The Federal Trade Commission's Approach to Regulating Health Claims in Food Advertising

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I. INTRODUCTION

Prior to 1984, federal regulations effectively prohibited health claims in food labeling and advertising. In recent years, however, public policy makers have taken a more permissive approach. The result has been a proliferation of claims in food advertising suggesting that use of a product decreases the risk of certain chronic diseases, such as coronary heart disease, high blood pressure, cancer, and osteoporosis. Behind the great increase in the use of health claims in food advertising a public policy debate continues over how much scientific support should exist before food processors may lawfully make these health claims. The two federal agencies that oversee the use of health claims in food promotions, the Federal Trade Commission ("FTC") and the Food and Drug Administration ("FDA"), differ on the necessary level of scientific support.

In the fall of 1990, Congress passed, and President Bush signed, the Nutrition Labeling and Education Act of 1990. The passage of this Act ends the debate surrounding the standard that the FDA should apply. The Act permits health claims on labels for a limited number of diet-disease relationships and will require a "significant agreement . . . among qualified experts" on claims, before allowing the use of those claims. This does not, however, end the entire public policy debate; the FTC still has a different standard, and even the FDA will have to apply and interpret the standard that Congress has now established.

This article explores the different approaches to health claims by the FTC and FDA. First, the article examines the regulatory mandates of the FTC and the FDA and summarizes the historical development of each agency's approach to health claims. Second, the article provides a comparative analysis of the FTC's flexible approach and the FDA's newly proposed "significant agreement" standard. Finally, the article concludes that although there is agreement between the agencies that health claims should be permitted, the FTC's standard is preferable to the proposed FDA rule because it provides a more flexible approach that protects consumer interests without obstructing the free flow of information.

II. BACKGROUND TO THE FDA AND FTC APPROACHES TO HEALTH CLAIMS.

Although the FTC and FDA are separate and distinct agencies, each with its own enabling legislation and regulations, a large overlap exists in the FTC's and the FDA's jurisdiction. Section 5 of the FTC Act empowers the Commission to prevent unfair or deceptive acts or practices in or affecting commerce. In addition, the Act specifically makes it unlawful to disseminate any false or deceptive advertisement, by any means, if its purpose is to induce the public to buy food, drugs, devices, or cosmetics. Although not expressly stated, the FTC assumes broad discretion to regulate both advertising and labeling practices generally.

Conversely, the FDA has specific statutory authority over food labeling and only indirect authority over advertising. The Food Drug and Cosmetic Act provides that a food is misbranded and subject to seizure if "[i]ts labeling is false or misleading. . . ." The FDA's indirect authority over food advertising is through its authorization to regulate the sale of drugs. A food can be considered a drug if promotional materials including advertisements for it made disease-specific health claims. As a drug, the product would have to meet stringent FDA testing requirements; otherwise, it could be seized. Thus, health claims in food advertising may effectively subject a product to the FDA's authority and regulations affecting both food and drugs.

With two agencies regulating the same area of commerce, potential for duplication of efforts and differences in enforcement policies inevitably arise. Because food pro-
producers are subject to liability under either Act, they logically prefer to err on the side of caution and follow the agency with the more restrictive policies. As a consequence, the standards and practices of the agency with the least restrictive policies become redundant and confusing to the public, not to mention wasteful of government resources. To lessen the possibility of such problems arising, the FDA and the FTC entered into an informal agreement in 1971, which gives the FTC primary jurisdiction over food advertising, and the FDA primary jurisdiction over food labeling.15

In the last decade, the two agencies have taken very different approaches to health claims. Prior to 1984, FDA regulations prohibited the use of health claims in promoting foods. Indeed, a food was considered misbranded if its labeling represented, suggested, or implied:

(1) [t]hat the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom."16

The FTC, on the other hand, did not adopt any specific regulations dealing with health claims despite a contrary staff recommendation in 1978.17 Instead, the FTC dealt with health claims on a case-by-case basis, applying its unfairness and deception standards.18 Although the FTC had no prohibition against using health claims, the FDA’s prohibition was sufficient to foreclose such claims in labeling and advertising, since the FDA continued its practice of ensuring that food products advertised did not make disease-specific health claims.19

In 1984, when the Kellogg Company began using health messages in All Bran advertisements, the FDA suspended its practice of prohibiting health claims in advertising, effectively allowing the advertisements.

III. FTC POLICY GOVERNING HEALTH CLAIMS IN ADVERTISING

Recent statements by individual Commissioners and by FTC staff indicate a desire to continue with the approach it has taken until now. The FTC staff has submitted written comments three times since the FDA began its formal rulemaking procedures.20 Each time, the FTC staff emphasized the virtue of its own case-by-case approach as being more flexible. Indeed, three Commissioners have each recently argued that truthful non-deceptive claims should not be suppressed.21

Under the FTC standard, health claims in food advertising must conform to the same scrutiny applied to any other product. Thus, a deceptive representation is one that is material and is likely to mislead a consumer acting reasonably under the circumstances.22 The representation, whether express or implied, must therefore meet each of the following three criteria to violate the Act: (1) it must be false or misleading, (2) when viewed from the perspective of a consumer acting reasonably under the circumstances, and (3) it must cause consumer injury, whether measurable or presumed from the circumstances.23

An advertising claim can be false or misleading, in violation of the FTC Act, when the claim itself is false or when there is no reasonable basis for the claim.24 In the area of food and health care products, the FTC has generally viewed outlandish claims of magic elixirs, unqualified claims of cures or misrepresentations of specific studies to be false claims in advertising. Qualified health claims about the special health benefits of foods are more likely to be analyzed under the "substantiation doctrine.”

A. Claims That Are False or Misleading In Themselves

Proving that a food product claim is false or misleading presents a special problem when the claim deals with health. Health claims are unlike other more "concrete" claims such as those promoting the sale of a franchise or memberships in travel clubs. If a franchisor claims to have one hundred franchisees or a travel club claims that members can fly to Hawaii for $50.00, it is possible to ultimately prove the truth or falsity of the claim. Health claims, however, are more amorphous and commonly involve the many intricacies and unknowns of biochemistry and nutrition. Biochemists, endocrinologists, epidemiologists and other scientists are reluctant to state that a given proposition cannot be proven true. Rather, they would reason that a proposition has not been proven since there is always the possibility that it could be true.

Despite this difficulty, the FTC has filed many actions in which it has alleged, and succeeded in proving, that a health claim is false or misleading. For example, in Pharmtech Research, Inc.,25 a National Academy of Sciences report encouraged the use of dried greens to reduce the risk of cancer. It was a relatively simple matter to determine whether the report substantiated the express claims. The FTC without much effort proved that (continued on page 6)
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the claim was false. In fact, the case was clear enough for a district court to grant a preliminary injunction to enjoin promotion of the claim. Similarly, the FTC challenged an unqualified claim that "there is no evidence that eating eggs will increase the risk of heart disease"; the claim was found to be false, as were claims associated with weight-loss pills.

Upon a finding that a claim is false or misleading, the FTC or a court may prohibit all future use of the challenged claim. A party under an order containing such a flat prohibition would have to seek an order modification or risk immediate civil penalties or contempt proceedings before reasserting the false claim. Thus, in order to modify a flat prohibition, the claimant must prove that a scientific breakthrough has occurred warranting an order modification.

B. Claims That Are False Or Misleading Because They Lack Substantiation

Health claims made in a couched and qualified language that certain foods have special health benefits are more likely to be examined under the FTC's "substantiation doctrine" to determine if there is a reasonable basis for the claim. The advertising substantiation doctrine evolved from the notion that along with any product claim comes the added assertion, either express or implied, that there is a reasonable basis for the claim. For example, if a food advertiser claims that amino acid supplements will help build bigger muscles quickly, any reasonable consumer likely will believe that the advertiser has a reasonable basis for the claim. The advertising substantiation doctrine places the burden on the party making the claim to demonstrate a reasonable basis. Thus, the FTC does not have to determine whether or not the health claim is true or false, possible or impossible. Rather, the inquiry focuses on whether "prior, fully documented, adequate and well-controlled scientific studies or tests..." exist to substantiate the claim.36

The FTC first articulated the framework for applying this doctrine in Pfizer, Inc.37 The FTC reasoned that if an advertisement expressly states the level of substantiation, such as "clinically proven effective," then consumers and the FTC would expect that well-designed clinical tests to have been performed and that actual results support the claim. Accordingly, unsubstantiated health care claims in advertising would be misleading to the consuming public regardless of whether the substantive claim itself is false because the claim—that there is a reasonable basis for the substantive claim—is false.

In determining what level of substantiation should exist for a claim when no specific level of support is claimed (i.e. "clinically proven"), the FTC considers the following six factors: (1) the nature of the product involved, (2) the type of claim, (3) the benefits of a truthful claim, (4) the cost of developing substantiation, (5) the consequences of a false claim, and (6) the reasonable amount of substantiation according to experts in the field.38

Recently, the substantiation doctrine has been used to challenge the health claims of Kraft Singles, Campbell's Soup, and Mazola Corn Oil. Each illustrates the difficulties consumers and the FTC face in sorting out the health benefits of these food products. Thus, in Kraft, Inc., the FTC alleged that Kraft misrepresented that its Kraft Singles cheese slices contained as much calcium as five ounces of milk. Similarly, in Campbell Soup Co., the food ads link the low fat, low cholesterol content of its soups with a reduced risk of some forms of heart disease, but fail to disclose that the soups contain high sodium levels which may increase the risk of heart disease. The FTC has also charged CPC International, Inc., the maker of Mazola Corn Oil, with deceptively representing that adding Mazola to a diet without other dietary changes will cause a 17% reduction in serum cholesterol levels, when in fact it did not have a reasonable basis for that claim.

While a finding that a claim is false may result in a flat prohibition of that claim being made in the future, a finding that a claim lacks adequate substantiation results in only a prohibition of the dissemination of that claim unless and until it has been substantiated. The possibility that the claim itself may be true is left open for future testing. Thus, when the finding is merely that there is a lack of adequate substantiation, there are difficulties in bringing an enforcement action.
IV. THE FDA'S APPROACH IN CONTRAST TO THE FTC'S

In contrast to the FTC's case-by-case, six-factor flexible approach, the FDA has proposed rules which would enable the agency to develop uniform labeling statements and consumer health messages for the six health areas identified in the interim enforcement policy where the relationship of diet to health has been established — specifically, (1) calcium and osteoporosis, (2) dietary fiber and cancer, (3) lipids and cardiovascular disease, (4) lipids and cancer, (5) sodium and hypertension, and (6) dietary fiber and cardiovascular disease. According to the rule, these statements and summaries must be based on a uniformly high level of agreement among scientists:

[s]uch a statement [health message] must be based on the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles. A significant agreement must exist among qualified experts that the statement is supported by such evidence. Moreover, the rule provides that any manufacturer who deviates from these accepted findings, "would subject their products to substantial risk of regulatory action under the food and drug misbranding provisions as well as the new drug provisions of the act." This same standard has been adopted in the "Nutrition Labeling and Education Act of 1990." The significant agreement standard is quite different from the FTC's approach in several respects. First, the new standard requires significant scientific agreement. By contrast, the FTC may permit scientifically controversial claims provided that one or two well-designed tests support the claims. Second, the proposal requires scientific evidence to be publicly available, while the FTC accepts non-public proprietary evidence.

Rules and enforcement policies that limit health claims can err either by permitting too many deceptive claims to slip through the regulatory nets or by chilling even non-deceptive claims from being released. The FDA's "significant agreement" approach runs the risk of over-deterrence. It may prevent even truthful non-deceptive claims from being made. For example, conspicuously absent from the list of six areas in which the FDA suggests that there may be agreement is the relationship between foods high in beta carotene such as broccoli, cabbage, brussels sprouts, and cancer risks. Perhaps, the FDA does not believe that the scientific community has reached significant agreement on this diet-disease connection. Nevertheless, consumers would benefit from allowing food processors to provide information about the diet-disease relationships in marketing their products. Likewise, there would appear to be injury to consumers from withholding this information.

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V. ROOTS OF THE DIFFERENT APPROACHES

The different mandates of the FTC and the FDA and the different media that the agencies regulate provide assistance in explaining the basis of the different standards. The FTC's mandate directs the Commission "to prevent persons, partnerships or corporations... from using unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce." In addition to preventing unfair and deceptive trade practices, the FTC mandate ensures a competitive marketplace through enforcement of the antitrust laws over which it has jurisdiction. To fulfill its mission, the FTC employs lawyers and economists, and most of its efforts focus on preventing economic injury. To prevent consumer injury and maximize consumer welfare...
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The FTC operates to remove obstacles to the free flow of information. Because economic injury that results from false or imperfect information is often reversible, some under-deterrence is tolerable.

By contrast, the FDA's "first level of concern is related to protection of the public health." To fulfill its mandate, the FDA employs largely health care professionals, and most of its efforts are focused on preventing physical injury to the public. Because physical injury is often irreversible, the FDA tolerates little under-deterrence.

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The FTC's perspective is also influenced by the fact that it has primary responsibility for food advertising, but not for packaging or labeling. The different goals and limitations of advertising and labeling may justify different rules for health claims. The Association of National Advertisers ("ANA") has recently taken this position in commenting on the FDA's Proposed Rulemaking:

[w]hile the advertising industry has a legitimate and real interest in the development of food labeling regulation, ANA must stress that advertising is not labeling and must not be expected to convey the same quantity or kind of information to consumers. Overloading advertising with excessively detailed governmentally [sic] mandated requirements will destroy the effectiveness of advertising in the marketplace. Also, unlike labeling, differences in the nature and capacity of the various media must be taken into account in regard to advertising regulation. The FTC staff filed comments in the FDA rulemaking proceedings that gave at least nodding assent to this distinction: "[w]e recognize...that significant differences between health claims on food labels and those in advertising may require different regulatory approaches." The differences in the nature and capacity of the media used in labeling and advertising may warrant some regulatory differences. It may make sense, for example, to require specific uniform words in labeling or to require disclosures that would be overly costly and even ineffective in advertisements on television or radio. However, the differing nature of advertising and labeling does not justify requiring a consensus of scientific opinion for health claims in labeling while only a reasonable basis is required for health claims in advertising. These contrasting approaches do not appear to have any basis in the different media through which the claim is communicated.

V. CONCLUSION

The FTC's approach provides the necessary flexibility to consider the special risks of injury involved in health claims for food while at the same time taking into account the potential for the benefit of permitting health claims. At least for now, it appears that the FTC and FDA approaches will continue. These differences have actually become less pronounced in recent years. The Nutrition Labeling and Education Act of 1990 and the FDA's recently proposed regulations will formalize a more permissive policy toward health claims. On the fundamental question there appears to be agreement—both agencies agree that health claims should be permitted. The existing differences that were highlighted in the debate over the correct standard will influence the future application of these standards to specific fact situations.
See supra, note 6. It should be noted that staff comments represent the views of the Bureaus that submitted them and not necessarily those of the Commission itself or any individual Commissioner. However, the Commission, with Commissioner Strenio dissenting, voted to authorize the staff to submit the two most recent comments. In the earliest comment, January 11, 1988, Commissioner Bailey, whose term has since expired, also dissented.

Comments were also submitted in January and June 1990.


51 While the FTC does not have regulations that would pre-screen such claims, it could seek to enjoin them preliminarily pending the outcome of the lengthier administrative trial.


55 Comments of the Staff of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission, at 2 (Jan. 5, 1990). This has not always been the position of the FTC staff. Responding to a 1976 proposed trade regulation, the FTC staff commented:... where there is no evidence supporting a differential between promotion which takes the form of advertising as opposed to labeling, it will subvert FDA's efforts to prevent the promotion of foods in violation of the Federal Food, Drug, and Cosmetic Act if the FTC does not prohibit the use of these claims in advertising. Proposed Trade Regulation Rule on Food Advertising: Staff Report and Recommendations at p. 256.