# Industry Spotlight

## Cholesterol Drug Tied to Rhabdomyolysis

At high doses, the drug simvastatin (Merck, also known as Zocor), puts patients at risk of developing rhabdomyolysis, a severe breakdown of muscle that can result in acute kidney injury, dysfunction, and even death.

In mid-March, the Food and Drug Administation issued a warning message that patients taking the highest allowable dose of Zocor, 80 mg, had an increased risk for muscle injury. The FDA issued the news partly in response to findings from the trial Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH).

Known risk factors for developing rhabdomyolysis include age above 65 years old, low thyroid hormone levels (hypothyroidism), and poor kidney function.

According to the FDA, myopathy is a known side effect of all statin medications. In fact, Merck said warnings about myopathy have always been part of the drug information package. "The labeling for simvastatin has reflected information about potential muscle effects since approval," according to a Merck statement about the FDA announcement.

"Simvastatin, when used as a supplement to a healthy diet, can help reduce LDL cholesterol and reduce the risk of death from cardiovascular disease in patients at high risk of coronary events," said Michael Rosenblatt, MD, Merck's chief medical officer. "We support the FDA's recommendation that patients continue taking their medication as prescribed by their physicians, and that patients speak to their physician if they have symptoms or questions."

The company is working with regulatory agencies to update the drug's labeling as needed.

The FDA recommends that health care professionals:

- be aware of the potential increased risk of muscle injury with the 80 mg dose of simvastatin compared to lower doses of simvastatin and possibly other statin drugs.
- review patients' medical history and medications to determine whether simvastatin is clinically appropriate for each patient.
- discuss with patients the benefits and risks, including the risk of myopathy and rhabdomyolysis, of simvastatin therapy.
- be aware of potential drug-drug interactions with simvastatin.
- report any adverse events associated with the use of simvastatin to FDA's MedWatch program. Visit www.fda.gov for more information.

## Dialysis Company Owes U.S. $19.4 Million

In deciding a "whistleblower" case originally filed in St. Louis in 2005, a federal court in Nashville on March 23 awarded the United States $19,366,705, plus interest, says the U.S. Department of Justice. The U.S. District Court concluded that Renal Care Group, Renal Care Group Supply Company (RCGSC), and Fresenius Medical Care Holdings, which acquired Renal Care Group in 2005, "recklessly disregarded federal law when billing the Medicare program for home dialysis supplies and equipment from 1999 to 2005."

U.S. District Judge William J. Haynes, Jr., held that defendants disregarded the mandates of the applicable Medicare statutes and regulations. He said that Renal Care Group employees raised complaints and concerns about the operation and Medicare billing activity of the RCGSC.

According to *Nashville Business Journal*, in October 1998, the company's chief operating officer for the south central region protested a corporate request that "encouraged some dialysis patients to switch from primarily facility care to much more at-home care—in which they used fluids and a machine or catheter to provide their own treatment," because of higher federal reimbursement.

The court scrutinized Renal Care Group and RCGSC in light of the two tiers of payments that Medicare gives to dialysis companies. Companies that operate dialysis facilities are supposed to bill Medicare using "Method I," which applied to Renal Care Group. Companies that supply patients with dialysis at-home supplies but don't run dialysis facilities, like RCGSC, are paid under Medicare "Method II," which pays 30 percent more.

The court's order noted that Renal Care Group did not follow the advice of the company's lawyers when operating the supply company, and discussed an internal audit of the supply company that found that 100 percent of the company's files were missing information that Medicare required for billing the government program.

The court held that "reckless disregard is sufficient for liability" under the federal False Claims Act, and that specific intent to defraud was not a standard that had to be met.

Fresenius has appealed the District Court decision. "We disagree with the court's conclusion that payment by the government (Medicare program) of claims by Renal Care Group's Method II company constituted 'unjust enrichment,'" Fresenius spokeswoman Terry Morris said in a statement.