Federal Trade Commission

A HIGH-FIBER, LOW-CHOLESTEROL APPROACH TO HEALTH CLAIMS: THE FEDERAL TRADE COMMISSION'S "REASONABLE BASIS" STANDARD

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The views expressed are those of the Commissioner and do not necessarily reflect those of the Federal Trade Commission or the other Commissioners.

I want to thank the Food and Drug Law Institute for giving me the opportunity to offer my views on one of the most important and challenging consumer protection issues of the day: health claims in food advertising and labeling. No doubt everyone here agrees that false health claims can cause serious harm to consumers, and that the government should prohibit such claims. But it is also clear that truthful claims can be a valuable source of information for consumers who are trying to establish or maintain a healthy diet. The real challenge for government agencies such as the Federal Trade Commission is to develop policies that discourage the deceptive claims without restricting the truthful ones.

Today I want to tell you about a landmark FTC staff study of health claims in the cereal market. This study should be required reading for anyone who has a serious interest in the use of health claims in advertising. Then I will address the Commission's substantiation policy for health claims in food advertising, which I believe strikes the appropriate balance between overregulation and underregulation of health claims. Before saying any more, I offer the usual disclosure that the opinions I express today are my own, and are not necessarily the views of the Commission or any other individual commissioner.

Some of you may have read the story in the May 7, 1990, issue of *Advertising Age* about so-called "buy or die" advertising. "Buy or die" ads are those that link consumption of the advertised food to a lower risk of heart attack, cancer, or

other serious health problem. One television commercial described in the article features a thirtysomething heart attack survivor who tells the audience "[d]on't wait for a heart attack to change your life." She goes on to explain that you can lower your risk of heart disease by eating a diet low in cholesterol and saturated fat, and that the margarine that is the subject of the ad can be part of such a diet.

The *Ad Age* story reports that "buy or die" ads have been toned down and suggests two possible explanations for that apparent change in advertising philosophy. First, according to some of the advertising experts quoted in the article, consumers may not respond favorably to advertising that uses scare tactics to sell a product. Second, increased scrutiny of health claims by the FTC, FDA, and other government agencies may be making advertisers increasingly "nervous," according to the president of one food company whose latest ad campaign steered clear of specific health claims in favor of an "Eat well, live long and be happy" message.

Let us assume that fear of government action is at least partly responsible for the trend away from "buy or die" advertising. Is that something that government officials should be proud of? Or should we be concerned? Your answer to that question may depend on whether you believe the government's primary goal in this area should be to discourage advertising that contains deceptive health claims, or to encourage broader dissemination of truthful information about nutrition and health.

If any of you has doubts that advertising can be a good source of health information, I recommend that you take a look at a report published last year by two members of the FTC's Bureau of Economics, Pauline Ippolito and Alan Mathios.[1] That report, which is titled *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, is a significant piece of research that adds a great deal to our understanding of the value of truthful health claims. In the 1970's, researchers began to note a relationship between fiber consumption and the incidence of certain kinds of cancer. That relationship was noted in government reports and newspaper accounts, but those reports seemed to have had little or no effect on consumer behavior: consumption of high-fiber cereals did not increase between 1978 and 1984. In October 1984, the Kellogg Company launched an advertising campaign that stressed the fiber-cancer relationship. Other manufacturers joined in.

The response to these advertising campaigns was dramatic. Between 1985 and 1987, consumption of high-fiber cereal and consumer awareness of the benefits of fiber in the diet increased significantly. Advertising may have had more of an effect both because it reached more consumers more often and because it linked the health benefits to specific brand-name products. The government studies and newspaper reports had told consumers that

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[1] P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (1989) (FTC Bureau of Economics staff report).

high-fiber cereals were healthy; the advertising told consumers which cereals were high in fiber.

The increase in consumption of high-fiber cereals was particularly marked in certain population groups whose members ate relatively little high-fiber cereal before the advertising linking fiber and health began to appear. For example, smokers -- who might pay less attention to government reports on health than non-smokers -- increased their consumption of fiber cereals significantly after 1985.

Cereal manufacturers, in turn, responded to the increased demand for high-fiber cereal by introducing a number of new high-fiber brands. In 1984, the average cereal had about one and a half grams of fiber per serving. But the average fiber content of all the new cereal brands that were introduced between 1985 and 1987 was two and a half grams per serving, an increase of 66%.

This study makes it clear that a ban on health claims in advertising would limit the flow of information to consumers, especially those consumers who obtain little health information or little understanding of health information from government sources and the news media. It also suggests that consumers may be harmed when truthful advertising is prohibited just as they are when deceptive advertising is allowed.

In its opinion in *International Harvester*,[2] the Commission said that "[d]eception is a particularly troublesome form of

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[2] 104 F.T.C. 949 (1984).

conduct"[3] because it harms consumers, undermines the rational functioning of the marketplace and offers no countervailing benefits. Deceptive health claims are a particularly troubling form of deception. For one thing, it is often difficult or impossible for consumers to judge the accuracy of health claims. For another, very serious harm can result from a deceptive claim that a product will prevent or cure a disease or other health problem, particularly if those who use the product forego alternative treatments or therapies that are more effective.

An article titled "The Radium Water Worked Fine Until His Jaw Came Off" appeared in the *Wall Street Journal* recently.[4] As the title suggests, the article concerns a deceptive health claim with particularly gruesome consequences. Soon after the discovery of radium, mildly radioactive patent medicines began to appear in the marketplace. Proponents of "mild radiation therapy," including some respectable scientists, believed that small doses of radioactive substances could increase metabolism and rejuvenate aging or unhealthy glands and organs. In 1927, E. M. Byers, a wealthy businessman who was also an avid sportsman and reportedly a notorious ladies' man, began drinking two or three bottles of one radioactive tonic daily. He continued this level of consumption until 1930, when he began to lose weight, suffer headaches, and lose teeth. He died of radium poisoning in

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[3] Id. at 1056.

[4] Winslow, *The Radium Water Worked Fine Until His Jaw Came Off*, Wall St. J., Aug. 1, 1990, at 1, col. 4.

1932, only a few months after the FTC entered an order prohibiting a number of false representations by the makers of the radium potion.[5]

Harm from a deceptive claim that slips through the regulatory net is often more obvious and more dramatic than the harm that results when consumers are not permitted to hear truthful claims. But the latter harm can also be serious, as the history of the federal government's handling of cholesterol claims demonstrates.[6] About 1950, researchers observed that vegetarians had lower serum cholesterol levels and a lower incidence of heart disease than non-vegetarians. In 1957, a report prepared for the American Heart Association concluded that diet and nutrition are "very probably" important factors in heart disease. In 1961, the heart association recommended the reduction or control of fat consumption "with reasonable substitution of poly-unsaturated for saturated fats" as a "possible" means of decreasing the risk of heart attacks and strokes. It also recommended that food manufacturers disclose on their labels how much saturated, mono-unsaturated, and poly-unsaturated fats their products contained. A year later, the American Medical Association concluded that increasing the ratio of polyunsaturated to saturated fat in the diet was advisable

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[5] *Bailey Radium Laboratories, Inc.*, 15 F.T.C. 419 (1931).

[6] See Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 40 Food Drug Cosm. L.J. 3, 27-34 (1986), for a more detailed description of the federal government's response to fat and cholesterol claims in the 1950's and 1960's.

given the apparent relationship between high levels of blood cholesterol and heart disease.

Not surprisingly, some manufacturers reported these developments in their advertising. I have here a copy of a 1959 magazine ad for Mazola Corn Oil, which states that "it has been demonstrated repeatedly that Mazola Corn Oil lowers the cholesterol level of the blood stream -- considered important in both the prevention and treatment of heart disease." The ad goes on to point out that Mazola is "unsaturated, not hydrogenated. Many nutritionists now suggest that from one-third to one-half of the fat we eat should be unsaturated vegetable oil." But a Mazola ad that appeared three years later did not mention heart disease. It stated that Mazola was "best for cutting down saturated fats in your diet," but did not explain why that was good. Highly informed readers probably would make the connection between saturated fat content and heart disease, but other consumers probably would not. Looking back to the early 1960's, my guess is that very few consumers had that expertise.

Why did Mazola tone down its health claims? Perhaps for the same reason given by the food company executive quoted in the *Advertising Age* article I mentioned earlier: fear of government action. In 1959, the FDA announced that the advisability of making extensive changes in the nature of dietary fat intake had not been demonstrated, and that any labeling claim related to

heart disease would be regarded as illegal.[7] My intent here is not to point an accusing finger at one particular government agency, or to suggest that the FTC was without sin. Indeed, according to trade press reports, the FTC was ready to move against advertising linking fat and heart disease if the FDA was unable to take care of the perceived problem by itself.[8] Five years later, after the American Heart Association and American Medical Association reports mentioned earlier, the FDA stated that legal action would be taken against claims that vegetable oil products contained polyunsaturated fat. That year, the FDA actually seized Nabisco Shredded Wheat because a discussion of the relationship between serum cholesterol and heart disease was printed on the back of the package.[9] "Medical studies would indicate a decrease in the occurrence of heart disease when vegetable fats replace animal fats in the diet," the package read. "Nabisco Shredded Wheat is an excellent way to lower the amount of animal fats you consume. A bowlful each morning can help you lower blood-cholesterol levels."

Assuming initial uncertainty concerning the accuracy of these claims, there appears to have been little or no consideration of the potential benefits of such claims if they turned out to be true compared to the potential harm that would result if they turned out to be false. The potential benefits

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[7] Id. at 29.

[8] *See, e.g.*, Printer's Ink, Dec. 18, 1959, at 13.

[9] Hutt, *supra* note 6, at 33-34.

were enormous -- heart disease was, and is, one of our most serious public health problems. The potential harm was comparatively small. Shredded Wheat may not taste as good as a high-octane eggs-bacon-and-buttered-toast breakfast, but replacing the latter with the former surely poses no serious risk to your health. Some of the "buy or die" ads from the 1950's and 1960's may have exaggerated the benefits of the advertised products, but banning the claims altogether was a cure that was undoubtedly worse than the disease.

The FTC's effort to eliminate tar and nicotine claims in cigarette advertising in the late 1950's is another example of government action that, with the benefit of hindsight, appears to have been counterproductive.[10] In the early 1950's, medical research linking smoking and lung cancer inspired cigarette companies to introduce a number of filter brands. Around 1957, claims relating to tar and nicotine content became a prominent theme in cigarette advertising. This so-called "tar derby" resulted in dramatic reductions in average tar and nicotine content over the next few years. By 1960, for example, the sales-weighted tar content of filter brands was 31% less than it had been in 1957. But that year, the FTC persuaded the six major cigarette manufacturers to eliminate all tar and nicotine content references from cigarette advertising. The decline in average tar and nicotine content came to an abrupt halt; one magazine

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[10] See J. Calfee, Cigarette Advertising, Health Information and Regulation Before 1970 (1985) (FTC Bureau of Economics working paper), for a more detailed history of this effort.

article concluded, "When the tar derby ended, so did research for safer cigarettes."[11] Several years later, of course, the FTC changed its mind and told the cigarette companies that it would not challenge accurate tar and nicotine content claims.

What can those of us in government do to minimize the harm caused by deceptive claims without giving up the benefits that result from truthful claims? In other words, how can we keep the radium water salesmen out of the marketplace without muzzling truthful claims about the polyunsaturated fat content of vegetable oil? Is there a regulatory formula that allows us to have our high-fiber, low-fat, beta-carotene cake, and eat it too?

The Commission's "reasonable basis" standard comes close to achieving both of these goals. In its 1972 *Pfizer* decision,[12] the Commission first announced what has come to be known as the "reasonable basis" doctrine. Under that doctrine, advertisers need not have absolute proof that their objective claims are true before making those claims, but they must have a "reasonable basis" for believing the claims are true. The Commission has long believed that an objective claim about a product's performance or effectiveness necessarily carries with it an implied representation that the advertiser has some reasonable basis for the claim. Objective claims for which the advertiser can provide no reasonable basis, therefore, are deceptive under Section 5 of the FTC Act.

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[11] *Report to Consumers*, Reader's Digest, Aug. 1963, at 99.

[12] *Pfizer, Inc.*, 81 F.T.C. 23 (1972).

The Commission considers six factors before deciding whether an advertiser possesses a reasonable basis for a claim. The first factor is the type of product being advertised. If the product is a familiar item the use of which presents little risk of harm to consumers, a lower level of substantiation is required. The second factor is the type of claim. Claims that refer to specific facts or figures require a higher level of substantiation than claims that contain more generalized descriptions of performance or effectiveness. Claims that are difficult or impossible for consumers to evaluate by themselves -- such as a claim that eating a certain food will lower your risk of cancer or heart disease -- are also held to a higher standard.

The third factor to consider is how much consumers will benefit if the claim proves to be true. The likelihood that this factor would ever be important may seem counter-intuitive to people who consider advertising to be generally distasteful and of no redeeming social value. But the Bureau of Economics study of cereal advertising I described earlier demonstrates that advertising can indeed contain information of real value to consumers. The fourth factor is the seriousness of the harm that will result if the claim proves to be false. The economic consequences of a false claim are more serious for expensive products than for inexpensive products. And the health consequences of a false claim are more serious if the ad represents that a product will prevent or cure a serious disease,

particularly if the advertised product is chosen instead of an alternative product or treatment that is known to be effective.

The fifth factor is the cost of developing substantiation for the claim. All else being equal, we require a higher level of substantiation for claims that are less expensive to evaluate, particularly if the potential profits from sale of the product are relatively large. The sixth and final factor is how much substantiation is considered reasonable by experts in the field. Although the Commission consults outside experts, it does not delegate its responsibility to decide the appropriate level of substantiation.

The crucial factors in evaluating health claims are often numbers three and four, that is, the two things that I have been talking about today, the potential benefit if the claim is true and the potential harm if a claim is false. It is important to give full consideration to both of these factors. That is why there is reason to question the so-called "consensus" standard for judging health claims.[13] According to one definition, a consensus standard "would require that the statement be supported by a sound body of scientific evidence upon which a significant agreement exists among qualified experts."[14] I presume that "significant agreement" is something less than unanimity, but not much less.

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[13] *See, e.g.*, Comments of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission, FDA Docket No. 85N-0061 (Feb. 13, 1990).

[14] 55 Fed. Reg. 5181 (1990).

In 1971, the FTC and FDA signed a formal "Memorandum of Understanding" that gave the FTC primary responsibility for food advertising and the FDA primary responsibility for food labeling. As the FDA and others have pointed out, it may not be appropriate to apply the same standards to both advertising claims and labeling claims because consumers may view them differently. For example, consumers may be more skeptical of advertising than they are of labeling. But even if we conclude that labeling claims should be held to a higher standard, it is still important to consider the potential benefits of a true claim as well as the potential harm of a false claim. A "consensus" standard, which demands a uniformly high probability of truth for all claims, protects consumers against false claims, but also may bar some claims that eventually prove to be true and beneficial.

Some people mistakenly believe that a poorly designed study or a study the results of which conflict with the results of other studies is enough to meet the Commission's "reasonable basis" test. This reveals a misunderstanding of the standard. Insignificant, contradictory or poorly designed studies will rarely, if ever, satisfy the "reasonable basis" standard, which often requires a high level of substantiation. The order in *Thompson Medical*,[15] for example, required substantiation in the form of "at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons." The

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[15] 104 F.T.C. 648, 844 (1984).

"reasonable basis" standard may even require a consensus in some instances.

In his famous dissent in *Abrams v. United States*,[16] Justice Holmes observed that "[e]very year if not every day we have to wager our salvation upon some prophecy based upon imperfect knowledge." Many of the decisions government agencies are asked to make in the health claims area are "prophecies based upon imperfect knowledge." Scientists rarely know for certain that a particular nutrient or food component exerts a particular effect on a particular disease. More commonly, the Commission is faced with a body of studies, each with its own limitations, that suggest certain relationships but do not prove causal links between diet and health. I would like to think that all the Commission's future decisions on health claims will be the right ones, but it would be foolish to choose a policy that works only when we are able to predict the future with precision. Some of our "prophecies" will no doubt turn out to be mistaken.

This reminds me of the young boy who asked his teacher how a thermos bottle worked. She answered by explaining that a thermos keeps hot things hot and cold things cold. "I know that," the child said, "but how does it know the difference?" Unfortunately, we do not have the same instantaneous and unerring ability to know the difference between a deceptive health claim and a truthful one. But we can take some comfort from the knowledge that our "reasonable basis" substantiation standard, if

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[16] 250 U.S. at 624 (1919).

properly applied, will minimize the harm that results from any imperfect prophecies based on necessarily imperfect information.

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