myopathy." At the time, he told me [for my August 30, 2004 piece, "Cholesterol Study Poses Dangers For Merck",] that a Merck clinical trial using the 80 mg dose of Zocor had "pushed the dose of a good drug beyond its safe limits." [Emphasis added.]

Second, we get these **number-of-users** facts which show the extent of this *(not)* new drug safety issue about Zocor, generic simvastatin pills, Vytorin, and Simcor, from Herper's June 9, 2011 report, "The Scary Thing About the FDA's Simvastatin Decision"

Simvastatin Snapshot

	Number of prescriptions, 2010
All cholesterol drugs	253 million
simvastatin, all doses	94.3 m
simvastatin alone, 80 mg	11 m
Vytorin, all doses	8.6 m
Vytorin, 80mg	1.3 m
Simcor, all doses	0.94 m
Simcor, 80mg	0.18 m
All simvastatin, 80mg	12.4 m

Source: IMS Health

We have been monitoring the FDA's review of the Zocor 80 mg - rhabdomyolysis "link", which started back in March of 2010.

Our law firm is well-experienced in handling statin-induced rhabdomyolysis lawsuits based on our involvement with the Baycol litigation. Like Zocor, Baycol (cerivastatin) was a statin cholesterol drug; Baycol was recalled by the FDA and Bayer in August **2001** due to its association with an increased risk of developing rhabdomyolysis.

We are currently investigating and preparing to file rhabdomyolysis, or rhabdo, lawsuits against Merck and other drug companies involving Zocor 80 mg pills as well as generic simvastatin pills and Vytorin pills containing 80 mg simvastatin.

Of course, we will continue to report significant developments regarding this rhabdomyolysis - Zocor (simvastatin) drug safety alert issued by the FDA in June 2011.

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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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