

## **Cheerios® Are a Drug? - Why Lower Cholesterol Anyway?**

**by Joel M. Kauffman. Ph.D.**

On Wed, 13 May 2009, the following news was made public: U.S. supplements and foods makers cannot make claims to treat or diagnose a disease. Cheerios® has made the same FDA approved claims for 12 years, so why the sudden change? The cereal entered the US market in 1941.

In a letter to General Mills, the FDA said, "Based on claims made on your product's label, we have determined that your Cheerios® Toasted Whole Grain Oat Cereal is promoted for conditions that cause it to be a drug."

Cheerios® labels claimed that eating the cereal can help lower bad cholesterol by four percent in six weeks. "Because of these intended uses, the product is a drug," the FDA said.

Additionally, Cheerios® is a new drug because it has not been "recognized as safe and effective for use in preventing or treating hypercholesterolemia or coronary heart disease," the FDA also said.

Their instructions further state that General Mills may not legally market Cheerios® unless they apply for approval as a new drug or change the way the product is labeled. FDA is now taking the stand that any substance, be it nutritional supplement or, apparently, even basic cereal must become a drug and handled like any other pharmaceutical if it makes claims for treatment of a disease or illness.

Under this interpretation, it suggests that makers of iodine may not make claims for treatment of the iodine deficiency state of thyroid goiter unless it first becomes a drug and is studied and approved by FDA. The same for iron in iron deficiency anemia, niacin in pellagra, thiamine in beri-beri and folic acid in prevention of spinal cord malformations.

General Mills defended the claims on Cheerios® packaging, saying in a statement that Cheerios'® soluble fiber heart health claim has been FDA approved for 12 years, and that its "lower your cholesterol four percent in six weeks" message has been featured on the box for more than two years.

Regardless, FDA warned in its letter that if General Mills fails to "correct the violations" on its labels, boxes of Cheerios® could disappear from supermarket and wholesaler shelves around the United States and the company could face legal action.

### **Why Lower Cholesterol Anyway?**

This section includes excerpts from the book Malignant Medical Myths by Joel M. Kauffman

This news does not reflect the best dietary science on a number of issues. Lowering total cholesterol by 4% would mean about 8 mg/dL, a trivial change. The assay is  $\pm 25\%$  and total serum cholesterol varies depending on a recent meal, exercise (up) and stress (up).

Hypercholesterolemia is a made up condition now said to mean that total serum cholesterol is above 200 mg/dL or LDL-C is over 125 mg/dL. This was done to advance the sales of cholesterol-lowering drugs, and Cheerios® incidentally benefited.

A 2004 observational study from the University of Innsbruck, Austria, on 150,000 subjects showed that low cholesterol levels predict premature death in men of all ages, and in women over the age of 50.

In the 1990 Quebec Cardiovascular Study on 4576 men aged 35-64 years to start, serum total cholesterol levels were not associated with either cardiovascular disease or all-cause mortality.

Even in dialysis patients, all-cause mortality was highest at the lowest total cholesterol levels, being 30% lower when total cholesterol was approximately 240 mg/dL compared with TC <160. Also, mortality was 17% lower at low-density-lipoprotein (LDL-C) approximately 190 mg/dL compared with LDL-C <130 in a 2004 study.

Among the elderly the effects of low serum total cholesterol and low LDL-C were found to be deadly. In a study on residents of northern Manhattan, NY, 2,277 subjects were followed for 10 years with results reported in 2005. Two-thirds were female and 1/3 of the total were Hispanic, African American and white. Subjects were 65-98 years old at baseline, mean age 76. The chance of dying was twice as great in the lowest quartile of total cholesterol or LDL-C levels, while HDL-C and triglyceride levels were not related to all-cause mortality in this age group.

Women had higher baseline total cholesterol and LDL-C levels (206 and 124) than men (191 and 117), yet the women lived longer. Men with the same total cholesterol and LDL-C levels as women lived as long. Of the subjects, 1/5 were taking statin drugs to lower total cholesterol and LDL-C, which would have pushed them into the lowest quartile.

This is an excellent confirmation that high total cholesterol and LDL-C ( low density lipoprotein cholesterol ) levels are beneficial, certainly in the elderly who are most likely to be prescribed a statin drug. The emphasis on the value of lowering LDL-C, rather than lowering total cholesterol, taken by Big Pharma in the last few years, is invalidated by this study. LDL-C is not bad cholesterol; it is an essential form!

Dr. Bernard Forette and a team of French researchers from Paris reported in 1989 that women of mean age 82 with high cholesterol and followed for 5 years lived the longest. When the data of Forette are graphed, the age-adjusted data show a minimal risk of dying out to total cholesterol = 320 mg/dL for elderly women. The minimum death rate occurred with a total cholesterol level of 272 mg/dL, far higher than the current National Cholesterol Education Program (NCEP) recommendations of approximately 200 mg/dL for everyone.

The death rate was 5.2 times higher for women who had very low cholesterol, specifically, 155 mg/dL. The death rate was 1.8 times higher for women who had very high cholesterol, specifically, 348 mg/dL, and also 1.8 times higher at 200 mg/dL.

What possible basis could there be for the NCEP recommendations for <200? In their report, the French doctors warned against lowering cholesterol in elderly women.

Serum total cholesterol rises naturally with age from a mean level of 178 mg/dL in 18-24 year-olds to a maximum mean level of 230 mg/dL in 55-64 year-olds. Men over 55 and women of all ages who have the highest cholesterol levels live the longest, since high total cholesterol protects against cardiovascular disease (CVD) and infections (Ravnskov U. High cholesterol may protect against infections and atherosclerosis. Quarterly Journal of Medicine, 2003;96:927-934).

For people of a narrow age range, even in a 13-year span, say ages 50-62 years, a graph of total cholesterol levels of men who did and did not have CVD has been published in 2001.

There is so much overlap between the men with or without CVD that there is no likelihood that the slightly greater chance for CVD at the higher total cholesterol levels could be used for prediction in any one individual, even in this group spanning 13 years in age.

This is the reason that drug advertising claims that higher total cholesterol means quicker death from CVD are false - in large groups of people of mixed ages, the older ones will have higher total cholesterol and LDL-C, and older people die sooner than younger ones, not necessarily from CVD.

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