

# Shoddy science: will the statin scandal finally force a U-turn on cholesterol?

Another nail in the coffin of the “cholesterol causes heart disease” hypothesis has come with the failures of statins, the anti-cholesterol drugs, to significantly improve heart disease outcomes. **Prof Brian Peskin**, internationally famous for his work on essential fatty acids, has co-authored a new paper on statins with the subtitle “Bad Cholesterol or Bad Theory?” **CAM editor Simon Martin** caught up with him at the four-day BoulderFest nutrition conference, where Prof Peskin offered delegates a preview.

**S**tatin drugs are proving to be both dangerous and ineffective. Prof Brian Peskin and co-author Dr David Sim, MD, were moved to review the statin story – and to directly attack the lack of science behind the heart disease/cholesterol hypothesis – following the scandal surrounding the clinical failure of Vytorin.

The drug is a combination of two best-selling (and expensive) drugs made by Merck/Schering Plough, one a statin whose patent protection ended just as Vytorin was launched.

In 2006, the ENHANCE study was completed and provided very bad news for Vytorin in particular, and for statins and the cholesterol theory in general.

## Lowering LDL

It turned out that while Vytorin did indeed do what it was designed to do – significantly lower LDL, the so-called “bad” cholesterol – results showed that patients taking the new combo had more heart attacks (including two deaths) and other serious problems associated with

high cholesterol than those taking a non-statin anti-LDL drug, while both groups ended up with MORE plaque in their arteries than they started out with. Atherosclerosis nearly doubled in the Vytorin group.

As if that wasn't bad enough, although the results were known in 2006, Merck and Schering-Plough didn't release the news of them for 20 months. And when they did, it was in a Press release on their website. The peer-reviewed article containing the full details wasn't published until April 2008. (1)

## If you must lower cholesterol...natural alternatives are better than statins

Red yeast rice and fish oil work better than statins in reducing LDL cholesterol, but with none of the serious side-effects.

US researchers followed 74 patients with high blood cholesterol who met standard criteria for using statin therapy. Patients were randomly assigned to either the alternative treatment group or the statin group and followed for three months.

The alternative group received daily fish oil and red yeast rice supplements, and they were enrolled in a 12-week multidisciplinary lifestyle programme that involved weekly 3.5-hour educational meetings led by a cardiologist, dietitian, exercise physiologist and several CAM practitioners.

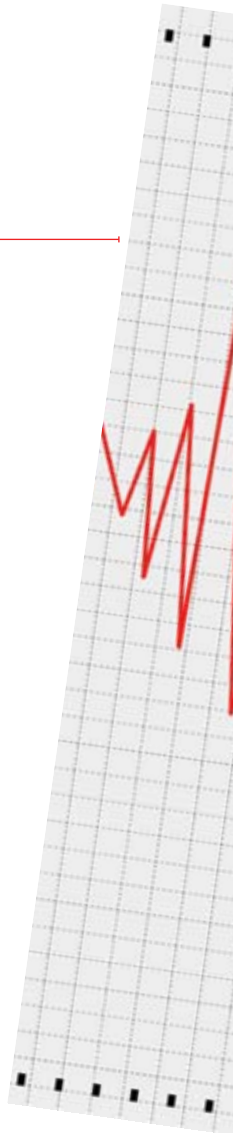
The statin group received Zocor (simvastatin) daily, as well as

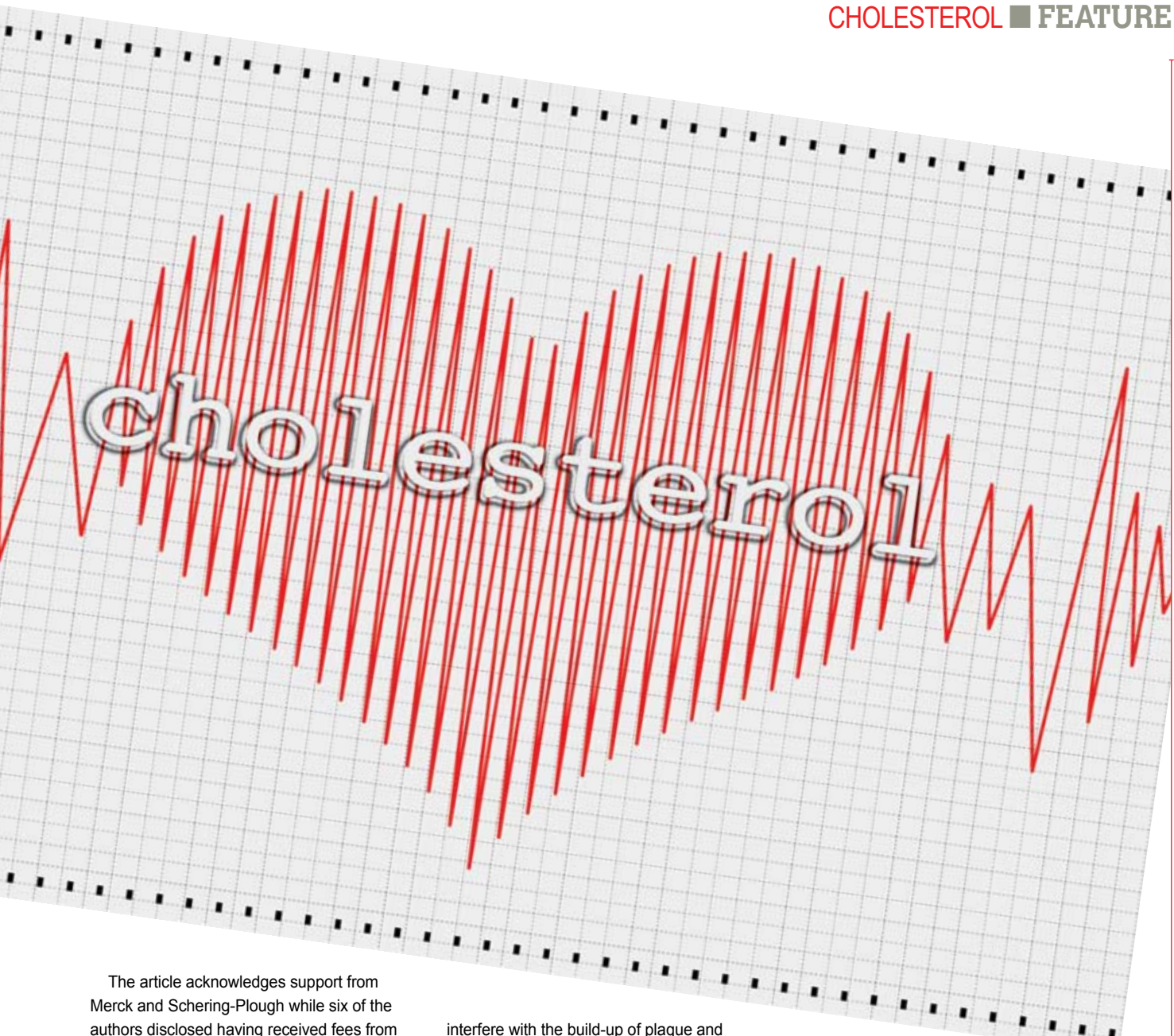
printed materials about diet and exercise recommendations.

After 3 months the alternative treatment group showed a 42.4% reduction, and the statin group 39.6%. Members of the alternative therapy group also had a substantial reduction in triglycerides, and lost more weight.

Lead author, David Becker, MD, a cardiologist at the University of Pennsylvania, said: “These results are intriguing and show a potential benefit of an alternative, or naturopathic, approach to a common medical condition”.

\* Becker JD et al, Simvastatin vs Therapeutic Lifestyle Changes and Supplements: Randomized Primary Prevention Trial. *Mayo Clin Proc.* 2008, 83:758-64.





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This was the last straw for Peskin and Sim, as not only had evidence of the dangers and downright ineffectiveness of statins been accumulating ever since the drugs were launched, but the most recent review of the evidence, a meta-analysis so beloved of the “evidence-based medicine” aficionados, published in 2007 (2), led them to the inescapable conclusion that: “statin treatment is clearly not effective – it is a dismal failure”. Peskin and Sim continue: “Clearly, a new level of understanding and synthesis of well-understood physiologic principles is required”.

The real problem with statins, Peskin says, is that their development isn’t based on biochemical or physiological science, but on two incorrect assumptions. First, that a build-up of the “wrong” kind of cholesterol is the cause of the plaque that builds up in atherosclerosis (it isn’t). And second, that using statins to lower “bad” LDL cholesterol and raise “good” HDL cholesterol would

interfere with the build-up of plaque and prevent or cure atherosclerosis (it doesn’t).

In fact, as Peskin told delegates at the BoulderFest conference on nutrition organized by Crayhon Research (3), study after study has concluded that cholesterol levels are a poor predictor of disease and/or mortality in everyone under 70. The medical community has known this since at least 1964, when the world famous heart surgeon Michael DeBakey, “the father of modern cardiovascular surgery” according to the Journal of the American Medical Association, led an analysis of the cholesterol levels of 1700 atherosclerotic surgical patients; the team found NO relationship between blood cholesterol levels and the incidence or extent of atherosclerosis (4).

**No relationship**

What’s more, studies across different countries, such as the Seven Countries Study into CHD mortality, have shown an up to 300% difference in death rates at the same LDL

cholesterol number, says Peskin. For instance, an 18% rate in Northern Europe, versus 6% in the Mediterranean. A five country study tracking early and late coronary and other cardiovascular deaths in thousands of men aged 40-59 years in five European countries for 35 years concluded: “No significant relationship were found between serum cholesterol and stroke and all-cause mortality, while intermediate findings were obtained for cardiovascular diseases.” (5)

When it comes to the HDL aspect of the cholesterol theory, Peskin and Sims do not mince words. The theory that high levels of HDL are “good” is, they say, incorrect. It “has no biochemical, physiological or clinical basis”.

In 2004, the New England Journal of Medicine published a study on the drug torcetrapib. The preliminary results were good: the drug increased plasma HDL by 61% or 46% depending on whether it was used with a statin. Torcetrapib plus a statin



## Now it's statins for children

It's medical "science" gone crazy – again. The American Academy of Paediatrics has recommended that children as young as 8 years old with very high levels of cholesterol should be started on statins.

Yet there are no long-term studies on the use of statins in children.

The APA says its new guidelines are a response to the high rate of obesity among US children and concerns that they could face increased risk of heart disease as adults.

The guidelines advise cholesterol testing for millions of children ages 2 to 10 who have a family history of early heart disease or other risk factors such as obesity or high blood pressure. But some doctors predicted that the guidelines would lead to the use of drugs in children with only moderately high cholesterol levels – and have questioned the emphasis on drugs rather than diet and exercise.

→ also reduced LDL by 17%. (6) Pfizer's chief executive described the drug as "one of the most important compounds of our generation". That was just days before Pfizer announced it was halting development of the drug because phase 111 studies showed more people dying and experiencing heart failure in the drug treatment group than in the control group.

In their paper, due to be published this autumn in the *Journal of American Physicians and Surgeons*, Peskin and Sim castigate the shoddy science and the unwarranted assumptions that lie behind the cholesterol theory of heart disease. They also highlight the negative influence of the pharmaceutical industry.

### Not evidence-based

They conclude that neither "treating" cholesterol, nor the use of statins, are in the least bit "evidence-based". Yet, they reveal, the current recommendations of the US National Cholesterol Education Project are forcing American physicians to use statins and to have lowering cholesterol as a primary target of therapy, while actually claiming that trials have provided "conclusive evidence" that lowering LDL reduces heart attacks and CHD deaths. At the same time, the dietary authorities are pushing a sickness-inducing

"food pyramid" majoring on getting people to eat more carbohydrates (50-60% by calories).

Peskin is adamant that perhaps the most important way to treat and protect heart disease, cancer and the epidemics of obesity and diabetes, is through nutrition. Specifically, he promotes rebalancing levels of what he calls "Parent Essential Oils" (PEOs) through supplements of "physiological, fully functional" linoleic acid (omega-6) and alpha linoleic acid (omega 3).

"There is no doubt that Western diets, which feature physiologically improper protein:fat:carbohydrate ratios skewed toward high (unnecessary), pathogenic carbohydrate intake, and supraphysiological omega-6:3 ratios (10:1 to 15:1), with significant non-functional LA from processed food, are responsible for this pathological situation", he says.

### Hard core EFAs

Peskin is hard-core about essential fatty acids. He regards LA and ALA as the only true essentials, and everything else, such as EPA and DHA, as "derivatives". Natural health practitioners have gone overboard on flaxseed and fish oil, he says, even though from the best of intentions. Physiologically, we need far more omega-6 fatty acids in the diet than omega-3s. We've gone wrong in attempting to heroically rebalance our diets with massive amounts of omega-3s because while it is true that the modern diet contains too much omega 6 and too little omega 3 fatty acids, what we've missed is the fact that the majority of the omega-6s in our diets are damaged or destroyed by processing and cooking. They are not bio-available. "We have 100 trillion cells and, essentially, half of every cell is lipid – with lots of Parent Essential Oils – and the other half protein", he says. "The foundation of healthy cellular structure and disease prevention begins with PEOs; in particular LA."


For those of us committed to using downstream "derivatives" because we have bought into the notion that we are side-stepping real or imagine deficiencies in the delta-6 desaturase driven conversion process that enables the body to manufacture "EFAs" from the two "parents" – he has this to say:

"Surprise! The conversion is much less than everyone states. 99% of PEOs stay in the cell's membranes – all 100 trillion cells." He quotes research from the *British Medical Journal* of 1982 that apparently shows that theoretically no more than 37% of

parent omega 3 fatty acids are converted to derivatives. "Real-life results?" he says, "it is actually only 1%-5% derivatives."

And as a bonus for anyone worried about heart disease, restoring an intake of fresh, minimally processed omega 6 linoleic acid to the diet and backing off the flaxseed and fish oil to a ratio of 2.5:1-1:1 Omega 6:Omega 3 will have another important benefit. It will restore healthy levels of "Nature's Natural Statin", as Peskin dubs the omega-6 derived Prostacyclin and PGE1, "the body's most potent anti-inflammatory" – stronger than omega-3 derived PGE2, he says.

Of course to do this we're going to have to lose our fear not only of omega 6s, but also of the much-maligned arachidonic acid.

"Prostacyclin is the body's most potent natural blood thinner and platelet anti-coagulant" says Peskin, "and it's made from AA. Humans obtain AA either ready-made in foods like meat or when it is made in the body – if the parent omega-8 is unadulterated." 

### References

1. Kastelein JJP et al. "Simvastatin with or without Ezetimibe in Familial Hypercholesterolemia". *N Engl J Med* 2008, 358(14): 1431-43. Full text available online via <http://content.nejm.org>
2. Abramson J, Wright JM. Are lipid-lowering guidelines evidence-based?. *Lancet* 2007, 369: 168-9.
3. [www.crayhonresearch.com](http://www.crayhonresearch.com)
4. Garrett HE et al. Serum cholesterol values in patients treated surgically for atherosclerosis". *JAMA* 1964, 189: 655-9.
5. Menotti A et al. Short and long term association of a single serum cholesterol measurement in middle-aged men in prediction of fatal coronary and other cardiovascular events: a cross-cultural comparison through Europe. *Eur J Epidemiol.* 2005, 20(7): 597-604.
6. Berenson, Alex "Pfizer Ends Studies on Drug for Heart Disease", *The New York Times*, Dec 3, 2006. Also see <http://en.wikipedia.org/wiki/Torcetrapib>

## About the author

**Brian Peskin, BSEE**, earned a BS in Electrical Engineering (BSEE) from Massachusetts Institute of Technology in 1979, and founded the field of Life-Systems Engineering Science in 1995. He was appointed adjunct professor in the College of Pharmacy and Health Sciences at Texas Southern University (1998-1999). He is chief research scientist for Cambridge International Institute of Medical Science. He is the author of "The Hidden Story of Cancer" (Pinnacle Press, Houston, Texas, 2008 4th ed) – [www.brianpeskin.com](http://www.brianpeskin.com).