

Comments of the Bureaus of Competition,  
Consumer Protection and Economics of the  
Federal Trade Commission\*

Submitted to the  
Food and Drug Administration  
Department of Health and Human Services  
In Response to a Request for  
Comments on its Proposal to  
Amend the Rules Governing  
Health Messages on Food Labels and Labeling  
Docket No. 85N-0061  
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Food and Drug Administration  
Room 4-62, 5600 Fishers Lane  
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\* These comments represent the views of the Federal Trade Commission's Bureaus of Competition, Consumer Protection and Economics and not necessarily those of the Commission itself or any individual Commissioner. However the Commission, with Commissioners Bailey and Strenio dissenting, has voted to authorize the staff to submit these comments to you. Commissioners Bailey and Strenio do not disapprove of FDA's proposed rule but wish to disassociate themselves from the reasoning set forth in the Commission staff's comment.

## I. INTRODUCTION

In its Notice of Proposed Rulemaking,<sup>1</sup> the Food and Drug Administration (FDA) has requested comments on the revision of its rules governing health claims on food labels. The revised rules would permit food manufacturers to include health information on labels as long as the information is truthful, supported by valid evidence and consistent with generally recognized medical and nutritional principles. If health claims are made, however, the label must also include certain additional nutritional information.

Rapidly accumulating scientific evidence indicates that diet has an important influence on health. The FDA's proposed revision to its rules will allow food manufacturers to provide consumers with truthful information on the relationship between diet and health. By removing current restrictions on the food marketers' ability to communicate health information to consumers, the FDA's revision will make an important contribution to the public's welfare.

The Federal Trade Commission is a law enforcement agency charged with prosecuting violations of Sections 5 and 12 of the

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<sup>1</sup> 52 Fed. Reg. 28843 (1987) (to be codified at 21 C.F.R. Part 101).

Federal Trade Commission Act, which prohibit deceptive or unfair practices in or affecting commerce.<sup>2</sup> One of the FTC's major efforts is to regulate national advertising in a way that protects consumers from deception, but at the same time does not chill or prevent dissemination of truthful ads. The FTC has developed widely accepted standards for the regulation of deceptive advertising with minimum disruption to the dissemination of truthful information.<sup>3</sup> We support the FDA's proposal to adopt an approach to the regulation of labeling that reflects the same objectives.

This comment discusses how the FDA can assure itself that its regulations are stringent enough to protect consumers from deceptive information but not so restrictive as to stifle dissemination of truthful information. Our main suggestion is that a more flexible standard for substantiation of health claims would benefit consumers by increasing the amount of information available without jeopardizing consumers' health. In light of

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<sup>2</sup> 15 U.S.C. § 45 et seq. The FTC has concurrent jurisdiction with the FDA over the advertising of food, and has concurrent jurisdiction with the FDA and the Department of Agriculture over the labeling of food. The FTC also has statutory authority to administer a number of laws that mandate disclosure such as the Federal Cigarette Labeling and Advertising Act, Truth In Lending Act, Energy Policy and Conservation Act (appliance labeling). In addition, the FTC has promulgated disclosure rules such as the R-Value (thermal insulation labeling) and Care Labeling rules.

<sup>3</sup> The Commission's approach has been cited with approval in Supreme Court decisions articulating the reach of the First Amendment to commercial speech. See *Zauderer v. Office of Disciplinary Counsel*, 105 S.Ct. 2265, 2279 (1985).

the FTC's successful experience with reliance on proprietary data, we also suggest that the FDA consider accepting proprietary data as substantiation for health claims. Finally, we question whether it is necessary to establish a committee to draft model health claims when manufacturers are permitted, under the proposed rules, to devise their own, adequately supported, health claims for labels. In sum, we support the FDA on this important proposal, but suggest that FDA revise the proposed substantiation standard to make it consistent with the more flexible substantiation standard used by the FTC to evaluate claims in food advertising.

## II. Benefits of Allowing Truthful Health Claims on Food Labeling

### A. Consumers Want Nutritional Information

A growing body of evidence indicates that important links exist between diet and health. As a result, government guidelines point to relationships between high dietary cholesterol and saturated fat diets and increased risks of heart disease,<sup>4</sup> sodium intake and hypertension,<sup>5</sup> and low-fat, high-

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<sup>4</sup> See, e.g., U. S. Dep'ts. of Agriculture and Health and Human Services, *Dietary Guidelines for Americans* 15. (2d ed. 1985).

<sup>5</sup> *Id.* at 21.

fiber diets and reduced risks of some forms of cancer.<sup>6</sup> The importance of these concerns to consumers is reflected in the substantial interest consumers express in receiving more nutritional information. A 1985 national survey reportedly found that 68% of consumers surveyed wanted more information about nutrition.<sup>7</sup> The General Accounting Office has reported that Americans believe that good diets are important but are confused about nutrition and lack information on how to eat healthfully.<sup>8</sup> Consumers appear to be responding to available information by changing their dietary habits. The USDA's 1985 national food survey found that American women are consuming 60% more skim and low-fat milk than they did in 1977, 29% more grain and roughly 30% less meat and eggs.<sup>9</sup> These changes presumably reflect increasing awareness and concern about the relationship between diet and health. Indeed, an FDA telephone survey in 1986 found

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<sup>6</sup> See, e.g., U. S. Dep't. of Health and Human Services, Diet, Nutrition & Cancer Prevention 5 (1984).

<sup>7</sup> Lord, Health Claims in Food Advertising, 27 J. of Advertising Research 11 (1987)(citing results of "The Gallup Study of Changing Food Preparation and Eating Habits").

<sup>8</sup> Government Accounting Office, What Food Should Americans Eat? Better Information Needed on Nutrition Quality of Foods, Pub. No. CED-80-68 1 (April 30, 1980).

<sup>9</sup> U.S. Dep't. of Agriculture, Nationwide Food Consumption Survey Continuing Survey of Food Intakes By Individuals, Women 19-50 and Their Children 1-5, Day (1985).

that 61% of those surveyed reported eating differently because of health concerns.<sup>10</sup>

Allowing manufacturers to combine general health information with information on their products' characteristics is likely to increase the manufacturers' incentives to supply health information.<sup>11</sup> The producers of low-salt foods, for example, could use marketing claims to explain how salt consumption is related to existing hypertension. However, any particular manufacturer may be reluctant to supply general health information because the information supplied also benefits its competitors at no cost to them. Therefore, there may be disincentives for a manufacturer to supply some types of health information. Thus allowing manufacturers to make health claims about nutrients contained in their particular products should encourage the dissemination of information.

#### B. Benefits From the Advertising of Health Claims

Even though health claims are not the predominant themes in food advertising, advertising has played an important role in

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<sup>10</sup> Remarks of James T. Heimbach, Head Consumer Research Staff, FDA, at the Journalist Conference on Food Safety and Nutrition (October 1986 and October 1987).

<sup>11</sup> A review of nutritional advertising, see, e.g., ads cited at notes 13-19, indicates that typically advertising relates the nutritional information to the individual brand or product advertised.

informing consumers about the relationship between diet and health. In the early 1970's, for example, food manufacturers were advising consumers to reduce cholesterol levels by substituting polyunsaturated fats for some saturated fats.<sup>12</sup> Similarly, other advertisers promoted egg substitutes as a way to help meet the American Heart Association's then-recommended levels of dietary cholesterol intake.<sup>13</sup> More recently, following Kellogg's highly successful advertising and labeling campaign discussing the National Cancer Institute's recommendations on high-fiber low-fat diets, several food manufacturers have begun more aggressive marketing strategies based on the relationship between diet and health. For example, other cereal manufacturers, such as General Mills, began making claims for fiber.<sup>14</sup> Quaker Oats has undertaken a campaign that describes the benefits of oatmeal as part of a low-fat, low-cholesterol diet.<sup>15</sup> The California Prune Board employed a campaign that informs consumers that prunes are a good source of fiber and

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12 One example is the Promise Margarine campaign that ran in major newspapers and magazines in 1973. See, e.g., Potomac Magazine, May 27, 1973.

13 See advertising for Fleischmann's Egg Beaters in the Wall Street Journal, March 21, 1973. The use of this advertisement, as well as the others in this comment, are for illustration purposes only and do not suggest approval or disapproval of their content.

14 General Mills' television ad for Fiber-One that ran in 1986 and 1987.

15 Quaker Oats' advertisement in Newsweek, September 14, 1987.

explained how a high-fiber, low-fat diet may reduce the risk of contracting some types of cancer.<sup>16</sup> Another cereal manufacturer has begun to advertise that its Shredded Wheat product was rated the highest by Consumer Reports primarily because the product was a source of fiber and had no added sugar or salt.<sup>17</sup>

Other food advertisements have sought to correct consumers' misimpressions about diet and health. For example, a newspaper advertisement for Promise Spread<sup>18</sup> explains:

Many grocery shoppers believe that any product labeled "no cholesterol" is "good for your heart" and poses no risk of increasing the amount of cholesterol in the blood. Many shoppers also assume that "no cholesterol" means no saturated fat. But, both assumptions are totally wrong, since a product labeled "no cholesterol" may, in fact contain a large amount of saturated fat.

In sum, at least some manufacturers have found advertising to be an effective vehicle for providing health information related to their products to consumers.

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<sup>16</sup> Advertising by the California Prune Board, Better Homes and Gardens, January 1987.

<sup>17</sup> Nabisco Brands' television advertising for Shredded Wheat, January 1987.

<sup>18</sup> Promise advertisement, USA Today, May 6, 1987, at 7A.



C. Additional Benefits from an FDA Policy Allowing Truthful Health Claims on Food Labels

The FDA's revisions of its food labeling regulations will, allow food manufacturers to provide more information on food labels. Accurate health information on labels could produce substantial consumer benefits. Information conveniently placed on labels would significantly reduce the cost to consumers of searching for health information and of identifying products that can be associated with specific health benefits. As a result, consumers are likely to become better informed and make healthier choices from among available foods.

Recent studies indicate that many consumer purchasing decisions are made in stores,<sup>19</sup> and that consumers use information presented clearly and conveniently at the point-of-purchase in making those decisions. More specifically, a 1981 study of Giant Food Stores' "Special Diet Alert" program, which flagged items low in sodium, calories, fat and cholesterol with shelf markers, indicated that consumers did use that information in making purchasing decisions.<sup>20</sup> Indeed, 31% of the shoppers

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<sup>19</sup> Results of Point-Of-Purchase Advertising Institute Study as reported in Advertising Age, October 5, 1987, at 93. The Institute reportedly found that two out of three supermarket purchase decisions are made while shopping.

<sup>20</sup> A comparison of stores employing the program with stores that did not revealed that sales of the flagged items were greater in the stores using the shelf markers than in the control stores. Schucker and Levy, Division of Consumers Studies, Center For Food Safety & Applied Nutrition, Special Diet Alert: Evaluation Of A Successful In-Store Program (September 1984).

interviewed reported using the shelf markers when they shopped.<sup>21</sup> These studies suggest that having health messages available on labels may help facilitate more informed purchasing decisions.

Finally, the new rule may help bring about more informative advertising. Although the preamble to the FDA's proposed rule clearly states that the rule's requirements "apply to health claims made on food labels, but not to health claims made in food advertising," the FDA's former ban on labeling claims may have had at least some chilling effect on advertising claims as well.<sup>22</sup> Thus, the FDA's revisions may encourage health claims in advertising as well as in labeling.

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While the effects of shelf markers may differ from the effects of labels, the results suggest that consumers will use in-store information to make purchasing decisions.

21 Id. at 3.

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[The FDA] took the position that any product for which drug claims were made in advertising became a drug as well as a food, whose label must bear the adequate directions for use required for a drug under Section 502 (A) of the FD&C Act. This position, commonly referred to as the "squeeze play," was upheld by the courts. More recently, FDA took the position that a nutrition claim made solely in advertising is sufficient to trigger mandatory nutrition labeling under the FD&C Act).

Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosm. L. J. 3, 25-26 (1986)(footnotes omitted).

In summary, truthful health information in both food labeling and advertising offers a powerful means of providing consumers with information that may enable them to improve their health. Manufacturers may respond to the greater opportunity to use truthful health claims in marketing their products by devoting additional resources to producing information about diet and health. Moreover, allowing food manufacturers greater latitude to emphasize the health benefits of their products is likely to increase demand for products with those benefits and thus increase incentives to produce such products.<sup>23</sup> The FDA's action in removing its prior ban on such information on food labels can thus lead to a healthier population.

D. Risk Of Injury From Deceptive Health Claims

From a public policy standpoint, it is important to balance the benefits and the risks of allowing food manufacturers greater latitude to make health claims on labels. The most important risk is that some deceptive claims will also be made. Deceptive health claims can harm consumers in three different ways. First, in some instances, the claim may directly injure consumers by persuading them to change their diet in a way that actually

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<sup>23</sup> In fact, a recent Newsweek article reported that, in response to the public's concern about saturated fat consumption, "The meat industry is feverishly developing less fatty cuts of beef and pork, and supermarket shelves are laden with low-fat dairy products." Controlling Cholesterol, Newsweek, October 19, 1987, at 97.

injures their health. Second, the claim may indirectly injure consumers' health by leading them to refrain from making changes in their diets that would help them, or by encouraging them not to seek effective medical treatment. Finally, deceptive claims may injure consumers economically if they pay a premium price for the food, or if they purchase items they otherwise would not because of the deceptive claims.

The market itself currently provides some safeguards against misleading and potentially harmful claims. For example, if one manufacturer makes a bogus claim, competitors can react swiftly.<sup>24</sup> Other information suppliers, especially the media, are also likely to help dispel resulting misconceptions. And, manufacturers whose success depends upon their good reputations may also be restrained from making exaggerated claims for particular products for fear of tarnishing their reputations.

However, because the truthfulness of health claims is often difficult or impossible for consumers to evaluate even after purchase and use of a product, market safeguards may offer insufficient protection against some harmful health claims. The regulation of health claims should be designed to identify and deter claims that are likely to be harmful. Because the

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<sup>24</sup> They may complain to the FTC, run comparative advertising countering the misinformation, seek a preliminary injunction under the Lanham Act, 15 U.S.C. §1125(a), or file a complaint with the National Advertising Division of the Council of Better Business Bureaus, an industry self-regulatory body.

potential benefits and risks of particular claims vary widely, we believe that this can best be accomplished by a flexible approach to evaluating individual claims rather than a rigid rule that applies to every possible claim.<sup>25</sup> This is particularly true for the area of deceptive health claims on food labeling because some unsubstantiated claims could result in health injury while others present only de minimis risks of economic harm.<sup>26</sup>

III. COMPARISON OF THE FTC'S APPROACH TO ADVERTISING OF HEALTH CLAIMS TO THE FDA'S PROPOSED FOOD LABELING RULE

A. The FTC Approach

The Federal Trade Commission Act prohibits unfair and deceptive acts or practices.<sup>27</sup> The Commission's deception and advertising substantiation policy statements<sup>28</sup> have made it clear

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<sup>25</sup> We recognize that fixed regulatory standards may be appropriate remedies for some problems. For example, a fixed standard might be more effective than a flexible standard when the likely consequences of allowing (or prohibiting) an action are not apt to vary much from case to case, such as regulations setting tolerance limits for toxins in various foods or drinking water. However, a fixed standard appears inappropriate for health claims because the consequences may vary significantly.

<sup>26</sup> See discussion infra note 43.

<sup>27</sup> 15 U.S.C. § 45 et seq. (1982).

<sup>28</sup> Both statements have been adopted in Commission decisions. Deception Policy Statement, appended to Cliffdale Associates, Inc., 103 F.T.C. 163, 174-84 (1983); Ad Substantiation Policy Statement, appended to Thompson Medical Company, 104 F.T.C. 648, 839-42 (1984), aff'd 791 F.2d 189 (D.C. Cir. 1986).

that advertising claims must not mislead consumers and must be substantiated if they are to pass muster under the FTC Act. In determining whether a claim misleads or deceives consumers, the Commission evaluates the overall impression created by the ad and considers how reasonable consumers read or perceive the claim in the context of the ad.<sup>29</sup> With regard to determining the appropriate level of support for a claim, the Commission employs a flexible substantiation doctrine that it has found to be an effective, but not overly restrictive, means of assessing the adequacy of such support.

Under the Commission's ad substantiation doctrine, claims must be supported by the level of substantiation they communicate, either expressly or impliedly, to the reader or listener. Thus, if an ad claims a particular level of substantiation, e.g., that six major studies support the existence of a particular diet/health relationship, then that amount of evidence must indeed substantiate the claim.<sup>30</sup> When an advertisement expressly or impliedly claims that there is a consensus of opinion that a diet/health claim is true, then this consensus must exist. Similarly, where a manufacturer has substantiating evidence that is subject to some limitation or

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<sup>29</sup> See Cliffdale, 103 F.T.C. at 177-79.

<sup>30</sup> In the example used above, the six studies relied upon would have to be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in science to yield accurate and reliable results. See generally Thompson Medical, 104 F.T.C. at 825-28.

qualification, the claim is allowed provided it is appropriately qualified so that the limited nature of the substantiation is apparent to consumers and the advertisement does not imply to consumers that a higher level of substantiation exists.<sup>31</sup>

In the most typical kind of advertising, however, where no express or implied level of support is claimed, the Commission examines several factors to determine what type of "reasonable basis" the advertiser should have for the claim.<sup>32</sup> In particular, the Commission considers: (1) the type of claim; (2) the type of product;<sup>33</sup> (3) the benefits of a truthful claim; (4)

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<sup>31</sup> Likewise, if there is substantial inconsistency in the evidence, it may be necessary for a manufacturer to disclose the existence of contrary evidence in order to ensure that consumers are not misled. See National Commission on Egg Nutrition, 88 F.T.C. 89 (1976) aff'd 570 F.2d 157 (7th Cir. 1977), cert. denied 439 U.S. 821 (1978). Of course, where such disclosure is necessary to prevent consumers from being misled, the disclosure must be legible and understandable to ensure that the overall message communicated is accurate. In short, the disclosure must be effective. See generally Cliffdale, 103 F.T.C. 179-81 and cases cited therein.

<sup>32</sup> This requirement is based on the well-established proposition that objective claims convey to consumers that advertisers possess some reasonable amount of support for the claim. Firestone Tire & Rubber Co. v. FTC, 481 F.2d 246, 250-51 (6th Cir.) cert. denied, 414 U.S. 1112 (1973); see also Cliffdale, 103 F.T.C. at 175, n. 5.

<sup>33</sup> With respect to the first two factors, the Commission considers whether the product involved raises health, safety, or other special concerns, whether the claims at issue are specific or general, and whether consumers are capable of evaluating the claims. Thompson Medical, 104 F.T.C. at 822-23.

the cost of developing substantiation for the claim;<sup>34</sup> (5) the consequences of a false claim;<sup>35</sup> and (6) the amount of substantiation experts in the field believe is reasonable.<sup>36</sup>

These six factors allow the Commission to weigh carefully the potential benefits from the dissemination of information if it turns out to be true against the potential harm that may result if the information turns out to be false. The reasonable basis standard thus deals with uncertainty as to the existence of the diet/health relationship, not by simply prohibiting all claims based upon uncertain data, but by evaluating the value and risk that attend dissemination of the information and by setting the required level of substantiation accordingly. In sum, the six criteria are part of a balancing analysis that enables the Commission to consider not only the likelihood that a particular claim is true, but also to weigh the likely consequences of allowing claims based on the available substantiation.

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<sup>34</sup> The third and fourth factors are often considered simultaneously. This ensures that the level of substantiation expected of the advertiser is not likely to prevent consumers from receiving potentially valuable information. *Id.* at 823.

<sup>35</sup> In considering the fifth factor, all adverse effects, including potential economic and health injury, are taken into account. *Id.* at 824-25.

<sup>36</sup> Under the sixth factor, the Commission looks to what the scientific or medical community would require, as evidenced by such sources as FDA regulations, expert opinion and/or expert panel reports, to substantiate the claim. *Id.* at 825-26.



Under this flexible approach, the required level of substantiation rises with the potential for consumer injury should the claim turn out to be false. For example, where the particular product claim raises concerns about possible injury to the health or safety of consumers or will be difficult or impossible for consumers to assess for themselves, the Commission requires a relatively high level of substantiation.<sup>37</sup>

B. The FDA's Revised Rule

FDA's revised rule is in large measure consistent with the FTC's approach to regulating the advertising of health claims. First, the rule prohibits claims that are not truthful or are misleading. Similarly, the FTC Act, which prohibits deceptive acts or practices, proscribes claims which are misleading or untruthful.

Second, the rule requires that a claim be supported by valid, reliable, scientific evidence; that this evidence be derived from well-designed and conducted studies consistent with generally-accepted scientific procedures and principles; and that the studies be performed and evaluated by persons qualified by expertise and training in appropriate disciplines. These requirements also parallel well-established principles under the

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<sup>37</sup> Id at 822.

FTC's ad substantiation doctrine. Commission orders often require that advertisers possess "reliable and competent" evidence to substantiate their representations, and typically define such evidence as "those tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."<sup>38</sup>

Third, the rule requires that the claim must be consistent with generally-recognized medical and nutritional principles for a sound dietary pattern. This also seems consistent with the Commission's application of its deception policy. A health claim that is unqualified as to the strength and source of its support and is inconsistent with generally-recognized medical and nutritional principles would be deceptive.<sup>39</sup> Moreover, the very nature of the epidemiological evidence currently supporting

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<sup>38</sup> PharmTech Research, Inc., 103 F.T.C. 448, 459 (1984). See also Porter & Dietsch, Inc., 90 F.T.C. 770, 868, 885, aff'd 603 F.2d 294 (7th Cir. 1979) (company whose claims were not supported by a reasonable basis consisting of "competent scientific tests" placed under order requiring such substantiation).

<sup>39</sup> In National Commission on Egg Nutrition, 88 F.T.C. 89 (1976), the Commission successfully challenged as deceptive advertising for eggs that claimed there was absolutely no scientific evidence that eggs increased the risk of heart attack, that characterized evidence that eggs increased the risk of heart disease as a "myth," and that asserted that cholesterol was not all that bad for you. The Commission found these ads deceptive because, by failing to inform consumers of the inconsistencies in the evidence supporting the position stated, the ads were likely to mislead consumers.

health claims for food products (i.e., studies which may analyze certain foods in the context of a total dietary regimen) virtually requires that the advice be consistent with nutritional principles for a sound total diet in order to avoid misleading consumers.

C. Differences Between The FTC Policy And FDA's Revised Rule

1. Amount Of Substantiation Required

FDA's revised rule does not explicitly set forth the amount of substantiation that would be required to support a health claim on a food label. However, the preamble to the regulation sets out what could be construed to be a very restrictive standard. In discussing the revised rule's requirement that the claim be based on valid scientific test data obtained by using proper testing procedures, the preamble states that labeling claims must "reflect the weight of scientific evidence" and that preliminary results must be confirmed. If these statements, by stressing that study results must be internally consistent and internally confirmed, are mere elaboration on the section's general requirement that the claim be based on scientific data

that is valid and reliable, then the provision parallels the FTC's approach to advertising regulation.<sup>40</sup>

However, the preamble could also be read to indicate that the FDA will interpret the rule to prohibit any claim supported only by preliminary evidence, even if the preliminary nature of such evidence is expressly cited or explained. Further, it is possible that the general "weight of the scientific evidence" standard could be interpreted like the 1985 interim "consensus" guidelines announced by FDA staff.<sup>41</sup> If these two interpretations are intended and are incorporated into the text of the revised rule, then the revised rule will continue to ban some health claims that are supported by competent and reliable scientific evidence simply because the findings are preliminary, or because valid, reliable, scientific evidence has not yet

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<sup>40</sup> Similarly, the results of one study that contradict the results of a number of other studies may simply reflect a false positive result and not be appropriate substantiation unless those results are confirmed.

<sup>41</sup> Remarks of Joseph P. Hile, Associate Commissioner for Regulatory Affairs before the Food and Drug Law Institute (March 1985). In his remarks, Mr. Hile suggested that a "consensus" of the scientific community would be needed to substantiate health claims on labels.

The preamble to the revised rule does not use the term consensus, instead employing the term "weight of the scientific evidence." The amount of evidence needed to satisfy this standard is not explained in either the preamble or the revised rule. It is therefore possible that this standard could also be interpreted to require that a consensus of the scientific community exist before the "weight of the scientific evidence" is established.

become known and therefore generally accepted in the medical community.

If, of course, the FDA has concerns about the safety of either the product being promoted, or the dietary advice being given, then a higher level of substantiation is appropriate.<sup>42</sup> If, however, the FDA is merely concerned that consumers not be misled about the underlying strength of the substantiation for the claim and the weight that consumers should attach to it, then there are more flexible formulations, such as the FTC's substantiation doctrine, that would achieve that goal.

The revised rule will allow the FDA more flexibility in determining whether claims are adequately substantiated than the

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<sup>42</sup> In most cases, however, it is unlikely that the FDA will have concerns about whether a food is a safety or a health hazard, or that the nature of the claims being made for a otherwise harmless product renders their very consumption a health risk. Thus, for example, when FTC officials commented on the Kellogg's All-Bran ad in 1985 they noted that they were aware of no grave health or safety risks that flowed from choosing All-Bran over another breakfast cereal.

In contrast, there are instances where consumption of the food as advertised does raise health or safety concerns. In Estee, Inc., for example, the Commission alleged claims that Estee's advertising encouraged diabetics to consume foods without adequate substantiation about how those foods affected blood sugar levels. Estee, Inc., 102 F.T.C. 1804 (1983). In such cases, the health or safety risk obviously demands a high level of substantiation. Indeed, the Commission has repeatedly stressed that a high level of substantiation is required for claims involving consumer health or safety. See Thompson Medical, 104 F.T.C. at 822. However, in the food advertising area, cases that involve health or safety threats seem to be the exception rather than the rule. The flexible substantiation doctrine used by the Commission would allow the FDA to deal firmly with these cases without jeopardizing truthful claims.

agency has enjoyed in the past. The FDA's experience with the regulation of cholesterol claims on food labels is illustrative. Although evidence existed from as early as 1957 that low-fat, low-cholesterol diets were associated with reductions in the risk of heart disease, FDA rules precluded the use of this information on package labels.<sup>43</sup> At that time FDA officials had no means of predicting the strength of the evidence that would ultimately accumulate on the relationship between cholesterol, saturated fat intake and health.<sup>44</sup> In the early 1970's, the FDA began to permit the labeling of fatty acid content but not more explicit health claims. Since then<sup>45</sup> the relationship between

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<sup>43</sup> Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosm. L.J. 3 (1986).

<sup>44</sup> Medical authorities now widely accept that a high cholesterol level is an important risk factor for heart attack and stroke and that limiting dietary intake of cholesterol and saturated fat can play an important role in lowering cholesterol levels. American Heart Association, The American Heart Association Diet, An Eating Plan For Healthy Americans (1985). Indeed, new guidelines for physicians released by the National Cholesterol Education Program, an arm of the National Health, Lung and Blood Institute, recommend dietary modifications (restrictions of fats to 30 percent of total calories, saturated fats to 10 percent of total calories and cholesterol to 300 milligrams daily) for persons with cholesterol levels above 200 as one step in reducing cholesterol levels and so, the risk of heart disease. See, e.g., Controlling Cholesterol, Newsweek, October 19, 1987, at 95.

<sup>45</sup> In 1973, the FDA adopted regulations permitting labels to include specific numerical information about cholesterol and fat levels. The regulations restrict the information to content information and a required statement that the information is provided for individuals modifying their dietary fat intake on the advice of a physician. All other health claims were prohibited by the regulations. See 21 C.F.R. § 101.25. In 1986, the FDA proposed to modify these regulations. Food Labeling, Definitions of Cholesterol Free, Low Cholesterol and Reduced Cholesterol, 51 Fed. Reg. 42584 (1986)(to be codified at 21

cholesterol, saturated fat and an increased risk of heart disease has gained broad acceptance.<sup>46</sup> However, the history of the FDA's past approach is instructive. On the question of diet and health, it will often be the case that fully confirmatory data are not available until some time after the association has begun to be established. This being the case, we think consumers would be better off with a policy that permits carefully qualified truthful information about diet-health relationships than with a policy that prohibits such claims.

It is important to balance the desire for certainty against lost benefits of truthful claims if an inflexible standard is used. The FTC's substantiation doctrine offers an alternative of addressing questions that may arise in the future, balancing as it does the benefits of a truthful claim with risks of a false one. In fact, in recent years the Commission has applied its ad substantiation standards to cholesterol and fatty acids. The Commission has both allowed truthful advertising about the  

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C.F.R. Part 101).

<sup>46</sup> The claims made in the past about the relationship between cholesterol, saturated fat and heart disease were prohibited by the FDA's regulations specifically governing cholesterol and fat labeling (21 C.F.R. § 101.25) (under which virtually all cholesterol and fat-related health claims had been effectively prohibited). The FDA indicated in the 1986 notice proposing changes to its current cholesterol labeling rules that an upcoming revised health claims rulemaking would address and set out the FDA's policy regarding health claims including cholesterol/fat health claims. 51 Fed. Reg. at 42587. Thus, the proposal that is the subject of this comment would govern these claims if they were made today.

relationship between cholesterol, saturated fat and heart disease, as well as taken action where necessary to correct misstatement.<sup>47</sup>

## 2. Evidence Must Be Publicly Available

The FDA's revised rule also differs from the Commission's substantiation policy in that it does not permit reliance on proprietary data to support claims. The requirement that the data be publicly available has benefits and drawbacks.

One benefit of such a restriction may be that, to the extent that manufacturers conduct research and release it in order to make claims, the public will gain access to additional information. Moreover, a substantiation standard incorporating such a requirement will probably require fewer FDA enforcement resources because the data will be subject to the review and criticism of the scientific community before it is used as substantiation, thus providing the FDA with a better basis on which to assess labeling claims. In addition, because of the peer review and criticism that publicly available research will face, such research is likely to be more rigorously tested and carefully performed than in-house proprietary research.

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<sup>47</sup> See, e.g., National Commission on Egg Nutrition, 88 F.T.C. 89 (1976).



There are, however, costs associated with an absolute prohibition on claims based on proprietary information. In particular, the benefits to a firm of investing in research are eroded when the research results are made available to competitors as a basis for parallel claims by them. Firms therefore might not make beneficial health claims that can be substantiated by proprietary research if in doing so they are required to make that research data public.<sup>48</sup> If proprietary research cannot be used as a basis for health claims, firms may decide to invest less in such health research than they might otherwise have done. Either action could be detrimental to consumers.

### 3. The Nutritional Labeling Requirement

The FDA's rule requires that food labels with health claims must also contain complete nutritional labeling. This requirement is different from the FTC's approach with respect to food advertising, which is to require disclosure of additional information only when the failure to provide it would be unfair or deceptive. The FDA's proposed revision has both benefits and costs which should be weighed.

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<sup>48</sup> It is, of course, clear that the FDA itself would need access to any proprietary data on which a firm relied and to any proprietary data that did not support the claim.

The FDA's across-the-board nutritional labeling requirement, which would be automatically triggered by a health claim on the label, would provide consumers with more information concerning health claims. Thus, this requirement addresses concerns that consumers will be misled by labeling that does not disclose nutritional flaws.

However, the nutritional labeling requirement may raise the cost of making health claims. These costs might deter manufacturers from making some beneficial claims. Moreover, the goal of providing protection against potentially misleading claims might be better attained through means other than the proposed across-the-board nutritional labeling requirement. For example, disclosure of additional information -- including disclosure of relevant nutritional flaws -- could be required on a case-by-case basis in those instances where deception would exist without the disclosure.<sup>49</sup> Alternatively, in a regulatory environment in which competitors are free to make adequately substantiated comparative health claims, the market might provide adequate incentives for competitors to supply useful information

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<sup>49</sup> See, e.g., *Adria Laboratories Inc.*, 103 F.T.C. 512, 524-25 (1984) (Commission required manufacturer of a non-aspirin product with side effects similar to aspirin to disclose such fact whenever it made representations that the product contained no aspirin or made representations that compared the product to aspirin).

about the nutritional attributes of competing products if consumers desired to receive the information.<sup>50</sup>

#### 4. Health Message Committee

The preamble to the FDA's proposed revision to its rule on health claims states that the Assistant Secretary for Health intends to establish a standing Public Health Service Committee to draft model health messages for food labeling. Such model messages might have been an aid to compliance if FDA adopted the more vaguely-worded consensus standard it had originally proposed. However, the FDA has not adopted that approach, and we hope that the FDA will further clarify the current standard in response to these comments. Such revisions would make regulatory guidance in the form of model messages much less necessary. More importantly, although the preamble expressly states that food manufacturers are not required to use the model messages, there is at least some risk that manufacturers will use the standardized messages exclusively in order to avoid the possibility of having to undergo costly revisions of their labels. If so, the model message may interfere with ordinary competitive forces that would otherwise lead food marketers to make health messages as noticeable as possible. Standardized

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<sup>50</sup> See, e.g., the Promise Margarine advertisement discussed at footnote 19.

messages may decrease the diversity of the messages, which may in turn decrease the possibility that the consumer will notice the information and understand it.<sup>51</sup>

This is not to say that the government cannot serve other important functions to encourage better dissemination of health information. For example, it may participate in joint promotions such as Kelloggs' and the National Cancer Institute's All-Bran campaign. Similarly, the Public Health Service committee might serve an important coordinating function in helping develop jointly sponsored public health campaigns.

#### IV. CONCLUSION

We support FDA's action in proposing revisions to its rules regarding health messages on food labeling because it will encourage the dissemination by food manufacturers of important information about the relationship between diet and health. We do recommend, however, that FDA adopt a more flexible standard than it has proposed for the substantiation of health claims that adjusts the level of substantiation to the type of claim. We

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<sup>51</sup> This was the case in the single mandated health warning in cigarette advertising. See Federal Trade Commission, Staff Report On The Cigarette Advertising Investigation, pp. 4-10 to 4-12 (1981). In addition, the currently required disclosure that cholesterol content information "is provided for individuals who on advice of a physician are modifying their dietary intake of fat" may diminish the attention given to this information by ordinary consumers who are not under a doctor's care. 21 C.F.R. § 101.25(d).

also suggest that FDA consider accepting proprietary data as well as publicly available data as substantiation for health claims. Finally, we question the necessity or advisability of a committee to draft model health claim messages.