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Zetia And Vytorin: Steven Nissen Calls For A "Moratorium" On Their Use Due To Failed Study

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POSTED: Monday, January 14, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Long-Awaited Results Of ENHANCE Study Show Zocor + Zetia (= Vytorin) Does Not Improve Patient Outcomes

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

A January 14, 2008 *Bloomberg* article, "[Merck, Schering's Vytorin No Better Than Generic](#)", reported the long-awaited results of a study concerning Zetia and Vytorin as well as the immediate fall-out:

Merck & Co. and Schering-Plough Corp. said their combination cholesterol drug Vytorin worked no better than an older, generic medication in reducing the buildup of artery-clogging fat in a key study.

Steven Nissen, head of cardiology at the Cleveland Clinic in Ohio, immediately called for a "moratorium" on the use of Vytorin and Zetia. Vytorin is a combination of Zetia and simvastatin, the generic medication used in the trial. The two cholesterol drugs generated \$1.3 billion in third-quarter sales....

"In the absence of any evidence of a clinical benefit, these drugs should now be used as a last resort," said Nissen, who was not involved in the study, in a telephone interview.

Some basic information about the underlying study and its outcome was set forth in a January 14, 2007 *Dow Jones Newswire* piece, "[Merck: No Significant Difference Between Grps In ENHANCE Trial](#)":

ENHANCE was a surrogate endpoint trial conducted in 720 patients with Heterozygous Familial Hypercholesterolemia.

All analyses were conducted in accordance with the original statistical analysis plan. The primary endpoint was the mean change in the intima-media thickness measured at three sites in the carotid arteries (the right and left common carotid, internal carotid and carotid bulb)

between patients treated with ezetimibe/simvastatin 10/80 mg versus patients treated with simvastatin 80 mg alone over a two year period. There was no statistically significant difference between treatment groups on the primary endpoint. There was also no statistically significant difference between the treatment groups for each of the components of the primary endpoint, including the common carotid artery. Key secondary imaging endpoints showed no statistical difference between treatment groups.

[Schering-Plough issued a press release about the ENHANCE study results](#) -- oddly dated "Nov. 19, 2007" -- which announced:

Merck/Schering-Plough has submitted an abstract on the ENHANCE trial for presentation at the American College of Cardiology meeting, which will be held in March 2008, and is awaiting notification of acceptance from the College.

Vytorin is a combination of Zetia (ezetimibe) and simvastatin (brand name: Zocor). [There have been reports that Zetia may cause drug-induced hepatitis and liver failure.](#) The potential for Zetia to cause liver injury was first raised by Health Canada in February 2005. This drug-safety issue received renewed attention in December 2007 when an article in *The New York Times* suggested that Merck and Schering-Plough, in fact, knew about these Zetia side effects but that this information was withheld by the drug companies.

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