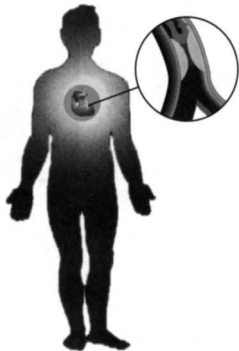


THE CHOLESTEROL SCAM

Challenging The Cholesterol Myth



U.S. physicians and health professionals demand an independent review of statin therapy.

by Marjorie Mazel Hecht

The latest guidelines of the National Cholesterol Education Program (NCEP) of the National Institutes of Health, issued in July 2004, would have millions more Americans taking statin drugs to reduce their risk of heart disease from cholesterol. But the evidence on which the new guidelines were based has come into question by the medical community—and for good reason: The studies behind the new guidelines don't show what the NCEP says they show, and statin drugs don't lower most people's risk of heart disease.

On Sept. 23, 2004, 35 prominent physicians, epidemiologists, and other scientists wrote to the heads of the National Institutes of Health, the National Heart, Lung, and Blood

Institute, and the National Cholesterol Education Program to urge an independent review of the scientific studies on which the new guidelines are based: "There is strong evidence to suggest that an objective, independent re-evaluation of the scientific evidence from the five new studies of statin therapy would lead to different conclusions than those presented by the current National Cholesterol Education Program," the letter states.

Among the signers of the letter are John Abramson, M.D., Clinical Instructor, Primary Care, Harvard Medical School; R. James Barnard, Ph.D., Professor, Department of Physiological Science at UCLA; Christopher Gardner, Ph.D., Assistant Professor of Medicine, Stanford University; Jerome R.

Hoffman, M.D., Professor of Medicine, UCLA School of Medicine; Marion Nestle, Ph.D., Paulette Goddard Professor of Nutrition, Food Studies, and Public Health, New York University; David L. Brown, M.D., Professor of Medicine and Epidemiology, Albert Einstein College of Medicine and Director, Interventional Cardiology, Beth Israel Medical Center; and the Center for Science in the Public Interest.

The letter notes that eight of the nine authors of the July recommendations have financial ties to statin manufacturers, including Pfizer, Merck, Bristol-Meyers Squibb, and AstraZeneca, a fact that was not made known when the recommendations were first published in the journal *Circulation*. "Such conflicts," the letter states, "certainly could affect authors' judgment and undermine public confidence in the report. . . . But like surrogate endpoints in clinical studies, the conflicts are a diversion from the most important question: Are these lower LDL [low-density lipoproteins, or "bad" cholesterol] targets justified by the scientific evidence?"

The authors outline four major objections to the NCEP interpretation of the data. First, the letter states, "We believe the evidence does not support extending these guidelines to women who are at moderately high risk of CVD [cardio-vascular disease] (so-called 'primary prevention')." Not one of the six studies used "provides significant evidence to support" the claim that "statins reduce the risk of heart disease in moderately high risk women under the age of 65."


Second, the letter states, "We believe the evidence does not support extending these guidelines to older persons who are at risk of CVD (primary prevention)." There were nine studies involved, and not one of them "provided significant evidence that statins protect senior citizens without heart disease." The authors of the letter note that those above 65 and treated with a statin "did not experience significantly fewer heart attacks and strokes. But they did develop 25 percent more new cancers than the people in the control group (statistically significant)."

Third, the authors state: "We believe the evidence in the five latest clinical trials for extending these guidelines to primary prevention of coronary heart disease in patients with diabetes is mixed." They note that for 250 diabetic patients treated with a statin, in one study, "one death was prevented each year"—but four times as many lives would be saved if those sedentary diabetic patients would become physically active. "The relative importance of statin therapy and routine exercise was not mentioned in the NCEP recommendations," the authors note.

Fourth, the authors state that one study, designated as ALLHAT, "did not show a benefit from more than tripling the number of people taking statins (as rec-

National Cholesterol Education Program

High Blood Cholesterol What you need to know



Why Is Cholesterol Important?

Your blood cholesterol level has a lot to do with your chance of getting heart disease. High blood cholesterol is one of the major risk factors for heart disease. A risk factor is a condition that increases your chance of getting a disease. In fact, the high your blood cholesterol level, the greater your risk for developing heart disease or having a heart attack. Heart disease is the number one killer of men and women in the United States. Each year, more than a million Americans have heart attack and about a half million people die from heart disease.

How Does Cholesterol Cause Heart Disease?

When there is too much cholesterol in fat-like substances in your blood, it builds up in the walls of your arteries. Over time, this buildup causes "hardening of the arteries," so that arteries become narrower and blood flow to the heart is slowed down or blocked. The blood carries oxygen to the heart and if enough blood and oxygen cannot reach it, you may suffer chest pain. If the blood supply to a portion of the heart is completely cut off by a portion of the block, it is a heart attack.

9- to 12-hour fast and gives information about your:

- **Total cholesterol**
- **LDL (bad) cholesterol** - the main source of cholesterol buildup and blockage in the arteries
- **HDL (good) cholesterol** - helps keep cholesterol from building up in the arteries
- **Triglycerides** - another form of fat in your blood

If it is not possible to get a lipoprotein profile done, knowing your total cholesterol and HDL can give you a general idea about your cholesterol levels. If your total cholesterol is 200 mg/dL or more or if your HDL is less than 40 mg/dL, you will need to have a lipoprotein profile done. See how your cholesterol numbers compare to the tables below.

Total Cholesterol Level	Category
Less than 200 mg/dL	Desirable
200-239 mg/dL	Borderline high
240 mg/dL and above	High

LDL Cholesterol Level	LDL Cholesterol Category
Less than 100 mg/dL	Optimal
100-129 mg/dL	Near optimal/above optimal
130-159 mg/dL	Borderline high
160-189 mg/dL	High
190 mg/dL and above	Very high

*Cholesterol levels are measured in milligrams (mg) of cholesterol per deciliter (dL) of blood.

HDL (good) cholesterol protects against heart disease, so for HDL, higher numbers are better. A level less than 40 mg/dL is low and is considered a major risk factor because it increases your risk for developing heart disease. HDL levels of 60 mg/dL or more help to lower your risk for heart disease.

Triglycerides can also raise heart disease risk. Levels that are borderline high (150-199 mg/dL) or high (200 mg/dL or more) may need treatment in some people.

What Affects Cholesterol Levels?

A variety of things can affect cholesterol levels. These are things you can do something about:

The July 2004 guidelines of the National Cholesterol Education Program have lowered the threshold for recommending statin drugs, making millions more Americans candidates for these expensive and questionable drugs.

ommended by the 2001 and 2004 NCEP updates). . . . The results show that tripling the number of people taking statins . . . provides no additional benefit—not to those older or younger, male or female, with or without diabetes, with or without heart disease, and among those without heart disease, not to those with LDL-cholesterol higher or lower than 130

Thirty-five physicians and health professionals, and the Center for Science in the Public Interest, sent a petition Sept. 23, 2004, to the National Institutes of Health calling for an independent review panel to re-evaluate the cholesterol guidelines. ▼

PETITION TO THE NATIONAL INSTITUTES OF HEALTH
SEEKING AN INDEPENDENT REVIEW PANEL TO RE-EVALUATE
THE NATIONAL CHOLESTEROL EDUCATION PROGRAM GUIDELINES

September 23, 2004

Dr. Eric Zelnick

Director, National Institutes of Health

Dr. Barbara Alving

Acting Director, National Heart, Lung and Blood Institute

Dr. James I. Cleeman

Director, National Cholesterol Education Program

Dear Sirs and Madam,

On July 12, 2004, the National Cholesterol Education Program of the National Heart, Lung and Blood Institute issued updated recommendations for "cholesterol management"¹ based on five studies released since the 2001 update of treatment guidelines.

The new NCEP report lowers the threshold for considering statin therapy.

According to this report, people at *moderately high risk* of developing, but no previous history of heart disease ("primary prevention") and LDL-cholesterol levels between 100 and 129 mg/dL should now be offered the "therapeutic option" of cholesterol-lowering

mg/dL. The only group that derived any significant benefit from more statins was African-Americans, who had fewer episodes of heart disease, but not fewer deaths. . . ."

In conclusion, the authors state: "The American people are poorly served when government-sanctioned clinical recommendations, uncritically amplified by the media, misdirect attention and resources to expensive medical therapies that may not be scientifically justified. Only an independent review, totally free from conflicts of interest, can restore public confidence by determining if that has happened in this case. We therefore request that you move expeditiously to appoint such a panel and provide it with the resources needed to conduct the review."

The Fat Wars

This latest battle over cholesterol takes place after more than 40 years of propaganda—unsubstantiated by scientific evidence—that a low-fat, low-cholesterol diet will lower your risk of heart disease. One of the principal investigators in the famous Framingham Study of heart disease, George V. Mann, M.D., called this "the great diet-heart scam," and "the greatest scientific deception of our times." Mann devoted much of his career to promoting the truth—as opposed to the officially sponsored fiction, and he named the names of those in the medical profession who preferred their funding from the corn oil companies to telling the truth. These doctors, including Harvard's famed Frederick Stare, shamelessly spread the line that polyunsaturated vegetable fats were good for your heart, while animal fats, like butter and lard, were bad. As Mann characterized those scientists who accepted the diet-heart idea: "Fearing to lose their soft money funding, the academicians who should speak up and stop this wasteful anti-science are strangely quiet. Their silence has delayed a solution for coronary heart disease by a generation."

Mann organized a conference on the issue in November 1991 in Washington, D.C. In the invitation to the conference he wrote: "Hundreds of millions of tax dollars are wasted by the bureaucracy and the self-interested Heart Association. Segments of the food industry play the game for profits. Research on the true causes and prevention is stifled by denying funding to the 'unbelievers.' This meeting will review the data and expose the rascals."¹

In an article in *Nutrition Today* magazine, Mann wrote: "Those who manipulate data do not appreciate that understanding the nature of things cannot be permanently distorted—the true explanations cannot be permanently ignored. Inexorably, truth is revealed and deception is exposed. . . . In due time, truth will come out. This is the relieving grace in this sorry sequence."

Although more than a decade has passed since Mann made these statements, the truth is still waiting to "come out."

Notes

1. An article by George Mann, "The Great Diet-Heart Scam," appeared in the May-June 1989 issue of *21st Century Science & Technology* magazine.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Blood Institute
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OCT 23 2004

Mr. Merrill Ostermer

Director, Integrity in Biotech
Center for Biotech in the Public Interest
1979 Connecticut Avenue, NW, Suite 300
Washington, D.C. 20038-4728

Dear Mr. Ostermer:

I am responding to the letter of September 23 addressed to Dr. Zelnick, Director, National Institutes of Health, myself, and Dr. Cleeman, which was submitted by you for the signatories. The letter questions the validity of current Adult Treatment Panel III (ATP III) recommendations for cholesterol management developed by the National Cholesterol Education Program (NCEP) and requests that NCEP conduct a re-review of the data in the studies at issue. The NCEP is coordinated by the National Heart, Lung, and Blood Institute (NHLBI) on behalf of a national coalition of health-related non-profit organizations in the private and public sectors interested in reducing the toll from coronary heart disease (CHD) as well as other forms of atherosclerotic cardiovascular disease (CVD).

The letter raises two issues: whether the scientific basis for several recommendations is adequate, and concerns that the panel was influenced by conflict of interest arising from the interaction of panel members with industry. These two issues are addressed separately in this response.

I. The Scientific Basis for the Recommendations

The Institute does not agree with the letter's use of subgroup analyses, interpretation of the results of several of the clinical trials, and characterization of several recommendations of the ATP III, which I shall summarize. The letter does not appear to appreciate the 3-ATP method

▲ Dr. Barbara Alving, acting director of the National Heart, Lung, and Blood Institute, answered the Sept. 23 letter on Oct. 22, saying that "the Institute does not believe a re-review of the data is warranted at this time," and defending the integrity of the guidelines.