Popular Cholesterol Drug Causes Plaque in Arteries to Grow Almost Twice as Fast

According to a trial by Merck and Schering-Plough, Vytorin, has no medical benefits.

Vytorin, is a combination of two drugs, Zocor and Zetia, is prescribed to about 1 million people each week and accounts for about 20 percent of the cholesterol drugs on the U. S. market.

Drug company trials found that plaques in arteries grew nearly twice as fast in patients taking Vytorin than in those not taking Vytorin. The trials also show that Vytorin does not reduce heart attacks or strokes.

Dr. Steven Nissen, chairman of cardiology at the Cleveland Clinic, said, “This is as bad a result for the drug as anybody could have feared. Millions of patients may be taking a drug that has no benefits for them, raising their risk of heart attacks and exposing them to potential side effects.”

More than 100 million prescriptions for Zetia and Vytorin have been filled in the United States since the FDA approved them in November 2002 and August 2004 respectively.

These reports add to the controversy over Merck and Schering-Plough’s delays in releasing the results of the trial. The trial was completed in April 2006, with results scheduled to be released in March 2007. The companies, however, missed several deadlines, and only agreed to release the results after media outlets focused on their continued delays.

Reference: New York Times, “Drug Has No Benefit in Trial, Makers Say,” Alex Berenson, January 14, 2008.

Vytorin Update: Sep 2, 2008

Vytorin Cancer Study Blasted in New England Journal of Medicine Editorial

Vytorin is in trouble again. An editorial in the New England Journal of Medicine (NEJM) has blasted an analysis that dismissed the cholesterol drug's possible link to cancer. Concern about Vytorin and cancer surfaced in July, when the SEAS study was published, but since

The Report Provided by:
Ray Ellis
www.SaveYourHeart.com
rayellis@saveyourheart.com
1-800-280-5302

then, the makers of Vytorin have insisted that a higher incidence of cancer seen among patients taking the drug was an anomaly.

The SEAS study investigated the effects of Vytorin in patients with partial blockages of the aortic valve of the heart, known as aortic stenosis . According to the SEAS findings, Vytorin did little to help patients with aortic stenosis avoid other heart problems.

But even more disturbing, SEAS also found that Vytorin patients in the study had higher rates of cancer and cancer deaths. In the trial 102 patients taking Vytorin developed cancer, compared with 67 taking the placebo. Of those, 39 people taking Vytorin died from their cancer, compared with 23 taking placebo.

Merck and Schering-Plough downplayed the SEAS findings, however, by using an analysis of SEAS conducted by Richard Peto, an Oxford University statistician. According to an article in Forbes, Peto “pooled data from two much larger ongoing studies of Vytorin and said they showed that the cancer risk was a statistical fluke. He called the contention that Vytorin could cause cancer ‘bizarre’."

But the editors at the NEJM apparently aren't satisfied with those findings. A link to cancer deaths "should not be assumed to be a chance finding until further data are in," the editors wrote, adding that doctors and patients "are unfortunately left for now with uncertainty about the safety and efficacy of the drug."

Vytorin is a combination of cholesterol-lowering Zetia (ezetimibe) and the statin Zocor (simvastin). As mentioned in the NEJM editorial, some have theorized that Zetia could cause cancer because it blocks chemicals called plant sterols, which may cause heart disease but could also have some anti-cancer effect. Unfortunately, some experts feel that Zetia' potential cancer connection hasn't been studied enough.

"[Zetia] is certainly worthy of ongoing study, but it should not be used in clinical medicine until the justifiable and substantial cloud of uncertainty over it is resolved," Allen Taylor of the Walter Reed Army Medical Center, told Forbes.com.

For his analysis, which was published in this month's NEJM, along with the entire SEAS study, Peto lumped together data from two ongoing studies, SHARP and IMPROVE-IT, and found 97 cancer deaths on Zetia vs. 72 on placebo or Zocor. However, had he lumped the SEAS data together with SHARP and IMPROVE-IT, the cancer findings for Zetia would have become statistically significant.

The editors at the NEJM think he should have combined all three studies. Dr. Stephen Nissen, the prominent Cleveland Clinic cardiologists whose studies of drugs like Avandia

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www.SaveYourHeart.com
rayellis@saveyourheart.com
1-800-280-5302

have raised important safety issues, agrees. Nissen told Forbes that the cancer risk - along with a lack of evidence showing that either Zetia or Vytorin is more effective at stopping heart attacks than other cholesterol drugs - raises serious questions about whether either should be used.

It took years before a big study was launched to prove Vytorin does anything more to prevent heart attacks than statins alone --and it won't be done until 2012. In January, a smaller study, ENHANCE, found that Vytorin was no better at preventing clogged arteries than statins.

Nissen obviously feels more studies on Vytorin's effectiveness should have been done before it went on the market. But instead, Nissen told Forbes, "What they did was spend hundreds of millions of dollars annually on direct-to-consumer advertising."

Reference: http://www.fda.gov/Cder/Drug/early_comm/ezetimibe_simvastatin_SEAS.htm

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