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## PREVENTIVE MEDICINE IN THE NEWS

In light of the very widespread use of cholesterol lowering medications and antidepressants, recent new reports about the failure of medications used by millions of people are an urgent public health concern. Please see our three articles:

1. Zetia- and Vytorin doesn't work!
2. The Cholesterol hypothesis- does lowering cholesterol really prevent heart disease or not?
3. Antidepressants; more evidence of problems- less evidence of benefits. The "shelf effect"

As reported on the NY Times front page, Tuesday 1/15/08:

A clinical trial of Zetia, a widely used cholesterol drug raises doubts about both the medicine's effectiveness and the behavior of the pharmaceutical companies that conducted the study. Zetia, and a pill that contains Vytorin, failed to benefit patients in a two-year trial that ended in April 2006.

Merck and Schering, the company that markets the medication repeatedly missed their own deadlines for reporting the studies results. Thus, cardiologists around the world were waiting and wondering what the study would show and why it was not reported. At the same time, millions of patients have continued taking Zetia and Vytorin. Finally, a month after news articles reported the delay and Congress pressured the companies to disclose the study's findings, the results came out.

*Not only did Zetia fail to slow the accumulation of fatty plaque in the arteries, it actually seemed to contribute to plaque formation.*

Dr. Steven E. Nissen, the chairman of cardiology at the Cleveland Clinic, said the results were shocking. "This is as bad a result for the drug as anybody could have feared," said Dr. Nissen, an editor of the Journal of the American College of Cardiology. "Millions of patients may be taking a drug that does not benefit them, raising their risk of

heart attacks and exposing them to potential side effects. Patients should not be given prescriptions for Zetia unless all other cholesterol drugs have failed,” he said.

During the two years of the study, patients who took Zocor alone reduced their LDL (bad cholesterol) by 41 percent on average, while patients who took Vytorin reduced their LDL cholesterol by 58 percent. Yet despite the larger cholesterol reduction, patients taking Vytorin actually had more growth of fatty plaque in their carotid arteries than those on Zocor.

It is important to understand that Zetia does “work” to lower cholesterol and it did so in this study. This means that lowering Cholesterol may not be all that it’s cracked up to be. This study brings into question the “Cholesterol hypothesis”- the idea that elevated cholesterol leads directly to heart disease. Although this scientific hypothesis has never been clearly proven, it has become the holy grail of modern cardiology. See the next article in this newsletter to further understand that the link between cholesterol and heart disease, although seemingly no longer a debatable subject, is indeed still a subject of fierce debate in the scientific community.

Given the widespread use, billions in business that it means, and the aggressive marketing that accompanies cholesterol-lowering medications, the House Energy and Commerce Committee, is investigating the delay. “In light of today’s results, which were released nearly two years after the Enhance trial ended, it is easy to conclude that Merck and Schering-Plough intentionally sought to delay the release of this data,” Rep Stupak. D- Michigan, said in the statement.

Just 2 days after the results of the study showing the failure of Zetia and Vytorin, another article appears in the NY Times, which revisits the whole notion of a clear connection between elevated cholesterol and heart disease. It was entitled, *New Questions on Treating Cholesterol*

Top of form from NY Times: *New Questions on Treating Cholesterol*

For many years, the theory that lowering [cholesterol](#) is always beneficial has been a core principle of cardiology. It has been accepted by doctors and used by drug makers to win quick approval for new medicines to reduce cholesterol.

But now some prominent cardiologists say the results of two recent clinical trials have raised serious questions about that theory —

“The idea that you’re just going to lower LDL and people are going to get better, that’s too simplistic, much too simplistic,” said a leading cardiologist.

For patients and drug companies, the stakes are enormous. Cholesterol-lowering medicines, taken by tens of millions of patients daily, are the largest drug category worldwide, with annual sales of \$40 billion. Because the link between excessive LDL cholesterol and cardiovascular disease has been so widely accepted, the [Food and Drug Administration](#) generally has not required drug companies to prove that cholesterol medicines actually reduce heart attacks before approval.

(Editor's note- if you look carefully at the TV commercials you will often see the disclaimer in the commercial that the medication has not been proven to prevent heart disease - even though the message of the commercial seems to be that it does do that).

Cholesterol-lowering medications, therefore, have not had to conduct "events" trials beforehand. These studies would determine whether episodes like heart attacks are reduced.

So far, proof that a drug lowers LDL cholesterol has generally been enough to lead to approval. Only then does the drug's maker begin an events trial. And until the results of that trial are available, a process that can take several years, doctors and patients must accept the medicine's benefits largely on faith.

Doctors generally believe that the amount by which cholesterol is lowered, not the method of lowering it, is what matters. That continues to be the assumption. In the last 13 months, however, the failures of two important clinical trials have thrown that hypothesis into question.

In December 2006, Pfizer stopped development of a new experimental cholesterol drug torcetrapib, when a trial involving 15,000 patients showed that the medicine caused heart attacks and strokes. An essential point to be clear about is that the drug torcetrapib did lower LDL (bad) cholesterol while raising HDL, or good cholesterol. Torcetrapib's failure, Dr. Taylor said shows that lowering cholesterol alone does not prove a drug will benefit patients.

Then, on Monday, January 14<sup>th</sup>, drug makers announced that Vytorin, which combines Zetia with Zocor, had failed to reduce the growth of fatty arterial plaque in a trial of 720 patients. In fact, patients taking Vytorin actually had more plaque growth than those who took Zocor alone. This happened even though Vytorin and its component Zetia did lower cholesterol.

**For the second time in just over a year, a clinical trial found that LDL reduction did not translate into measurable medical benefits.**

The most recent edition of The [New England Journal of Medicine](#) reports that a third of the studies done by the makers of the antidepressants Paxil and Prozac were never reported. It would appear, they state that these unpublished studies, whose results are not as good as their published studies, was an act done to win government approval, misleading doctors and consumers about the drugs' true effectiveness. In studies that have been published about 60 percent of patients reported improvement with depression – but placebo pills (those that do not contain any active ingredient) are reported to help in 40 % of patients. When the unpublished studies are taken into account the difference between the drug therapy and placebo is significantly less, bringing into question effectiveness of the medications.

Previous research had found a similar bias toward reporting positive results for a variety of medications; and many researchers have questioned the reported effectiveness

of antidepressants. This latest investigation found that while 94 percent of the positive studies found their way into print, just 14 percent of those with disappointing or uncertain results did.

This is the “shelf” phenomenon. It means that a company has no legal obligation to publish a study that they do. If a company conducts two studies on a medication and one shows that it works while the other shows that it doesn’t, the company is fully within its legal rights to publish the positive study and put the other on a shelf only to be forgotten.

This phenomenon has troubled researchers and public health advocates as well as savvy consumers for years. Actually, we are all consumers of health care in one way or another and not having a fair way of evaluating the science affects all of us.

Last year, Congress passed legislation that expanded the type of studies that must be submitted to [clinicaltrials.gov](http://clinicaltrials.gov), a public database operated by the National Library of Medicine. Much more needs to be done.

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Dr. Sobo is a Medical Doctor practicing Holistic/ Nutritional Medicine in Stamford, CT. More information about natural hormones and about Dr. Sobo’s practice can be found on the Internet at <http://drsobo.com>. Dr. Sobo’s office phone number is 203-348-8805.

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