

# Letter to the Editor: The Pundit Speaks

By Randolph M. Howes, M.D., Ph.D.

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## “Statins – Helpful Or Harmful?”

Drug manufacturers have set out to "statinize" the world with cholesterol-lowering medicines. The stakes are high as total sales of statins may approach \$1 trillion worldwide by 2020; the most commercially successful drug in history, atorvastatin (Lipitor®), had sales exceeding \$120 billion between 1996 and 2011. Estimates of the number of US adults who would be newly eligible for statin use under the new guidelines may reach 45 million. In other words, about 1 in 3 American adults overall, and perhaps as many as 1 billion worldwide, would be potential candidates for statin treatment. Certain studies show statins can be helpful in reducing mortality from cardiovascular (CV) events. In 2012, Kostis and colleagues published a meta-analysis of 18 randomized trials demonstrating a significant reduction in all-cause mortality and cardiovascular (CV) events in both men and women who were taking statins compared with those taking placebo or receiving usual care. However, a meta-analysis of randomized trials and observational cohort studies involving 13,622 elderly participants, over a quarter of whom were 80 years old or older, found insufficient data to make any recommendation regarding statin treatment in this population. To confuse the issue, there are hundreds of studies proving the adverse effects of statins, which includes everything from memory loss, to muscle problems to diabetes and increased cancer risk. Thus, many people are concerned that the new ACC/AHA guidelines would lead to indiscriminate use of statins as primary prevention in populations that might not substantially benefit from them, especially women and the elderly. Most of the increase in the number of American adults theoretically eligible for statins under the new guidelines would be observed among those without CVD—the fourth subgroup— or about 10.4 million new people. The ACC/AHA guidelines, like its predecessors, do acknowledge the limited data available in the elderly, specifically those older than 75 years old. Harm from taking statins are a major concern and previous statin users have reported numerous anecdotal experiences with potentially statin-related side effects, ranging from decreased cognitive ability and fatigue to diabetes and liver and kidney damage. However, the vast majority described myalgia (muscle pain) and rhabdomyolysis (muscle breakdown) thought to be related to statin use. The actual rate of statin-related myopathy has been debated at length is believed to be low. Among observational studies, in the Prediction of Muscular Risk in Observational Conditions (PRIMO) project, a cohort of unselected hyperlipidemic patients received high-dose statin therapy in ambulatory settings in France, and 10.5% of patients reported muscular symptoms, with a median time to onset of 1 month after statin initiation.

In the America that I love, we must use common sense and not blindly follow strong marketing campaigns. Please talk to your doctor frequently.

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