

The Truth  *About Health*

Vytorin Test Shows No Benefit over Lower Cost Drug, Results Suppressed

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In the past few weeks, it has been made known that drug companies Merck/Schering-Plough Pharmaceuticals have been suppressing the results of an important investigation into the effectiveness of their cholesterol reducing products. As a result, Senator Chuck Grassley (Iowa), a ranking member of the Committee on Finance, has raised some important questions to the drug makers regarding their failure to release results of the study and how this affected charges to the federal Medicaid program.

Both Merck/Schering-Plough recently released results of a study named ENHANCE. The purpose of this trial was to determine if the drug trade named Vytorin performed as well or better than lower priced generic statin drugs to reduce cholesterol levels. It has been reported that the companies have known the results of the study for 2 years but have not released the data until now.

Vytorin is a combination of two separate drugs in pill form aimed at controlling cholesterol in two ways. One of these drugs is known as an ezetimibe. This substance is aimed at controlling cholesterol levels by decreasing cholesterol absorption in the intestines. In theory, an ezetimibe drug should work to reduce plaque build-up in the arteries because the body will not absorb reduced levels of cholesterol from food. The second drug involved is known as a simvastatin. This drug functions by blocking an enzyme that is necessary for the body to make cholesterol and in so doing it is aimed at preventing cardiovascular disease from occurring.

The ENHANCE study involved testing Vytorin against a generic statin drug on 720 people who were known to have high levels of cholesterol production in their families. The test was conducted over a 2-year period. Analysis was done to determine the amount of plaque growth differences on artery walls between those taking Vytorin and subjects using the generic statin drug.

The result of the study recently announced by Merck and Schering-Plough is that, "There was no statistically significant difference between treatment groups." This is opposite of what the drug makers had hoped for and predicted.

The announcement drew a raft of concern in the media, which has now extended to Congress with Senator Grassley leading the way in calling for an explanation. This does not stem from a concern for patient safety as there were no adverse effects reported as a result of test subjects taking Vytorin. It has to do with the alleged fact that Merck/Schering-Plough knew the results of this study some 2 years ago and has been suppressing the results from the public during that entire time. The outrage has all to do with money.

"In Iowa City," said Sen. Grassley, "generic simvastatin costs \$54.54 for a month's supply while Vytorin costs \$112.46. It's fair to assume the public would have benefited from knowing that a less expensive drug works just as well. Instead, people in Iowa and elsewhere paid more for nearly 2 years while industry leaders sat on a scientific study that would have revealed this information." The Senator is also interested because during this 2-year period the Medicaid program has been

paying for the higher priced Vytorin and this has cost taxpayers a good deal of money.

It is estimated that Merck/Schering-Plough sold an estimated \$5 Billion worth of Zetia and Vytorin during this time. These are both ezetimibe drugs produced and sold by these companies.

Source: Merck/Schering-Plough Pharmaceuticals, Press Release, January 2008.

http://www.merck.com/newsroom/press_releases/product/2008_0114.html and the Office of Senator Chuck Grassley, the United States Committee on Finance. January 2008.

<http://www.finance.senate.gov/press/Gpress/2008/prg012408.pdf>