



## Diabetes Warning Issued for Statin Drugs

March 8, 2012 by **Patrick A. Malone**

A class of drugs called statins lowers blood cholesterol levels by reducing the production of cholesterol by the liver. Lipid regulators, which are primarily statin drugs, are the most commonly prescribed medication in the U.S., according to a report by the **IMS Institute for Healthcare Informatics**.

Last month the FDA acknowledged that statins may play a role in elevated blood sugar, as well as memory and cognition problems. It determined that the increased risk of diabetes was sufficient to warrant a warning on statin labels.

Although cholesterol is essential to normal cellular function, it also contributes to the development of atherosclerosis, a condition in which cholesterol-containing plaques form within arteries. They can become blood clots and cause angina (chest pain) and heart attacks. If the clot occurs in the brain, the result is a stroke.

Statin drugs are prescribed to prevent and treat atherosclerosis. The most common statin brands are Liptor, Lescol, Mevacor, Crestor, Socor and Pravacahol, among others. They can save lives, but, as always with prescription medicine, are not without risk.

Despite the additional warnings, according to a story by **ABC News and MedPage Today**, the FDA said it "continues to believe that the cardiovascular benefits of statins outweigh these small increased risks."

The agency backed away from an earlier recommendation that patients taking statins undergo routine liver function tests, but advised that their doctors order one before starting patients on statins. The FDA has determined that the risk of liver damage is rare, but unpredictable.

The diabetes warning is not surprising, given that **one trial** resulted in an increase of 27 percent in new onset of diabetes among patients taking statins. Those results were curious, because the study subjects were people without a history of cardiovascular disease—a so-called “healthy patient trial.”

At the time, the FDA approved the study drug (rosuvastatin) for prevention of cardiovascular problems, but the scientific community took note of its peripheral results.

Another study reported in the ABC/MedPage story, showed that hyperglycemia (elevated levels of blood sugar) occurred among patients taking atorvastatin, and analysis of 13 different statin trials yielded increased risk of diabetes in nearly 1 in 10 subjects.

The other concerns noted by the FDA were mostly the result of adverse event reports, which are made by patients, practitioners, pharmacists, etc., after a drug reaches the consumer market. The agency said they generally involved individuals older than 50 “who experienced notable, but ill-defined memory loss or impairment that was reversible upon discontinuation of statin therapy.”

A few days after the diabetes/memory loss warning issued, the FDA said certain statins—atorvastatin (Lipitor), rosuvastatin (Crestor) and simvastatin (Zocor)—might prompt negative interactions in patients taking drugs to treat HIV/AIDS or hepatitis C. The agency issued a warning about those drugs, and reiterated its warning about combining lovastatin (Mevacor) with HIV and HCV drugs.

The potential problem here is kidney damage. If you take these drugs, consult your doctor immediately about lowering the dose or making other alterations.

Practitioners greeted the diabetes warning-label decision with mixed feelings. Although some expressed support for relaxing the liver function test, they were concerned that patients would be scared away from the statins they need to control their cholesterol.

“All drugs have side effects and rarely some patients will have an odd reaction to statins—cognitive effects are among those—and are usually mild and resolve with stopping the medication,” said Dr. Harlan Krumholz of Yale University.

Dr. Steven Nissen of the Cleveland Clinic said “these are reasonable and prudent recommendations. I am pleased that FDA did not overstate the diabetes and cognitive function risks. Both problems are uncommon and don’t diminish the importance of statins in cardiovascular protection. For the vast majority of patients, the benefits far outweigh the risks.”

Patrick A. Malone  
Patrick Malone & Associates, P.C.  
1331 H Street N.W.  
Suite 902  
Washington, DC 20005

[pmalone@patrickmalonelaw.com](mailto:pmalone@patrickmalonelaw.com)  
[www.patrickmalonelaw.com](http://www.patrickmalonelaw.com)  
202-742-1500  
202-742-1515 (fax)

If you take a statin drug, or are considering it, discuss potential side effects with your doctor. Ask him or her if you can try behavioral therapies—diet and exercise—first. We're hardly alone in [questioning whether statins are too often the go-to drug](#) for practitioners. So if your doctor is unwilling to consider options, especially if you are not yet taking statins, it's time to get a [second opinion](#).

Patrick A. Malone  
Patrick Malone & Associates, P.C.  
1331 H Street N.W.  
Suite 902  
Washington, DC 20005

[pmalone@patrickmalonelaw.com](mailto:pmalone@patrickmalonelaw.com)  
[www.patrickmalonelaw.com](http://www.patrickmalonelaw.com)  
202-742-1500  
202-742-1515 (fax)