

# How FDA Changes Affect Statins

## SECTION OF PREVENTIVE CARDIOLOGY AND ATHEROSCLEROSIS IMAGING

April 2012

### A Word from the Director



Dear Colleagues,  
The FDA  
approved safety  
label changes  
related to  
statin therapy

on February 28, 2012 and I  
wanted to bring them to your  
attention.

Best regards,  
Michael Shapiro, D.O.

Brought to you by  
**OHSU Preventive Cardiology**  
with services including:

- Cardiac risk evaluation and intervention
- Lipid management
- Cardiac imaging
- Lifestyle modification (nutrition, smoking cessation, exercise counseling & prescription)

### Three FDA Label Changes for Statin Therapy

**1. Monitoring of liver enzymes:** To address the rationale for the routine monitoring of hepatic enzymes in patients taking long-term statin therapy, the FDA reviewed current monitoring guidelines, including the national Lipid Association's Liver Expert Panel Statin Safety Task Force recommendations. Because irreversible liver damage due to statin therapy is exceptionally rare and likely to be idiosyncratic and because no data are available to show that routine monitoring of liver enzymes identifies the rare individual who may develop significant liver injury from chronic statin therapy, the rationale behind such routine monitoring has now been called into question. The FDA reviewed post marketing data on statins and hepatotoxicity and found an incidence of serious liver injury to be less than 2 per one million patient years. After an extensive review of the data, they determined that despite a rising use of statins as a class since the late 1990's, there has been no detectable increase in the annual rates of fatal or severe liver injury likely to be related to statin use. **As a result, the new labels for all statins have been revised to recommend that baseline liver enzymes should be obtained in patients before they are started on statin therapy and as clinically indicated thereafter. Routine monitoring of liver enzymes is no longer recommended.**

**2. Cognitive adverse effects:** Occasional patients over the age of 50 experience notable, but ill-defined memory loss or impairment that resolves upon

(continued on back)

# How FDA Changes Affect Statins

## SECTION OF PREVENTIVE CARDIOLOGY AND ATHEROSCLEROSIS IMAGING

April 2012

For questions, please e-mail  
OHSU Lipid Clinic Director at  
[shapirmi@ohsu.edu](mailto:shapirmi@ohsu.edu)

discontinuation of statin therapy. The time to onset of such symptoms is variable. In some patients it is immediately noticeable, and in others, it may occur after years of therapy. There is no evidence of association of statin therapy with progressive dementia, including Alzheimer's disease. There is no clear correlation between any specific statin, statin dose, the patient's age or statin drug-drug interaction. **The above mental status changes are uncommon, but when they occur, one should consider drug withdrawal if no other obvious etiology for the mental status changes is identified. Under these circumstances, particularly when lipid-altering therapy is felt to be important in the patient's preventive cardiovascular care, a Lipid Clinic consultation should be considered.**

**3. Increases in hemoglobin A1C and fasting plasma glucose:** The Justification for the Use of Statins in Primary Prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER) reported an increased incidence of investigator-reported diabetes in rosuvastatin-treated versus placebo treated patients. A meta-analysis of 13 statin trials showed a 9% increased risk of incident diabetes with little heterogeneity between trials. **Based on the above data, statin labels now reflect that this category of medication may be associated with an increase in hemoglobin A1C and fasting plasma glucose. In general however, the beneficial effects of statin therapy in appropriately selected patients far outweighs the negative effects associated with a mild rise in hemoglobin A1C or fasting plasma glucose.**