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COMMISSION AUTHORIZED

Comments of the Bureaus of 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
Food Labeling; Health Messages
and Label Statements;
Reproposed Rule
[Docket No. 85N-0061]
55 Fed. Reg. 5176
February 13, 1990

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* These comments represent the views of the Federal Trade Commission's Bureaus of Consumer Protection and Economics and not necessarily those of the Commission itself or any individual Commissioner. However, the Commission, with Commissioner Strenio dissenting, has voted to authorize the staff to submit these comments.

I. INTRODUCTION AND SUMMARY.[1]

In its Notice of Proposed Rulemaking,[2] the Food and Drug Administration (FDA) has requested comments on its reproposal of rules governing health claims for foods. This new proposal withdraws the August 4, 1987 proposal on health messages on food labels, which was adopted as an interim rule on that date. The notice also announces an interim enforcement policy to be followed until the final rule is adopted.

The staff of the Federal Trade Commission[3] twice has commented on this subject. A copy of the staff's most recent comment, which addresses some of the issues raised by the present notice, is attached. That comment reiterated the staff's support for the concept of truthful health messages and described the

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[1] These comments represent the views of the Federal Trade Commission's Bureaus of Consumer Protection and Economics and are not necessarily those of the Commission or any individual Commissioner. However, the Commission, with Commissioner Strenio dissenting, has voted to authorize the staff to submit these comments. Questions or comments concerning this document may be addressed to Judith Wilkenfeld, Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection (202-326-3150).

[2] 55 Fed. Reg. 5176, February 13, 1990, to be codified as part of 21 C.F.R. § 109(i)(1).

[3] The Federal Trade Commission is a law enforcement agency charged with prosecution of violations of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 et seq., which prohibit deceptive or unfair practices in or affecting commerce. While FDA regulates labels and labeling for food products, the FTC is charged with preventing false and misleading advertising and unfair practices. See Working Agreement Between the Federal Trade Commission and the Food and Drug Administration, 3 Trade Reg. Rep. (CCH) para. 9850 (1971).

results of a Bureau of Economics study analyzing the effects of advertising and labeling of health claims in the ready-to-eat cereal market.[4] The comment also recognized that significant differences between health claims on food labels and those in advertising may require different regulatory approaches.

This comment has four additional sections. Section II briefly focuses on the overall objectives of the government's regulation of health claims on food labeling. Section III describes the Commission's responsibility for advertising in the health claim area. Section IV addresses four aspects of FDA's reproposed rule:

A. the proposed Public Health Service Committee (PHS Committee) process for formulating scientific and consumer summaries and model label statements;

B. the proposed model label statement;

C. the proposed level of substantiation required to support health claims on food labels;

D. and the proposed areas of allowable claims.

Section V of the comment addresses FDA's interim enforcement policy.

Within the sections described above, the comment contains two specific recommendations:

1. In Section IV, the staff recommends that the Public Health Service Committee be established as an informal committee, the function of which would be to provide guidance by issuing scientific and consumer summaries; and

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[4] Pauline M. Ippolito & Alan D. Mathios, Health Claims in Advertising and Labeling, A Study of the Cereal Market (1989) (FTC Bureau of Economics Staff Report).

2. In Section V, the staff recommends that the FDA extend the period of operation of the interim enforcement policy to ascertain how well this program can work with appropriate enforcement action.

II. OVERALL OBJECTIVES OF THE GOVERNMENT'S NUTRITIONAL EDUCATION PROGRAM.

Until 1987, federal government regulation of health claims on food labels was based on the premise that such claims were likely to be misleading because foods (unlike drugs) were not likely to mitigate or reduce the risk of disease. This premise no longer seems valid. For example, in its draft report, Promoting Health/Preventing Disease: Year 2000 Objectives for the Nation, the Public Health Service of the Department of Health and Human Services concluded that:

> Nutrition has a major role in health promotion and disease prevention...Dietary factors are associated with five of the ten leading causes of death in the U.S., including coronary heart disease, some types of cancer, stroke, noninsulin-dependent diabetes mellitus, and atherosclerosis.[5]

The substantial body of evidence underlying these conclusions is summarized in two recent publications, the Surgeon General's Report on Nutrition and Health[6] and the Diet and Health Report of the National Research Council.[7] The importance of this

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[5] Promoting Health/ Preventing Disease: Year 2000 Objectives for the Nation 1-1 (PHS Sept. 1989)(draft).

[6] Department of Health and Human Services 1988.

[7] National Academy of Sciences 1989.

accumulated evidence is reflected in major federal educational programs.

The draft Public Health Service report on goals for the year 2000 calls for raising to a level of 90% the percentage of all people age 12 and older who are able to identify the principal dietary factors that are associated with heart disease, hypertension, cancer, and osteoporosis, thus enabling them to control their diets to achieve reductions in the risk of these chronic diseases. The growing body of scientific evidence on the role of diet and disease also led the National Cholesterol Education Program to recommend that the government engage in an extensive public education program on eating patterns to lower the risk of coronary heart disease. These actions are typical examples of recent governmental attempts to stimulate better consumer understanding of the relationship between diet and health.[8]

Efforts by the government and other public sources to provide understandable diet and health information to the public are an important component of any public education program. But there is evidence that these sources appear to be less than successful in reaching the population as a whole. For example, a recent study by the Commission's Bureau of Economics suggests that the advertising and promotion for high-fiber cereals focused a great deal of attention on the link between fiber consumption

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[8] Another example is the long-term National High Blood Pressure Education Program, which has been successful in alerting consumers to use food label information on sodium.

and cancer. It also stimulated new product introductions by cereal manufacturers. As a result of this advertising and labeling, fiber cereal consumption and knowledge about the benefits of fiber consumption increased significantly, especially among groups reached less well by government and other information sources.[9] The results of this study underscore the importance of insuring that the final regulation encourages increased dissemination of truthful information and promotion of food choices based on nutritional worth, while deterring unfair or deceptive claims.

III. FTC'S RESPONSIBILITY FOR ADVERTISING IN THE HEALTH CLAIM AREA.

As noted above,[10] the FTC and FDA have different areas of responsibility. Also as noted, significant differences between health claims on food labels and in food advertising may require different regulatory approaches. It is the staff's understanding that FDA intends its proposal to apply only to health claims on food labels, not health claims in advertising. The FTC intends to continue to review carefully and take action

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[9] See Ippolito & Mathios, supra note 4, and Alan Levy & James Heimbach, Recent Public Education Efforts About Health & Diet in the United States 6-12 (1989) (FDA staff paper).

[10] See supra note 3.

against any unfair, deceptive or unsubstantiated health claims made in food advertising.[11]

The Commission's policy regarding the substantiation of health claims is set forth in cases such as Pfizer, Inc., 81 FTC 23 (1972); Thompson Medical Co. v. FTC, 104 F.T.C. 648 (1984) aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. (1987); and General Nutrition, Inc., Docket No. 9175, settled by Consent Agreement, Jan. 25, 1988. In brief, claims must be supported by the level of substantiation they communicate, either expressly or impliedly, to the reader or the listener, whether the level of substantiation is a specific study or set of studies or a consensus of opinion.[12]

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[11] The Commission has taken action in a number of advertising cases involving health claims. On January 25, 1989 the Commission issued a complaint against Campbell Soup Co. charging that its advertising that a soup was low in fat and cholesterol and thus healthy for one's heart was deceptive without also disclosing that it was high in sodium. Campbell Soup Co., Docket No. 9223. Such claims are of concern to both the FTC and the FDA. As noted in the FDA proposal, claiming a beneficial attribute while the product contains a relevant detriment may be false and misleading:

> ...[T]he food, in addition to having a health benefit, may have other attributes that might make a health claim for the product misleading.

See also, Kraft, Inc., Docket No. 9208 (initial decision April 3, 1989) (where the Administrative Law Judge concluded that advertising that claimed the product contained the same level of calcium as five ounces of milk and more calcium than other competitive products was deceptive); and Schering Corp., Docket No. 9232 (complaint issued September 22, 1989) (complaint challenged claims that Fiber Trim is "One of the best sources of dietary fiber ..." and is an effective appetite suppressant.)

[12] The application of FTC's advertising substantiation policy and the FDA Interim Enforcement Policy for health claims (continued...)

IV. FDA'S PROPOSED RULE.

A. The Public Health Service Committee Process.

Under the current FDA proposal, a PHS Committee will be formed and charged with advising FDA on the use of food labels to communicate information on the relationship between diet and health, and specifically, with developing scientific and consumer summaries about each diet and chronic disease topic as well as model label statements for use on food products. We believe that the establishment of a PHS committee, if constituted as an informal committee, could have a number of benefits. As was done with the Surgeon General's and the National Research Council's reports,[13] the committee could collect and distribute scientific research and issue consumer and scientific summaries that provide useful nutrition guidance for consumers. These reviews could also provide ready guidance for food manufacturers, processors, and advertisers on appropriate claims regarding diet and chronic disease issues, and would be a useful reference tool for the various entities that have enforcement responsibilities (i.e., FDA, FTC, and state or local officials).

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[12](...continued)
on food labels should be generally consistent. Both agencies seek to prevent improper health claims, under their respective jurisdictions, in food labels and in food advertising. Both the FDA and FTC have made clear that preliminary, insignificant and poorly designed studies are an insufficient basis for claims.

[13] Supra, notes 6 and 7.

Beyond the function of providing guidance on the evidence relating to diet and disease topics, however, we have concerns about the proposed operation of the committee in regulating health claims and in making recommendations to FDA to issue formal summaries and approve model label statements. The PHS committee approach, as described in the FDA's proposal, appears to be similar to that used in the monograph process for over-the-counter (OTC) drugs. If that process is used, it may not be able to keep pace with the rapidly accumulating diet and health information. This could inhibit the dissemination of truthful, non-misleading diet and health information on food labels.[14] Moreover, once the committee has made its recommendations to FDA and its findings are issued, delay in revising model label statements and summaries in response to new scientific evidence or accumulated findings may result in advertisers' reliance on model label statements or scientific summaries that are no longer based on the most current information. We therefore believe that an informal committee, which would issue scientific summaries to serve as guidance but would not make recommendations to FDA to

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[14] The development and issuance of final monographs in the over-the counter drug review is an example. Formal government process can take considerable time. The program began in 1974 and covers over 48 categories with subcategories of products. Thus far thirteen monographs are final, thirty-two are proposed and eleven advanced notices of proposed rulemaking have been issued. (OTC staff report, FDA March 21, 1990)(See Testimony Appendix, Statement of Carl C. Peck, M.D., Director, Center for Drug Evaluation and Research, Before the Subcommittee on Regulation, Business and Energy, Committee on Small Business, House of Representatives, May, 7, 1990.)

issue binding regulations, would make a greater contribution for the good of consumers.[15]

B. Model Label Statements.

A major component of FDA's proposal is the development by the PHS committee of model label statements that may be used to convey appropriate information regarding a diet-health relationship. The model label statement is described as containing approximately a 50-word summary of the science, a statement of the extent to which the food does or does not contain the food component subject to the label, a reference to the availability of the Consumer Health Message Summary and how to obtain it, and a statement directing the consumer to the mandated nutrition label. Moreover, although the FDA proposal states that model statements may be varied, firms would be "urged" to use the proposed model label statements.

From a communications standpoint, use of standardized and unchanging language for health claims raises a number of concerns. The sheer quantity of text created by the content requirement of the model label statement may cause the message to be produced as a label statement in small-sized print. This format may defeat the purpose of the message by making it too

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[15] We also are concerned that committee pre-review of all data, including proprietary data, may discourage companies from conducting research for which they would not be able to obtain a first use and for which they could not have assurances of confidentiality. This issue should be addressed by any final rule.

long for prominent treatment on labels or to hold the consumer's attention. Food marketers are skilled at providing information in formats that consumers are likely to read and find useful. If given greater flexibility in styling claims, they are more likely to devise messages that consumers will notice and remember.[16] Further, if manufacturers have the flexibility to make changes, they may vary the messages on labels. Variations can often be more effective in reaching specific audiences and in keeping messages fresh and noticed by consumers. This has been evident in cereal packaging where the presentation and focus of health information has frequently been altered. In contrast, the model label statements initially may be noticed because of their novelty, but after a short time they are likely to become unnoticed, unheeded and hence ineffective.[17]

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[16] The FTC's experience with warning statements in cigarette advertising and labeling suggests that consumers stopped noticing and reading a single warning message. As a result, the Commission recommended that the then current warning system be replaced with a series of short, rotating warnings that would provide specific health information but that would change over time to better keep consumers' attention. 15 U.S.C. §§ 1331 et seq. Of course, because cigarette warnings involved information that manufacturers would be unlikely to disclose voluntarily, the options before the Commission and Congress to improve the communicative effect of the message were not nearly as broad as those before FDA.

[17] A perhaps unintended effect of model messages would be the prohibition of comparative claims on food labels. In general, comparative claims typically provide information about major product characteristics instead of mere product puffery. Truthful comparative claims are a source of important information that can assist consumers in making rational purchase decisions. See Statement of Policy Regarding Comparative Advertising, 44 Fed. Reg. 47328 (1979)(codified at 16 C.F.R. § 14.15).

C. Level of Substantiation Required for Health Claims on Food Labels.

In its notice, the FDA asks for comment on the best scientific standard to be used in deciding whether a health claim should be allowed on food labels. In particular, the FDA asks whether the standard should require that a "consensus" of scientific opinion in support of the claimed relationship or whether substantial evidence of the existence of the relationship would be adequate.

As stated in previous comments, the staff of the FTC does not believe that a consensus standard is the best choice for judging health claims on food labels. Instead, we suggest that the FDA adopt a flexible substantiation standard more akin to the FTC's reasonable basis standard for assessing health claims in advertising.[18] In making this recommendation, it is important to emphasize that a reasonable basis standard would require professionally conducted, statistically valid studies to support health claims. The tests or studies relied on must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the scientific community to yield accurate and reliable results. In some cases a reasonable basis standard would require a consensus. Preliminary, insignificant, contradictory or poorly designed

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[18] The characterization of the FTC's substantiation doctrine in 55 Fed. Reg. 5186 is inaccurate. See, n. 11.

studies would not provide a reasonable basis for health claims. There are important distinctions, however, between the consensus standard in the proposal and the FTC's reasonable basis approach. While both recognize that judgment is required to evaluate the body of science,[19] under the consensus approach the standard is met only if scientists agree that the diet-health relationship has been established. As the proposal states:

> This criterion would require that the statement be supported by a sound body of scientific evidence upon which a significant agreement exists among qualified experts as to the relationship between a dietary component and the reduction of risk presented by a particular chronic disease condition.[20]

Depending upon the type of claim made, this standard will equate to the reasonable basis standard.

In the more flexible reasonable basis standard, the amount of scientific certainty required is individually determined, depending upon the benefits of the information if it is true, the

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[19] We agree with the FDA's statement in its proposal that it:

> tentatively concludes that the agency will not prescribe a specific set of studies or types of studies as being sufficient to support a health message. The very nature of the various food components and the wide variability of possible studies make it difficult to outline precise requirements. The amount and type of evidence required may differ from case to case, depending on a number of variables. The ideal circumstances are to have data from well-designed and conducted studies to provide the scientific basis for any decision that might be made.

55 Fed. Reg. 5181.

[20] Id. at 5180.

costs if it is not, the amount of substantiation experts in the field believe is reasonable, and the costs of conducting more conclusive research. Application of the more rigid consensus rule on the extent of agreement (and consequent degree of certainty) about the existence of the diet-disease relationship may bar some valuable health claims. As the Diet and Health Report of the National Research Council report notes:

> The absence of consensus on certain diet disease relationships derives partly from a lack of knowledge and partly from the absence of generally accepted criteria for interpretation of the abundant though incomplete evidence on diet and chronic disease.[21]
>
> * * * *
>
> Absolute proof is difficult to obtain in any branch of science. As evidence accumulates, however, it often reaches the point of proof in an operational sense, even though proof in an absolute sense may be lacking. . . . The strength of the evidence might not be the only relevant criterion for determining the course of action. . . .[22]

Accordingly, the report considered that these failings should not diminish the need to communicate diet-health information to the public.[23] A reasonable basis standard incorporates the same types of considerations in judging when evidence is strong enough to allow health claims on labels.[24]

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[21] National Research Council, supra note 7 at 9.

[22] Id. at 5.

[23] Id. at 5-6.

[24] Under the FTC advertising standards, claims based on less than consensus or "weight of the evidence" will often not be allowed. Novel claims and claims that call for radical dietary change would require a great deal of scientific support under the (continued...)

D. Areas of Permissible Claims

FDA states that it will initially restrict permissible health claims on food labels to six areas:

> (1) Calcium and osteoporosis; (2) sodium and hypertension; (3) lipids and cardiovascular disease; (4) lipids and cancer; (5) dietary fiber and cancer; and (6) dietary fiber and cardiovascular disease.[25]

This restriction is based on FDA's belief that "these topic areas relate to problems of major health significance and are areas that have been the subject of sufficient scientific study to establish a science base adequate for review by FDA." Limiting permissible health claims to six areas, however, might have the effect of decreasing the number of beneficial claims that will be allowed. As the NRC report notes, the area of diet, health and nutrition is evolving rapidly. We believe that claims based upon developing evidence that are truthful and not misleading should be allowed. The specific level of substantiation for these label claims will depend on the claim, but clearly there are additional areas where truthful information expressed in a non-misleading manner may be useful to consumers. For example, diets high in certain fruits and vegetables that contain carotenoids

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[24](...continued)
reasonable basis standard. A reasonable basis for health claims will depend in part on consumer expectations and, as the FDA implies, consumers may have high expectations concerning the level of scientific substantiation supporting health claims.

[25] 55 Fed. Reg. 5184.

reportedly are associated with a lower incidence of some kinds of cancer.[26]

While the FDA states that claims in other areas may be proposed for review by the FDA,[27] the procedures for review and modification of labels may be time-consuming. Delay could deny consumers important information on these areas.

V. FDA'S INTERIM ENFORCEMENT POLICY FOR HEALTH CLAIMS

In its current proposal FDA revoked its 1987 interim rule under which certain health claims were permitted. FDA has replaced that regulation with a new "Interim Enforcement Policy," which provides that FDA will allow manufacturers to continue to include health messages on their products.[28] FDA will scrutinize each label statement on a case-by-case basis and in the exercise

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[26] National Research Council, supra note 7.

[27] According to the notice:

> the [FDA] acknowledges that, as knowledge about diet and health interaction continues to grow, health messages may be appropriate in other areas. Thus, the regulatory process set out in this reproposal would permit the development of other scientific summaries, consumer health message summaries, and model label statements, as advances in scientific knowledge warrant.

55 Fed. Reg. 5184.

[28] See infra. section V. B. for a discussion of FDA's position that such claims technically may be illegal drug claims.

of prosecutorial discretion will determine the "appropriate circumstance" for bringing enforcement actions.[29]

A. Adoption of the Approach of the Interim Enforcement Policy as a Final Position.

The staff of the FTC believes that the approach to health claims should be structured on a case-by-case basis as both an interim and final policy. If FDA were also to use a flexible substantiation standard in assessing which health claims are supported, the interim policy would present a substantial improvement over the proposed final rule. The interim policy does not mandate the specific language in which the label claims can be made. The factors that will be addressed by the FDA in application of its substantiation standard[30] include many that

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[29] 55 Fed. Reg. 5184.

[30] The FDA states that:

> [t]he health messages that are, for the present, less likely to run the risk of regulatory action are those regarding topic areas about which significant evidence and general scientific agreement exists. The two recent authoritative reports on the relationship between diet and health [from the Surgeon General and National Academy of Science] have identified six topic areas about which such evidence may exist: (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.
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> ...[T]he agency will consider such factors as whether the claim is adequately supported by the scientific evidence; whether the claim is exaggerated; whether the (continued...)

the FTC would review to ensure that advertising claims are not misleading or deceptive. Moreover, if a manufacturer makes a claim that is not substantiated or is contradicted by the Surgeon General's report or the National Research Council report, that manufacturer would bear a heavy burden under the FDA's interim policy for label claims, as it would under the FTC's standard for advertising, to show that valid evidence exists to substantiate the claim.

This interim policy approach provides needed flexibility while maintaining substantive guidelines for permissible claims. It is not bound to a formal pre-review or preclearance process, nor is it based on model messages and summaries. An extended period for its operation would provide an excellent opportunity to see how well this more flexible approach can work. Therefore, we recommend that the FDA extend the operation of the "interim enforcement policy" sufficiently to evaluate the effectiveness of this program.

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[30](...continued)
food component that is the subject of the claim is present in sufficient quantities (or reduced sufficiently) to justify the claim; and whether the benefits from the component (or the reduction of the component) are outweighed by the negative attributes of another component of the food with respect to the same chronic disease (e.g., a heart disease claim on low sodium food with a high saturated fat content).

A claim outside the six topic areas for which supporting scientific evidence is rapidly accumulating is at greater regulatory risk than those in the six areas, but the agency is still likely to consider the nature of the claim and the extent of support for the claim before taking regulatory actions.

Id.

B. Classifying All Health Claims as Illegal.

Despite similarities in approach, one major difference between the FTC's advertising substantiation doctrine and the FDA's proposed policy for health claims, both interim and final, is FDA's classification of all health claims on food labels as illegal drug claims.[31] Although we understand that the FDA has strong concerns about the impact of its health claims policy on efforts to prevent fraudulent promotions, we recommend that FDA's policy be changed so that truthful and non-misleading health claims meeting the interim or final guidelines would not be regarded as impermissible drug claims. Such an interpretation of the law is not necessary to achieve the goals of preventing false and misleading claims on labels.

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[31] However as noted above, FDA states that it will not bring legal action against claims that meet certain guidelines.

Comments of the Bureaus of Concumer Protection and Economics of the Federal Trade Commission

Submitted in Response to FDA Notice of Proposed Rulemaking, 54 Fed. Reg. 32,6]0 (]989)

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I. INTRODUCTION AND SUMMARY

The regulations governing food labels have been adopted over a course of decades, in part, to help Americans improve their diet. Yet, as reflected in the broad range of questions in the Food and Drug Administration (FDA) request for comments, there is still room for improvement in the system of regulations that has evolved. Based on our experience in analyzing the effects of information in consumer product markets and in considering regulations that address information issues, the staffs of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission (FTC) offer the following comments to assist the FDA in its deliberations.[1]

The FTC is a law enforcement agency charged with prosecuting violations of Sections 5 and 12 of the Federal Trade Commission Act, which prohibit deceptive or unfair practices in or affecting commerce.[2] One of the

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[1] These comments are the views of the staff of the Bureaus of Consumer Protection and Economics of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. However, the Commission, with Commissioner Strenio dissenting, has voted to authorize the staff to submit these comments. Commissioner Strenio cannot support submitting all of the recommendations set forth in the Commission staff's comment. Questions or comments concerning this document may be addressed to Pauline Ippolito (202-326-3477), Bureau of Economics.

[2] 15 U.S.C. §§ 45 et seq. The FTC has jurisdiction over the advertising of food and has concurrent jurisdiction with the FDA and U.S. Department of Agriculture (USDA) over the labeling of food. In their liaison agreement the two agencies allocated primary responsibility for advertising to the FTC and primary responsibility for labeling to the FDA. See Working Agreement Between the Federal Trade Commission and the Food and Drug Administration, 3 Trade Reg. Rep. (CCH) para. 9850 (1971). The FTC also has statutory authority to enforce a number of laws that mandate disclosure, including the Federal Cigarette Labeling and Advertising Act, the Truth in Lending Act, and the Energy Policy and Conservation Act, which regulates appliance labeling, and to enforce several laws relating to standard-setting, including the Wool Products Labeling Act and the Magnuson-Moss Warranty & FTC Improvement Act. In addition, the FTC has promulgated disclosure rules, such as the R-Value Rule, which regulates thermal insulation labeling, the Used Car Rule, which requires warranty disclosures, and the Care Labeling Rule, which regulates clothing labeling.

FTC's major goals is to regulate national advertising in a way that protects consumers from deception, but at the same time, minimizes the extent to which dissemination of truthful advertising is prevented or chilled. The staff of the FTC has developed considerable expertise in understanding the roles of advertising and labeling in providing consumers with information, and in analyzing the value of required information disclosure or mandated product standards when the market otherwise fails to provide adequate information.[3] We recognize, however, that significant differences between health claims on food labels and those in advertising may require different regulatory approaches.

Our analysis of the potential amendments to labeling regulations relies on two basic premises:

First, consumers need two types of health information to make better dietary choices. Consumers need information about how diet is related to health. Once alerted to a particular health issue, they also need information about how the characteristics of specific food products relate to that health issue. Required labeling of saturated fat content, for example, is of limited

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[3] Relevant FTC staff research includes M. Frankena, M. Cohen, T. Daniel, L. Ehrlich, N. Greenspun & D. Keenan, Alcohol Advertising, Consumption, and Abuse, (1985); M. Lynch, R. Miller, C. Plott & W. Porter, Experimental Studies of Markets with Buyers Ignorant of Quality Before Purchase: When do 'Lemons' Drive out High Quality Products? (1986); P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (1989); and J. Calfee & J. Pappalardo, How Should Health Claims for Food Products be Regulated? An Economic Perspective (1989). The FTC staff explicitly examined issues involving identity standards in its Comments to the Food Safety and Inspection Service, USDA, on the Standard for Frankfurters and Similar Cooked Sausages, Docket No. 85-009E, 52 Fed. Reg. 2,416 (1987) (9 C.F.R. § 319.180 (1989)). In addition, the FTC staff developed expertise on the entry deterring effects of standards in connection with a proposed FTC rulemaking (J. Mooney, R. Schroeder, D. Graybill, W. Lovejoy, Standards and Certification: Proposed Rule and Staff Report (1978)).

value to a consumer who does not know about the role of saturated fat in promoting heart disease. In revising its labeling regulations, we believe it is important for the FDA to consider both types of diet information.

Second, scientific understanding of the role of diet in health continues to change. Food technology (e.g. the use of fat substitutes, preservatives or new types of packaging) is also changing rapidly. Regulations adopted that reflect today's scientific understanding and today's food choices may become outdated. In assessing food labeling regulations, we believe it is important to recognize that these regulations address a dynamic problem: how to get timely information about an evolving body of scientific evidence about diet to consumers, so that they can make better choices about a changing array of food products.

Our analysis of the regulations governing food labeling and food identity standards focuses on how these regulatory policies affect the consumer's ability to make informed dietary choices in this changing environment. Our analysis leads us to recommend that the FDA consider adopting a flexible standard for substantiation of health claims on labels. Such a standard can provide effective protection against deceptive claims without unduly stifling the dissemination of truthful diet-health information. Although preapproval of claims, standardized language for health claims, and adoption of a rigid consensus standard limit deceptive claims, these approaches may also stifle too much truthful and nondeceptive information to make them desirable solutions for regulating health claims on labels.

In addition, because of certain rigidities in the current system of food identity standards, we believe the FDA should evaluate the overall benefits of the current system carefully. In particular, we recommend that serious

consideration be given to whether the more flexible "common name" approach to regulating food names, possibly with additional disclosure requirements, would generate most of the benefits of food identity standards without the restraints on food innovation caused by the current standards system. Finally, regardless of the labeling requirements the FDA decides to promulgate, reconsideration of the elements of the nutrition label seems appropriate in light of current scientific understanding of diet-health issues. However, it is also important that labeling regulations be flexible enough to keep current with the evolving science and technology. In particular, they should be designed to allow producers to add new dietary information to labels in a timely and accurate fashion as scientific evidence develops.

II. REGULATION OF HEALTH CLAIMS

In its advance notice of proposed rulemaking, the FDA asks "[w]hat should be FDA's policy for permitting or restricting the use of food labels that link a food to prevention or treatment of disease?"[4] More specifically, the notice requests comments on the desirability of its 1987 proposed rule and asks if another formulation would be preferable. The Bureaus of Competition, Consumer Protection, and Economics of the FTC submitted comments in response to the 1987 proposed rule. In those comments, the Bureaus noted that the proposed rule was, in large measure, consistent with the FTC's approach to regulating the advertising of health claims. The proposed rule would permit food manufacturers to include health information on labels as long as the information is truthful, supported by valid evidence as judged by generally recognized medical and nutritional research standards.

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[4] FDA Advance Notice of Proposed Rulemaking, 54 Fed. Reg. 32,610 (1989).

The Bureaus supported the FDA's 1987 proposal but suggested that the FDA might wish to consider clarifying the proposed substantiation standard along the lines of the flexible substantiation standard used by the FTC to evaluate health claims in food advertising.[5]

This comment restates our support for FDA's proposal to amend its rules to allow truthful, substantiated health claim messages on food labels[6] and discusses the results of a Bureau of Economics analysis of the effects of advertising and labeling of health claims in the ready-to-eat cereal market that began in 1984. Certainly there are differences between health claims made on labels and those made in advertising, and the best policies to address each area may differ accordingly. Nonetheless, there are common issues raised by allowing producers to make health claims in each medium that suggest that our experience with health claims in advertising and our experience with other advertising and labeling issues may be of use to the FDA as it considers the issues raised by allowing health claims on labels.

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[5] The FTC has successfully challenged health claims advertisements that were false and deceptive using its ad substantiation doctrine. See, General Nutrition, Inc., Docket No. 9175 (Feb. 2, 1989); Great Earth Int'l, Inc., 110 F.T.C. 188 (1988); Viobin Corp., 108 F.T.C. 385 (1986); P. Leiner Nutritional Products Corp., 105 F.T.C. 291 (1985); and Weider Health & Fitness, Inc., 106 F.T.C. 584 (1985); Pharmtech Research, Inc., 576 F. Supp. 294 (D.D.C. 1983), 103 F.T.C. 448 (1984). The FTC has also brought actions against Kraft, Inc. for allegedly misrepresenting one of its cheese products and against Campbell Soup Company for allegedly deceptively claiming that its low-fat, low-cholesterol soups may help reduce the risk of some forms of heart disease when it also did not disclose that these soups are high in sodium and that diets high in sodium may increase the risk of heart disease. Both cases are currently in litigation.

[6] We do not assess whether FDA currently has the statutory authority or the legal, economic or other resources necessary to implement this approach effectively.

A. Producer Claims in the Cereal Market as a Source of Diet and Health Information -- A Summary of the Evidence

In an attempt to better understand the effects of producer health claims on consumer and producer behavior, the FTC's Bureau of Economics recently undertook a detailed study of developments in the ready-to-eat cereal market, a market where health claims on labels and in advertising have now been used for a substantial period of time.[7] This study suggests that during the period in which producers made health claims, consumer information grew, as did the consumption of higher fiber cereal, compared with the period in which health claims were banned. Moreover, this increased consumption was most pronounced for demographic groups that were not reached well by government and general information sources. The study also indicates that health claims appear to have been an important stimulus to the development of more healthful cereals. Finally, the study suggests that the focus on one health dimension (fiber) did not adversely affect other health dimensions of cereal consumption (sodium and fat) and did not lead consumers to overreact to fiber information. Thus, this study suggests that in the ready-to-eat cereal market, the FDA's interim regulations appear to have had an overall beneficial effect. Because health claims were added to both advertising and labeling at the same time, the study does not assess the relative importance of the claims made on labels compared to those made in advertising, but only the combined effect of the two.

In October 1984, the Kellogg Company, in a cooperative effort with the National Cancer Prevention Awareness Program, began an advertising and

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[7] See Ippolito & Mathios, supra note 3. A copy of this recent study is included with our comments.

labeling campaign citing the National Cancer Institute's (NCI) statements on the link between fiber consumption and cancer.[8] Other cereal manufacturers followed by highlighting the health aspects relating to the fiber content of their products. The original Kellogg promotion was developed cooperatively with the NCI, but later Kellogg claims and other producers' claims that did not specifically use the NCI name do not appear to have been preapproved by any government agency. Claims that cited the NCI by name were reviewed and approved by the NCI prior to use.

The timing of these events provides two distinct periods: (1) prior to 1984, when only government and general sources provided information about fiber consumption and cancer to the public, and (2) since 1984, when producer advertising and labeling added to this flow of information. [We will refer to the latter period as "the health claims period" throughout our discussion.][9]

Scientific evidence of a link between fiber consumption and the risk of colon cancer continued to develop throughout the 1970s and 1980s. During the years 1978-1984, prior to the health claims period, the study found no significant shift in consumption toward higher fiber cereals. Once producer health claims were added to the flow of information from government and other nonadvertising sources, however, a significant shift did occur.

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[8] A. Levy & J. Heimbach, Recent Public Education Efforts About Health and Diet in the United States, at 11 (1989) (FDA Staff Paper).

[9] The National Cancer Institute also published a booklet Good News, Better News, Best News: Cancer Prevention and a book Nutrition and Cancer during this period in its continuing effort to spread the information about the role of diet in cancer prevention. See Levy & Heimbach, supra note 8, for a description of the NCI program.

Moreover, during the health claims period, cereal manufacturers responded to the growing demand for higher fiber cereals by developing new cereals. The study's examination of new product introductions shows that, while bran and whole wheat products were introduced throughout the years 1978-1987, the number and proportion of new fiber cereals to all new cereal introductions increased markedly during the health claims period. Cereals introduced between 1985-1987 averaged 2.59 grams of fiber per ounce of cereal, compared to an average of only 1.70 grams per ounce for cereals introduced between 1979-1984.

The study of the cereal market also shows that there were significant differences in the types of cereals chosen by women across demographic groups prior to the health claims period.[10] During the period when only government and general sources of information were available, women who had less education, were nonwhite, lived in households without a male head, or who smoked, all chose lower fiber cereals than their respective counterparts.

After the introduction of health claims, most groups increased their consumption of higher fiber cereals. However, the increases were generally larger for the groups that had consumed less high-fiber cereal prior to the labeling and advertising.[11] Thus, the addition of producer health claims seems to have reached those less successfully reached by the government and other information sources available prior to the advertising and labeling, and

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[10] The U.S. Department of Agriculture data used for this part of the cereal study includes consumption data for women but not for men.

[11] With the exception of high school graduates, women in all education groups consumed higher fiber cereals more frequently after the health claim advertising and labeling, but the pattern of increases was not systematically larger for the less educated group.

to have reduced the differences between groups in their consumption of higher fiber cereal.[12]

Finally, the study reveals an absence of evidence that individuals overreacted to the health claim labeling and advertising about fiber. None of the groups that reacted more during the health claims period achieved the level of fiber cereal consumption of the most educated group.[13] Despite the intensive advertising and labeling campaigns, only in the most highly educated group were more than 20% of consumers found to consume cereal. Moreover, an investigation of individual consumption behavior also showed no tendency for individuals to consume unusually large amounts of fiber cereal after the advertising and labeling began. Thus, in the cereal case, whether we look at the percent of consumers who ate cereal at the end of the health claims period or at the amount of cereal that individuals consumed, individuals do not appear to have been led to "overconsumption" of the promoted feature.

Independent results from FDA surveys[14] also suggest that advertising and labeling by cereal producers added information about the fiber-cancer relationship to the market and provided a broader distribution of knowledge.

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[12] However, some groups that increased their consumption of higher fiber cereal during the health claims period did not increase their consumption of higher fiber breads. This suggests that the brand specific nature of the advertising may limit the breadth of the health information conveyed. Specifically, some consumers reached primarily by producer health claims appeared not to transfer the brand or product specific information to other sources of fiber or to diet in general. However, producers of these other fiber sources also would be expected to promote their products' health features and, thus, to produce the broader diet message.

[13] These findings hold whether we consider the most educated group's behavior before or after the health claims period.

[14] Levy & Heimbach, supra note 8.

For example, in 1984, only 1% of respondents with less than a high school education said that dietary fiber might reduce the risk of cancer, compared to 18% in 1986. For high school graduates, the comparable figures are 5% and 27%, and for those who attended college, 15% and 41%. This survey evidence suggests that health claim labeling and advertising increased knowledge about the relationship between fiber and cancer for all education levels, but that prior to the health claims period this information was concentrated among the most educated consumers.[15] Thus, there is now evidence from the cereal market that consumer knowledge of the fiber health issue increased once product labeling and advertising were added to the flow of information from government and other sources.[16]

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[15] Earlier FDA survey data from 1978 also shows limited knowledge of the fiber-cancer relationship and a concentration of this knowledge among the most educated consumers. Moreover, with the exception of the most educated group, there was little increase in knowledge in the years before the health claim advertising began. Only 1% of those with less than a high school education reported knowledge of the fiber/cancer relationship in 1978, and this figure was unchanged in 1984; 3% of high school graduates reported knowledge of the issue in 1978, compared to 5% in 1984; and 8% of those with some college education reported this knowledge in 1978, compared with 15% in 1984.

[16] Government sponsored publicity efforts can also be successful in reaching the public with information about diet and health. Two widely publicized efforts are the FDA/National Heart Lung and Blood Institute's (NHLBI) sodium initiative in 1981, which publicized the relationship between dietary sodium and hypertension, and the release of the results of the NHLBI sponsored Coronary Primary Prevention Trial in 1984, which detailed the relationships between dietary fat intake, blood cholesterol, and heart disease. Studies of these campaigns have concluded that the impact of these campaigns on the public were significant. Heimbach & Levy, The Growing Impact of Sodium Labeling of Food, 102 Food Technology 102-04, 107 (1986); A. Levy, N. Ostrove, T. Guthrie, J. Heimbach, Div. of Consumer Studies, Center for Food Safety and Applied Nutrition, FDA, Speech on Recent Trends in Beliefs about Diet/Disease Relationships: Results of the 1979-1988 FDA Health and Diet Surveys (Presented at FDA/USDA Food Editor Conference, Dec. 1-2, 1989); Levy & Heimbach, supra note 8. There are market indications of significant behavioral changes accompanying these cognitive changes, e.g., increases in reports of changing diets to cut down on salt, major reductions in sales of table salt, new product innovations, etc.

In considering potential reasons for the effectiveness of advertising and labeling in communicating the fiber-cancer link, several factors are likely to be important. First, the original Kellogg's advertising and labeling health claims cited the National Cancer Institute as the scientific support for their promotions, as did some of the other cereal producers. We expect that this added to the effectiveness of the fiber advertising and labeling by enhancing its credibility. Second, producers devoted substantial resources to promoting the health benefits of fiber cereal consumption.[17] Finally, the methods used by the government and general information sources to disseminate information differ from the methods used by producers. Most cereal advertising was distributed through television with similar claims on package labels,[18] while government and general information is typically distributed through various broadcast news reports, print media, and consumer information brochures.

Although we would expect the economic characteristics of the market and the particular health claim to have an impact on the information effect in different markets, the potential for other food producers to profit by promoting the health features of their products is likely to be widespread, with the potential for considerable consumer benefit. In general, we would

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However, it should be noted that these government initiatives were also accompanied by significant cholesterol, fat, and sodium advertising by food manufacturers, making it difficult to isolate the effects of each information source.

[17] It has been estimated that in 1985 advertising expenditures were $15 million, a level of effort that "was an order of magnitude larger than anything in previous diet and health education campaigns." Levy & Heimbach, supra note 8.

[18] Schnorbus, Brantastic, 22(4) Marketing & Media Decisions 93 (1987).

expect the basic findings from the cereals market to apply to many food markets where the promotion of truthful health information is potentially important. In the cereal market, the evidence suggests that policies permitting the use of health information in advertising and on labels appear to have been advantageous to consumers on balance. Moreover, in this case these policies appear to have been particularly advantageous to consumers who received relatively less information from government and other nonadvertising information sources. The considerable body of research showing significant demographic differences in consumer knowledge of health issues and in consumption of other food nutrients suggests that the effectiveness of different information sources in reaching different consumer groups may be important in many food markets.[19]

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[19] A number of studies have found a significant relationship between demographic characteristics and nutritional aspects of diet. For instance, see Adrian & Daniel, Impact of Socioeconomic Factors on Consumption of Selected Food Nutrients in the United States, 58(1) Am. J. Agric. Econ. 31 (1976); Eastwood, Brooker & Terry, Household Nutrient Demand: Use of Characteristics Theory and a Common Attribute Model, 18 So. J. Agric. Econ. 235 (1986); Hama & Chern, Food Expenditures and Nutrient Availability in Elderly Households, 22(1) J. Cons. Aff. (Summer 1988); and studies reviewed in Davis, Linkages Between Socioeconomic Characteristics, Food Expenditure Patterns and Nutrition Status of Low Income Households: A Critical Review, 64 Am. J. Agric. Econ. 1017 (1982).

Also there is survey evidence indicating that different types of individuals use different sources for acquiring health information. For instance, a 1979 survey conducted for the National Institutes of Health (NIH) showed that the use of print media sources of health information differed for education and racial subgroups within the population. Similarly, this survey showed that these groups differed in their knowledge of the role of diet in heart disease. NIH, The Public and High Blood Pressure: Six-Year Followup Survey of Public Knowledge and Reported Behavior (Pub. No. 85-2118 Feb. 1985.)

B. Information Needs Addressed by Health Claims

It is becoming increasingly evident that diet has an important influence on health. Scientific evidence "demonstrate[s] that changes in present dietary practices of Americans could produce substantial gains in the health of the population . . . . [W]hat we eat may affect our risk for several of the leading causes of deaths for Americans, notably, coronary heart disease, stroke, atherosclerosis, diabetes, and some types of cancer."[20] Yet ingredient and nutrition labeling only provide information about technical characteristics of food products. They do not inform consumers about the potential relevance of food composition to health. As the cereal study discussed above demonstrates, information about how food choices may affect health is important if consumers are to use the nutrition information on labels effectively. Thus, the FDA's ongoing efforts to finalize revisions of its rules to allow food producers to communicate truthful, nondeceptive health information on their labels can substantially benefit consumers. We recommend the FDA consider adopting regulations that protect consumers from deceptive information, but that are not unduly restrictive.

C. The Regulation of Health Claims

From a public policy perspective, it is important to balance the benefits and risks of allowing food manufacturers greater leeway to make health

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[20] Public Health Service, U.S. Dep't of Health and Human Services, The Surgeon General's Report on Nutrition and Health, at vii, 1 (1988). Additional evidence on the link between diet and health is contained in Diet and Health: Implications for Reducing Chronic Disease Risk, National Academy Press (1989).

claims on labels.[21] The most important risk is that some deceptive claims will be made and cause injury. Deceptive health claims can harm consumers in several ways. First, such claims may injure consumers by persuading them to change their diets in a way that actually injures their health. Second, deceptive claims may injure consumers by leading them to refrain from making changes in their diets that otherwise would benefit them or from seeking effective medical treatment. Third, deceptive claims may injure consumers by leading them to purchase items they otherwise would not have purchased, or to pay higher prices for those items because they believed the deceptive claims. Finally, deceptive label claims may reduce the credibility of all label claims, diminishing consumer confidence in and use of labeling information, and reducing the incentives for honest producers to promote the health benefits of their products.

Conversely, truthful health claims on labels can provide consumers with information that may enable them to improve their health. If manufacturers are accorded an opportunity to make truthful health claims, we would expect (as in the case of cereals) that they will be led to market their products by providing more information about diet and health and by producing, in response to consumer demand, more products with those characteristics that consumers value.

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[21] Throughout our discussion of health claims, we assume that foods are made from otherwise safe ingredients; that is, we assume that safety issues are dealt with through other regulatory mechanisms, such as the GRAS (generally recognized as safe) procedures at the FDA. The safety of food products and food ingredients is an important issue that is independent of the type of promotion used to sell the product. For instance, there has been concern raised recently about the safety of adding psyllium, a grain high in soluble fiber, to food products.

Thus, it is important that any policy covering manufacturers' labeling of health claims attempt to maximize the benefits of increased information while limiting the risks that might occur. The truthfulness of health claims would often be difficult or impossible for consumers to evaluate even after purchase and use of a product. As a result, FDA regulation of health claims on labels is necessary. We suggest, however, that the FDA adopt a flexible approach to evaluating such claims rather than setting a rigid rule that attempts to anticipate every possible case. We recognize that differences in the roles and consumer perceptions of labels and advertising may lead to differences in the policies adopted in each case. Nonetheless, some of the basic features in health claims that led the FTC to adopt a flexible substantiation policy for health claims in advertising also appear important for health claims on labels. Thus, in this section, we will discuss some of the issues the FTC considers important to the regulation of health claims in advertising in the hope that this experience will also be of value to the FDA as it considers the best policy approach to regulating health claims on labels.

Conclusive evidence about the relationship between diet and health develops very slowly. It often takes years before sufficient data are accumulated to form a body of evidence that can be used by the scientific community to form a consensus view regarding the relationship between aspects of diets and particular diseases. The choice of a health claims policy is in large part a decision about when in the evolution of a body of scientific evidence and interpretation, producers should be allowed to claim the existence of a particular relationship between diet and health. If a standard is adopted that requires a very high degree of certainty (or consensus of scientific opinion) before any claims are permitted, consumers

will lose the benefits from receiving the evolving diet-health information earlier. On the other hand, if a policy is adopted that allows claims to be made based on weak, preliminary or insufficient evidence, consumers may be misled into taking costly and perhaps unhealthy actions. The FTC attempts to take the costs associated with each extreme into account when considering the appropriate level of substantiation to require for particular types of health claims in advertising.[22]

Because the potential benefits and risks of particular health claims for foods vary widely, the FTC has adopted a flexible approach to identify those claims that are likely to be harmful, without unduly restricting those claims that provide useful information. This approach is embodied in the FTC's ad substantiation doctrine which, in our view, provides a flexible but not overly permissive means of assessing the adequacy of support for particular health claims in advertising.

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, whether the level of substantiation is a specific study or set of studies, or a consensus of opinion, etc. The studies or tests relied on must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the scientific community to yield accurate and reliable results. Thus, it would be impermissible to claim as support one or even a set of studies that

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[22] A balancing type of standard is appropriate for, and often used in, areas of law and policy where the particular circumstances of the issue are important in determining the best decision. For an economic perspective on this issue in the context of health claims for foods, see Calfee and Pappalardo, supra note 3.

are improperly conducted.[23] Similarly, if an advertiser has substantiating evidence that is subject to some limitation or qualification, the claim would only be allowed if it can be 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.[24] If no level of support is expressed or implied, the FTC examines several factors to determine what type of "reasonable basis" an advertiser should have for a claim.[25] Specifically, the FTC considers: (1) the type of claim; (2) the type of product; (3) the benefits of a truthful claim; (4) the cost of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field believe is reasonable. Under this last factor, the FTC will look to what the scientific or medical community would require, as evidenced by such sources as FDA regulations, expert opinion or expert panel reports.

Using this flexible approach, the FTC can balance the likely benefits of a claim if it turns out to be true against the likely costs of a claim if it turns out to be false. Thus, the standard is actually designed to deal with uncertainties, such as those encountered in the diet-health relationship, by evaluating the likely value and harm that might attend dissemination of the information, and by setting the required level of substantiation accordingly.

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[23] See generally Thompson Medical Co., 104 F.T.C. 648, 825-28 (1984).

[24] See, e.g., 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).

[25] 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).

In the past, concerns have been expressed that the FTC's advertising substantiation standard would allow food manufacturers to base claims on the results of studies that are methodologically flawed or on the results of a single study that conflicts with the findings of other more complete or rigorous studies in the area. Such concerns miscomprehend the FTC's approach. Representations that scientific studies support a particular claim carry with them the implied representation that these studies are competent and reliable. Thus, under the FTC's standard such studies must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results.[26] To substantiate claims that a food, as part of an overall diet, reduces the risk of a disease, the FTC's advertising substantiation program would require that the claim be supported by competent and reliable scientific evidence. For example, a single study with results that are inconsistent with other similar studies in the area may represent nothing more than a random failure to confirm a well-established conclusion. Such a study would not constitute a reasonable basis for claims that are contrary to the weight of the evidence under the FTC's advertising substantiation program. Moreover, where the Commission has determined that sufficient scientific controversy exists, advertisements that presented one side of the issue have been required to disclose that controversy exists.[27]

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[26] See e.g., Removatron International Corp., Docket No. 9200, slip op. 12-19, aff'd, No. 88-2245 (1st Cir. 1989); P. Leiner Nutritional Products Corp., 105 F.T.C. 291, 294 (1985).

[27] See, e.g., 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).

1. **How Much Information Should be Disclosed?**

An issue that arises in regulating health claims in advertising is whether inclusion of a health claim in an advertisement should trigger a requirement to disclose additional information in the advertisement, and, if so, how broad such a requirement should be. Some have suggested that, if a health claim is made, manufacturers be required to give equal emphasis to the nutritional deficiencies of the food. This suggestion is based on the concern that consumers may be misled by advertising that does not adequately disclose nutritional weaknesses. There are certainly circumstances where health claims can be deceptive and where mandated disclosures in advertising would be beneficial for consumers, but this issue requires careful consideration. Excessive disclosure requirements could substantially raise the cost of making any health claim. The higher cost could lead to fewer health claims and a shift of competition away from health characteristics to other aspects of food choices.

In analyzing these questions, the FDA may wish to consider the FTC's experience requiring the disclosure of material information in advertisements. In a 1973 decision involving nutritional claims for a food product, the Commission determined that:

> [A]n absolute claim for good nutrition may well be objectionable for the reason that the advertisement omits things that should be said. On the other hand, it would be unrealistic to impose upon the advertiser the heavy burden of nutritional education, especially with respect to radio and TV commercials which in many cases are shorter than 30 seconds and seldom as long as 60 seconds. Therefore, we should not attempt to establish an overly restrictive standard of general application in this regard. To do so would be tantamount to a de facto ban on all nutritional advertising through the radio and TV media. In the final analysis, the question whether an advertisement requires affirmative disclosure would depend on the

> nature and extent of the nutritional claim made in the advertisement.[28]

Subsequent Commission decisions have also recognized that extensive disclosure requirements can raise the costs and burdens on communication and very possibly result in net harm to consumers.[29] Commission cases requiring disclosures of additional information look closely at the facts surrounding the matters at hand, including the specific expressed or implied claims made, as well as the injury that may result if the information is not disclosed.[30]

In fashioning regulations to ensure that health claim information is neither deceptively nor unfairly incomplete, we believe it is important to recognize that, under many market conditions, competition concerning a "desirable" product attribute may increase competition concerning other attributes of the product as producers are induced to highlight their

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[28] ITT Continental Baking Co., 83 F.T.C. 865, 965 (1973); appeal dismissed, 515 F. 2d 367 (D.C. Cir. 1975).

[29] International Harvester, 104 F.T.C. 949, 1060 (1984); appeal dismissed, No. 85-1111 (D.C. Cir. 1985).

[30] Thus, Commission actions dealing with deceptive omissions often deal with cases in which a seller fails to disclose qualifying information necessary to prevent an affirmative statement from creating a misleading impression. Similarly, under the FTC Act it can be deceptive for a seller to remain silent under circumstances that constitute an implied but false representation. Such implied representations may take several forms. They may arise from the physical appearance of the product, from the circumstances of a specific transaction, or from ordinary consumer expectations as to the irreducible minimum performance standards of a particular class of good. (International Harvester, supra note 29, at 1057-58.) Finally, even absent an express or implied representation, the FTC Act requires further disclosures in situations in which the failure to do so is likely to cause substantial consumer injury that is not outweighed by benefits to consumers or competition and that could not be reasonably avoided. (Id. at 1060-61.) In applying each of these standards, the Commission must necessarily analyze the facts surrounding the case, i.e., whether express or implied representations have been made or whether substantial consumer injury has occurred.

product's features.[31] The cereal study indicates that despite the focus on the health benefits of fiber (a good health feature), cereals changed in other dimensions as well during the health claims period. The average levels of sodium and fat in high-fiber cereals (both bad health features) continued to fall throughout the health claims period as these and other health dimensions became the focus of competition among sellers of high-fiber cereals.[32]

While competitive pressures tend to increase information in many cases, deception will sometimes occur. In these cases, enforcement against firms whose claims are deceptively or unfairly incomplete has been used successfully by the FTC to deter deception without reducing the flow of truthful diet-health information unnecessarily.

2. Preapproval of Health Claims

It has been suggested that all health claims should be preapproved or that only a narrow set of standardized health messages should be used by producers. A policy that requires preapproval of label claims or the use of standardized language may ultimately decrease the diversity of messages that appear and slow the spread of health messages, making the policies

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[31] See, e.g., Grossman, The Informational Role of Warranties and Private Disclosure about Product Quality, 24 J. L. & Econ. 461 (1981); Ippolito & Mathios, supra note 3, at 22-24.

[32] Similarly, in the markets for cooking oils and margarines, where "no cholesterol" claims have been prominent, the improved understanding of the role of saturated fat in health is leading to considerable advertising of the saturated fat content of the products and of the role saturated fat may play in determining serum cholesterol levels. See, for instance, recent advertisements for Puritan Oil (Newsweek, Oct. 9, 1989, at S-23), Promise Extra Light 40% Vegetable Oil Spread (Better Homes and Gardens, July 1989, at 135); Pam Cooking Spray (Good Housekeeping, June 1989, at 199), and Fleischmann's Margarine and Corn Oil Spread (Better Homes & Gardens, July 1989, at 121).

governing health claims less effective in getting truthful diet-health information to the public.

Information that is repetitive or uniform may be less likely to be noticed or acted on by consumers.[33] Changes in wording and emphasis can often be important in keeping a message fresh and prominent. Creative approaches to conveying diet-health relationships can also be important in getting health information to various segments of the population.[34] The very reason for permitting health claim messages could be weakened or defeated if messages become so repetitive as to be of little interest to consumers. Similarly, preapproval could delay or hamper efforts by food manufacturers to tailor their labels to reflect the particular characteristics of their products, which could diminish their incentives to compete by improving the health characteristics of their products.

Scientific understanding of diet-health relationships is constantly changing. The regulatory system should incorporate new learning and require labeling claims to be substantiated by the best scientific evidence available when the claims are made. Government preclearance of claims or standardized language for claims, which are more rigid and cumbersome

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[33] This was the case in the single mandated health warning in cigarette advertising. See FTC, Bureau of Consumer Protection Staff Report On The Cigarette Advertising Investigation at 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," 21 C.F.R. § 101.25(d), may diminish the attention given to this information by ordinary consumers who are not under a doctor's care.

[34] For instance, it may take different types of messages to reach different age groups within the population effectively, especially when dealing with the long term effects of diet.

regulatory approaches, may diminish the effectiveness of truthful health claims unnecessarily.

3. Conclusion

Our perspective on health claim issues has been shaped by our experience in regulating health claims in food advertising, as well as our long history of regulating other types of scientific claims in advertising and labeling. We recognize that health claims on food labels may raise different issues than health claims in advertising. Consumers' evaluation of and confidence in health claims made in advertisements may differ from claims made on food labels. In addition, the cost of required disclosures may vary depending on the type of advertisement (e.g., print, TV or radio) or the size of the food product (e.g., large cereal boxes versus canned goods).

Despite the clear differences between advertisements and labels, the fundamental features of health claims that shape our judgment of the best policy for advertising also appear to be important to labeling policies. First, truthful, nondeceptive information about the diet-health relationship is potentially very valuable to consumers. There is considerable evidence that many consumers do not know even the most well-established diet-health relationships. Federal regulatory policies should be designed to encourage the provision of such information. Second, scientific understanding of diet-health issues and food technology are changing. The regulatory construct governing diet-health claims should be able to encompass these changes. Deceptive claims cause consumer injury. But withholding information from consumers where there is a substantial scientific basis for it, but where a scientific consensus has not been reached, can also cause consumer harm.

We believe prudent regulatory policy should balance the potential for consumer harm of either type.

These concerns lead us to recommend that the FDA consider a flexible policy towards health claims on labels. Such a standard can be effectively implemented and can deter deceptive claims without unduly reducing truthful diet-health information that consumers could use to improve the healthfulness of their diets.

III. IDENTITY STANDARDS

A. Introduction

In its request for comments, the FDA asks whether the current method of naming foods should be changed. Specifically, the agency requests comments on whether food identity standards have continuing value in the 1990s and, if not, should efforts be made to replace them with a "common" or usual name standard.

As discussed below, rigid identity standards (or "recipe standards") can discourage desirable product innovation and indirectly inhibit manufacturers' ability to modify foods to address current health concerns, limiting consumer choice. Moreover, such standards would appear to be expensive to administer in markets where costs, preferences, and scientific information are changing.

For these reasons, the FDA might consider replacing the current rigid identity standard approach. One alternative system the FDA could consider would be less rigid common or usual name standards in conjunction with mandatory content disclosure. Such a system could encourage valuable product variety and innovation by making it less costly for producers to market new products that respond to consumers' demands for healthier foods.

B. Costs and Benefits of Rigid Food Standards

A recipe standard prescribes that certain ingredients in minimum or maximum proportions be present in a named product, includes a list of optional ingredients, and may also prescribe the way in which the ingredients may be manufactured and combined.[35] A product may be sold under the name designated by the identity standard if, and only if, it conforms to the standard.[36] A food that is similar to a standardized food and is

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[35] Some standards require very specific ingredients in the product with few options allowed. Other, more recent standards are less specific (and thus less constraining) about each of the ingredients of a defined food. Since about 1965, the FDA has used a "safe and suitable" standard for optional ingredients in foods. For example, the standard for frozen raw breaded shrimp allowed for the use of "safe and suitable" ingredients in major parts of the product, such as the batter and breading. Relative to rigid identity standards, such standards allow manufacturers flexibility with respect to new ingredients. See Vallowe, Informing Consumers of the Existence and Significance of Food and Drug Administration Food Standards of Identity, 38 Food Drug Cosm. L.J. 256, 260 (1983); R. Schaffner, The Effects of Government Policies on Technical Innovation in the Food Industry: A Government Perspective, in Critical Food Issues of the Eighties, 191-96, (M. Chou & D. Harmon, eds. 1979). The FDA has been altering existing identity standards to incorporate the more flexible "safe and suitable" standard for optional ingredients. See for example, Cheeses: Amendment of Standards of Identity to Permit Use of Antimycotics on the Exterior of Bulk Cheeses During Curing and Aging and to Update the Formats of Several Standards, 54 Fed. Reg. 32,050-59 (1989). In addition, the regulations for "common or usual names" devised in 1972, allow somewhat more flexibility in the use of a name so long as the name is accurate, simple, direct, and nonconfusing. The common names process allows the FDA to follow the procedures for notice and comment rulemaking rather than the more costly and time-consuming procedures associated with formal rulemaking. See 21 C.F.R. § 102-5 (1988). Therefore, changes in standards for foods falling under common or usual names rules may well be less onerous. See R. Merrill & E. Collier, Like Mother Used to Make: An Analysis of FDA Food Standards of Identity, 74 Colum. L.R. 561, 613-14 (1974).

[36] See section 403(g) of the Federal Food, Drug and Cosmetic Act of 1938. Even if a food is nutritionally superior to the defined food, it cannot be labelled as the defined food. For example, for many years prior to the passage of the Act, Quaker Oats had marketed a product named "Quaker Farina Wheat Cereal Enriched With Vitamin D." In 1938, the FDA adopted two standards: "plain farina" and "enriched farina." Neither standard allowed for the addition of vitamin D. Quaker's product did not conform to either standard and its production and sale were prohibited (despite the fact

nutritionally inferior to that food must prominently contain the word "imitation" immediately preceding the name of the food. A food that is similar to a standardized food but is nutritionally equal or superior to that food need not use the term "imitation," which may carry negative connotations, but must clearly distinguish itself from the standardized food.[37]

1. Rationales for Identity Standards

Recipe standards appear to have been motivated by three concerns. The main concern was with deceptive "economic adulteration."[38] It was feared that unregulated producers would substitute new and cheaper ingredients in traditional foods, and pass them off as traditional staples to unsuspecting consumers.[39] A second, related concern was that producers might add new ingredients to traditional products and that these products

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that its product was wholesome and truthfully labeled), because it purported to be enriched farina. Quaker appealed all the way to the Supreme Court and lost. Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943). This case was seen as an extension of Congressional intent to avoid not only economic debasement but also to protect against even wholesome additions to defined foods. See Vallowe, supra note 35, at 258.

[37] See Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993, 997-98 (1985) and 21 C.F.R. § 101.3(e), 102.5, 102.23. This is one of the most confusing areas of current law concerning standards enforcement. A food that is a substitute for a standardized food and is not nutritionally inferior to that food may not be able to use the name of the standardized food if the substitute does not contain the full complement of the "characterizing ingredient" (e.g., peanuts in peanut butter or milkfat in cheese).

[38] For an account of some "adulteration" problems encountered in the early part of this century, see Alsberg, Economic Aspects of Adulteration and Imitation, Q. J. Econ. 1 (Nov. 1931).

[39] Austern, The F-O-R-M-U-L-A-T-I-O-N of Mandatory Food Standards, 26(9) Food Drug Cosm. L. J. 380-82 (1971) and passim. (reprinted from the December 1947 issue).

might ultimately prove to be unsafe, even if the producers were not attempting to pass off their products as something they were not.[40] The third concern was that producers would add insignificant amounts of nutrients or other seemingly desirable ingredients and then exaggerate their importance and deceive consumers into paying premium prices greatly exceeding the value of the extra ingredients.[41] The second and third risks appear to have been greatly diminished due to changes in the law. Concerns about food safety are now largely handled by subsequent amendments to the Pure Food and Drug Act.[42] As to concerns regarding deceptive and misleading labeling and advertising, they are now addressed by the FDA, FTC and USDA regulations (1) requiring ingredient disclosure and (2) dealing directly with false and deceptive claims. Thus, the primary rationale for identity standards at this time appears to be a concern that "economic adulteration" would cause substantial consumer injury without the standards.

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[40] Merrill and Collier points out that although Congress conceived of food standards primarily as a means of combating economic adulteration, in practice "it is difficult to distinguish sharply between pocketbook and health interests of consumers." (Merrill & Collier, supra note 35, at 564).

[41] Id. at 597-99.

[42] Whatever was true in the past, risks to public safety no longer provide a compelling rationale for recipe standards. In 1958, Congress amended the Pure Food and Drug Act to require manufacturers to obtain prior approval for all food additives, whether for standardized or nonstandardized foods (Id. at 600). The only remaining potential safety gain from the use of recipe standards is in limiting the use of ingredients which are safe when consumed in moderation, but which pose a health risk to some consumers when consumed in large amounts (e.g., such concerns have been raised recently regarding certain fiber products and various substitutes for dairy and animal fats).

2. Benefits of Identity Standards

Currently, the major benefits of recipe standards appear to be that they save consumers the time and effort it takes to learn how to use the information disclosed and the time it takes to read and compare disclosures. Recipe standards can also eliminate "undesirable" foods (those that knowledgeable consumers would not buy) when it is difficult or expensive for consumers to become knowledgeable. Recipe standards work best when consumer tastes are known and vary little. For example, if no consumer would knowingly buy a peanut butter with less than 90 percent peanuts, then a standard that mandates a minimum peanut content of 90 percent would save consumers the time and trouble it would take to compare labels across brands to avoid such peanut butter. However, since tastes vary, a recipe standard will not provide the flexibility necessary to meet those variations. For example, the 90 percent peanut butter standard would bar sellers of a product that was 80 percent peanuts from calling it peanut butter. If consumers would value such products because they are similar in taste and texture to traditional peanut butter, yet less expensive or healthier, the recipe standard could substantially raise the cost of marketing such products because producers would have to promote the product under a new name that consumers would not be familiar with.

In sum, the main benefit of food identity standards is that they could protect consumers from buying products that they would not have purchased had they been fully informed about the characteristics of the product. Identity standards can also economize on shopping costs and producers' marketing costs for products for which consumers' tastes are known or vary little. These benefits of standards are likely to be most significant in those

instances where consumers cannot judge product quality at low cost.[43] For example, where competing food producers cannot credibly inform consumers of the quality of their products, there may not be sufficient information to assure appropriate quality.[44]

This lack of appropriate information could be remedied through the use of identity standards or by requiring disclosures. These two solutions, however, work through very different means. Identity standards simply disallow variation under the name. Disclosure requirements provide information to allow consumers to choose their preferred product characteristics.

3. Costs of Identity Standards

The major costs of recipe standards appear to be that: (1) they may decrease or retard desirable product innovation, limit consumer choice, and inhibit consumers' ability to improve their diets; and (2) they may be expensive to change and to administer, particularly in markets where costs, preferences, and scientific information are changing.

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[43] Information problems are most likely for expensive or infrequently purchased products, but most food products would not fit in those categories. Consumers can purchase most food products at low cost, and if they can judge the quality once they try it, are unlikely to repurchase the product if it is of low quality. Because introducing a new food product usually requires substantial introductory costs for producers, this quick consumer reaction is likely to make quality adulteration unprofitable for most food products where consumers can judge quality after purchase.

[44] The root cause of the problem is that consumers lack full information about the characteristics of the product. If they were fully informed, they would be able to choose the preferred quality products and economic adulteration could not exist.

a. Decreased Product Innovation

Recipe standards may reduce innovation and retard the rate at which innovations are introduced.[45] When a recipe standard applies, a firm that has found a new and lower cost way to manufacture an equally nutritious product covered by a recipe standard cannot market it under the common name until the old standard has been amended or revoked, or a new one promulgated. This may entail a long and arduous process, especially if the effort is opposed by other industry members.[46] Ice cream manufacturers, for example, who sought to amend the recipe to allow nondairy substitutes for milk (casein) in ice cream were opposed by the Dairy Association.[47]

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[45] See Merrill and Collier, supra note 35, at 602-03, 607-08; Goldby, The Effects of Government Policies on Technical Innovation in the Food Industry: An Industry Perspective, in Critical Food Issues of the Eighties, 197-215, M. Chou and D. Harmon, eds. (1979); Henry, The Future of Engineered Foods, in Critical Food Issues of the Eighties, at 216-221 M. Chou and D. Harmon (1979); and National Research Council, Designing Foods, National Academy Press, at 105-106 (1988).

[46] Being forced to use uncommon names is of concern because firms and consumer groups believe that it is much more costly to market products under novel, uncommon, or pejorative names than to market them under the name of the common food. In a recent debate about the fat content of ice cream and standards, a collection of consumer and health research groups, led by Public Voice, asked for a change in the rules to allow products with four to six percent milkfat that are currently called "ice milk" to be called "light ice cream". These groups and the International Ice Cream Association argued that products bearing the name "ice milk" were too difficult to promote. See Sugarman, The Future of Ice Milk: What's in a Name? Washington Post, July 6, 1988, at E-1. A similar argument was made by the American Meat Institute (AMI) regarding the use of uncommon names for cooked sausages. Firms could have marketed the lower fat, higher water content products under names such as "imitation frank" or "beef, water, and isolated soy protein product." The American Meat Institute (AMI) noted that "such nomenclature is unreasonably burdensome and has acted to inhibit the marketing and sale of new, innovative products." U.S. Dep't. of Agriculture, Standard for Frankfurters and Similar Cooked Sausage, 51 Fed. Reg. 42,239 (1986).

[47] Ice Cream Dairymen Imperiled by FDA's Recipe, 197 Science 844-45 (1977); FDA Backs Down on Protein Substitutes in Ice Cream Formula, Wall St. J., Dec. 19, 1977, at 3; M. Burros, Ice Cream Today is not the Kind that

Ingredient producers may have a vested interest not only in preserving existing standards, but in creating new standards that require the use of their ingredients. For example, the Dairy Association has unsuccessfully petitioned to amend the pizza standard to require real as opposed to imitation cheese in frozen pizzas.[48]

The innovation-inhibiting potential of recipe standards could also have an effect on development of fats and oils substitutes. Several firms (most notably Procter & Gamble and Nutrasweet) have developed products ("Olestra" and "Simplesse" respectively) that may serve as fat substitutes in various products.[49] If approved for safety, these products hold promise for being useful additions to many foods as substitutes for forms of fat that people are advised to avoid.[50] However, while the FDA may allow these products to be introduced as ingredients under the "safe and suitable" standard in some foods, many of the recipe standards would require complex and time consuming modifications before the ingredients could be included in those foods. For example, adding a fat substitute to dairy products (which are required to maintain high milkfat content in the identity standards) would likely require that the new product be given a new name distinct from

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Mother Used to Make, Washington Post, Aug. 11, 1977, at E-16.

[48] U.S. General Accounting Office, Frozen Pizza Cheese-Representative of Broader Food Labeling Issues, (GAO/RCED-88-70, 1988).

[49] A. Swasy, P&G Fat Substitute Moves Sluggishly Toward Market, Wall St. J., April 24, 1989, at B-1; Gillis, Fat Substitutes Create New Issues, 65 J. Am. Oil Chemists Soc. 1708-12 (1988).

[50] Some commentators have expressed safety concerns regarding Olestra, and possibly Simplesse, in part, due to the relatively large quantity of these substances that might ultimately become part of the diet. We take no position regarding the safety issues involved.

the food's usual name or use the negatively perceived term "imitation" on the label.[51]

b. Expense of Administration

Identity standards may also impose a significant burden on regulators. Generally, use of recipe standards requires that regulators decide: (1) which food characteristics are desirable; (2) how such characteristics should be traded off against each other or against undesirable characteristics (e.g., fat may taste good and provide nutrition, but too much fat may raise health concerns); and (3) how all characteristics should be traded off against money (fat is cheap in some meat products, but it is expensive in some dairy products). Moreover, because consumer tastes vary, the regulator's decision effectively may determine which consumer tastes ultimately are satisfied and which are not. A standard setter will generally be forced to adopt an arbitrary, "bright line" standard such as "ice cream can contain no less than 10 percent milkfat." Because of the added cost of marketing products under unfamiliar names, this process may limit product diversity and consumer choice. More importantly, as ingredient prices, technology, and preferences change, the standard setter must reevaluate all these decisions.

Government standards often require new rulemaking proceedings each time the "bright line" must be altered due to product innovation, changes in consumer preferences, or changes in scientific knowledge. The cost of

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[51] See Gillis, supra note 49 at 1710 (citing F. Edward Scarborough of the FDA's Office of Nutrition and Food Science).

promulgating or changing recipe standards may be large both for the taxpayer and for the firms involved.[52]

There are many instances where the proceedings to establish or alter standards have taken many years, as typified by the standards for peanut butter,[53] soft drinks and frozen desserts.[54] While stark examples of the

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[52] A GAO report has noted that "once a regulation is set, changing it is an arduous task that regulatory agencies try to avoid." See U.S. General Accounting Office, supra note 48, at 39. One means of avoiding the longest lags in the standards process is to obtain a temporary permit which allows initial market testing of a suitably labelled alternative product. This was recently done for light sour cream in May 1989 after the product had been seized by the FDA in November 1988 for not meeting the sour cream standard for milkfat content. See Food Chemical News, Nov. 28, 1988, at 24; Food Standards Box Score: FDA Interest Appears to Lag, Food Chemical News, Feb. 13, 1989, at 4, 6. The FDA also recently provided a temporary marketing permit for reduced fat "light" eggnog which did not meet the standards for six percent milkfat content. See 54 Fed. Reg. 35,725 (1989). Similarly, a temporary permit for "light ice cream" was recently issued (54 Fed. Reg. 47,829 (1989)). This temporary permit process has apparently become more popular in recent years, with seven temporary permits issued in 1988 and 15 issued in 1987 (mostly for canned salmon). See Food Chemical News, Feb. 13, 1989, at 6; Food Chemical News, Feb. 15, 1988, at 6.

[53] In 1958 Procter & Gamble (P&G) began to market a new peanut butter called "Jif." Unlike the two leading peanut butter brands of the time, "Skippy" and "Peter Pan," Jif contained a blend of hydrogenated nonpeanut oil in addition to peanut oil. The new mixture made Jif highly smooth and spreadable, and P&G hoped this innovation would attract a large market share. Though there was little, if any, evidence of complaints about diluted peanut butter prior to the FDA promulgation of the identity standard, in 1959 the FDA proposed a recipe standard for peanut butter. The proposed standard would have precluded the marketing of Jif under the name "peanut butter." A legal battle involving the three major manufacturers and the FDA ensued. The case ended in a victory for P&G 11 years later; under the new identity standard Jif was peanut butter, but Skippy and Peter Pan were not. The two leading firms had to reformulate their products. Merrill & Collier, supra note 35, at 585-91.

[54] Merrill and Collier report that it required 24 years to alter the softdrink standards, 19 years to alter the frozen dessert standards, and 22 months to add a safe ingredient to a standardized food that could have been added to any nonstandardized food without a review. Id. at 608-09. More recently, the USDA's amendment of the standard for cooked sausages took three and a half years (October 31, 1984 to April 14, 1988) from petition to the planned effective date of the final rule. Recent alterations in the cheese standards to allow "safe and suitable" antimycotics on the exterior of

difficulty in setting rigid food identity standards exist, it appears that the process is also difficult even in more routine cases.[55] At the end of 1988, 36 food standards proposals were pending at the FDA, compared to 33 the previous year and 31 at the end of 1986. During 1988, the food industry filed nine additional proposals for changes in standards. During 1988, reportedly only one food standard amendment became effective -- that providing for optional use of water buffalo milk in mozzarella cheese.[56]

C. Policy Alternatives

Identity standards can inhibit product innovation, but changing them frequently enough to avoid this effect is likely to impose significant administrative costs on FDA. There may be alternatives to the identity standards system that provide most, if not all, of the benefits of standards while avoiding these costs. Some of these alternatives are discussed below. While we have not attempted a complete analysis of the various alternatives to rigid identity standards, we identify some of the major benefits and costs of some of the leading alternatives.

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bulk cheeses will have required nearly four years barring further delay (December 18, 1985 to October 3, 1989).

[55] See Food Standards Called 'Dead as a Doornail' by Ronk, Food Chemical News, Dec. 5, 1988, at 24. (Mr. Ronk is Deputy Director of FDA's Center for Food Safety and Applied Nutrition).

[56] See Food Standards Box Score: Raw Milk Ban is Only 1987 Amendment, Food Chemical News, Feb. 15, 1988 at 3-10; Food Standards Box Score: FDA Interest Appears to Lag, Food Chemical News, Feb. 13, 1989, at 3-10. Although the identity standards process had been quite slow, the FDA's process to declare direct and indirect food additives and ingredients "generally recognized as safe" (GRAS) has speeded up, with 23 GRAS findings issued in 1988 compared to 6 in 1987. See GRAS Review Box Score: FDA GRAS Affirmation Action Quickens, Food Chemical News, Jan. 30, 1989, at 3-13.

1. Benefits and Costs of Disclosure Requirements

One alternative to identity standards would be mandated disclosure of product content. Mandated disclosure directly addresses the consumer information problem, and potentially could achieve most of the benefits available through rigid identity standards, at perhaps significantly less cost.[57] When compared with a recipe standard, mandatory disclosure may particularly benefit those consumers who value diversity and whose preferences differ from those chosen by the standard setter. In addition, disclosure would facilitate comparison of ingredient and nutrient content across various brands and products; disclosures may, therefore, be of significant value to those consumers who wish to comparison shop for "healthier" foods. Finally, mandatory disclosures would not retard appropriate innovation and appear to entail lower administrative costs.

Mandatory disclosure also may permit greater product variation than do rigid identity standards. For example, an identity standard that sets a minimum milkfat content of 50 percent for cheese disallows all variation below that level. If informed consumers would purchase cheeses with less fat (because they help lower fat intake, taste better, or are less expensive), the standard will deter such choice. An approach based on disclosure would not only allow those consumers to purchase the cheese of their choice under

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[57] We note that mandated disclosure could either cover all product ingredients or could be more limited in nature. For example, the disclosure might require that the percentage of the "characterizing ingredient(s)" in the traditional food be disclosed clearly on the label. In the case of ice cream made with safe milkfat substitutes, for instance, this approach could require that the manufacturer state that the food contains "0 percent milkfat and x percent milkfat substitute." This would help to maintain the integrity of the traditional name, without foreclosing the use of alternative ingredients.

the common name, but would also inform concerned consumers of the fat content of the product.

Consumers may well place a substantial value on the variation that disclosure could provide under the common name. Our previous example of "ice milk" indicates that producers and consumer groups believed that many consumers would prefer to purchase lower fat "ice creams" under the common name. However, the rigid identity standard requires manufacturers, who attempt to meet consumers' desire, to use less desirable names, such as ice milk.

Disclosure is not free from cost. The major costs appear to be the foregone benefits of whatever messages would have appeared in their stead, the costs of altering current labels, and the increased search required by consumers who previously r ed on standards and who would have to become more attentive to the particulars of labels. Of these three costs, the most important may be the increase in consumer search costs. That is, consumers who (1) relied either explicitly or implicitly on standards to set minimum levels of product characteristics and who (2) would not find it preferable to search to obtain products or brands that better matched their preferences, will nevertheless have to bear additional search costs as a result of a move away from identity standards or will have to purchase products that suit them less well. Consumers would have to educate themselves to use the disclosed information (e.g., they have to know how to relate nutrient content to health).[58] The added time and effort required to read and understand content disclosure may be significant for some consumers. We have no data

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[58] It may also be physically difficult to make the disclosure as in the case of foods in small packages.

on the magnitude of aggregate disclosure costs, but recognize that they may be significant.

2. Other Alternatives

The extremes of minimal mandatory disclosure alone or rigid identity standards are not the only policy alternatives available to the FDA. One alternative approach would be the less rigid name regulations (e.g., common or usual names regulation) in conjunction with mandatory content disclosure.[59] Common name regulation would allow more leeway in identifying modified foods without requiring pejorative title names or major modifications to rigid standards.

Another alternative remedy would be to give producers the option of either meeting any revised recipe standard, or making a clear and conspicuous disclosure of content. Makers of products that conform to the standard would not have to make the disclosure. Firms that choose to depart from the standard could make nonconforming products if they made the disclosure. If nonconforming products under the common name could be conspicuously marked as such, consumers who wish to rely on identity standards to insure a minimum quality level would not have to incur the search costs.

Although perhaps appropriate at the time adopted, the current system of identity standards may have become an imperfect way to address any

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[59] For example, manufacturers might be required to list major and minor ingredients and identify the percentage by weight of major ingredients. See, e.g., Center for Science in the Public Interest, Food Labeling Chaos: The Case for Reform 34 (1989). Alternatively, for standardized or common foods, manufacturers might be required to list the percentage of the characterizing ingredient on the label. In either case, the product could use the "common" name -- for example, ice cream.

existing consumer information problems about the quality and content of food products. There are a number of questions that need to be addressed before it can be determined whether it would be better to eliminate the identity standards, to use only common name regulation, to mandate various content disclosures, to rely on vigorous competition combined with effective enforcement of strictures against unfair or deceptive advertising or labels, or to use some combination of these options. Answers to the following questions would help policy makers assess the alternatives and would provide information to determine whether and how the existing system might be usefully altered.

(1) Is there evidence that significant market failures have occurred for foods not regulated by rigid identity standards (i.e., is there evidence of quality erosion in foods regulated under common or usual names or under other regulations)?

(2) Is there evidence concerning consumer shopping cost savings from the use of standards? Alternatively, is there evidence suggesting how much shopping costs (or producer marketing costs) would increase under alternatives to rigid identity standards?

(3) What do consumers assume about the characteristics of food products that do not disclose their nutrient value or content? If a product makes no disclosure, do consumers assume it is not "good" on the undisclosed dimensions?

(4) Is there evidence suggesting that the current rigid standards have deterred significant product innovations? If such deterrence is currently occurring, would "common or usual name" and "safe and suitable" ingredient regulations limit that problem?

(5) Is there evidence of the time and money costs to firms and the government of enforcing, administering and changing the existing system of identity standards? How would these costs be likely to change under the alternatives to the existing system?

IV. NUTRITION LABELING

Science has changed significantly since food labeling regulations were first promulgated. Two major diet and health reports, the National Research Council's Diet & Health Report (1989) and the Surgeon General's Report on Nutrition and Health (1988), have documented a large body of evidence linking certain nutrients to prevention of chronic diseases. For example, these reviews have concluded that cholesterol and saturated fat play a significant role in the development of heart disease, and that high-fiber, low-fat diets may reduce the risk of cancer. Present food labeling regulations, however, do not require cholesterol, saturated fat, or fiber disclosures, unless health claims or claims regarding these nutrients are made. Inclusion of these constituents on the label is at present optional and many food companies with products high in cholesterol, high in saturated fat, or low in fiber do not label or disclose the amounts of these substances voluntarily. This suggests that if the FDA were to continue to require some form of nutrition labeling, it should reconsider the elements that are mandated.

We also encourage the FDA to continue its review of available evidence (and, if necessary, to develop additional evidence) to determine what consumers know, what they want to know, whether labels are effective in getting information to consumers, the likely or potential costs of labeling and of alternatives to labeling, and how the present system might be

improved in communicating nutrition information to consumers. Without this evidence, changes in the food labeling regulations could prove to be of limited or no value and could harm consumers relative to existing regulations. We would like to assist the FDA in its efforts in any way we can, including assisting in designing consumer surveys.

At present, there is survey evidence suggesting that consumers use nutrition labeling. For instance, two recent consumer surveys, one published by the Food Marketing Institute in early 1989 (hereinafter cited as FMI survey) and the other published by the National Food Processors Association in November 1989 (hereinafter cited as NFPA survey) provide data regarding consumer use of and attitudes towards nutrition and ingredient labels.[60] The FMI survey found that about 91 percent of the respondents read labels for nutrition information and about 92 percent read labels for ingredients information. The NFPA survey found that 44 percent of respondents always read ingredient labeling when first purchasing a product and 36 percent sometimes read the label. The survey also found that 15 percent always referred to ingredient labels on subsequent purchases and 44 percent sometimes read the label on subsequent purchases. The FMI survey also found that only a small percentage (8-9 percent) of respondents never read labels for nutrition, ingredients, or expiration dates. The most common reason (40 percent) for not reading labels is "don't have time." Other major reasons for never reading include "already know the information" (26 percent) and "not interested" (16 percent). Only 4 percent of respondents said that they do not understand labels.[61]

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[60] We are not sure of the potential bias in responses arising from the possibility that consumers may not want to confess to not reading labels.

[61] FMI survey, supra, at 41.

Of those respondents who read labels, the FMI survey reports that over 40 percent felt that label information is insufficient. The most common suggested improvements were:

- Clearer explanations/easier to understand (25 percent).
- More information on calories (24 percent).
- Salt/sodium content (21 percent).
- Saturated fat/fat information (18 percent).[62]

A. Permit Manufacturers to Volunteer Nutrition Information

Information regarding the nutritional composition of food products can be conveyed on the labels of food products in various ways. Disclosures can be made through the use of either mandatory or voluntary nutrition labeling[63] or by listing the percentage of total weight for each ingredient in the ingredient list. The FDA may wish to examine each of these methods to determine which is likely to provide the most useful means of communicating nutrition information to the consumers without requiring so much information that the label becomes cluttered and unusable.

Current regulations require that when nutrition labeling is triggered, food producers list specific nutrients on the nutrition label.[64] However, even though current regulations require disclosure of these nutrients, we

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[62] Id. at 41, 44.

[63] It was estimated that more than 55 percent of food packages have nutrition labeling. U.S. Food & Drug Administration, Status of Nutrition Labeling on Processed Foods: 1986 - Food Label and Package Survey (FLAPS) (1989). We suspect that this number will increase over the years, especially as health claims, which currently trigger required nutrition labeling, continue to increase.

[64] We express no opinion on which or how many nutrients should be subject to the mandatory labeling requirement.

believe it is important that the labeling regulations not prevent or unnecessarily limit manufacturers' abilities to respond to consumers' demands for additional health information, particularly in light of rapidly evolving science and technology. The current system mandates label disclosure of micro-nutrients (e.g., vitamins) but tends to restrict the ability of producers to convey new health information about other nutrients through labeling. For example, firms were not permitted to label cholesterol content for years after the early evidence indicated its relationship to heart disease.[65] Allowing manufacturers voluntarily to label desirable nutrient information would help keep the nutrition label current. Thus, no matter which nutrients are mandated, the regulations should not restrict unnecessarily the manufacturers' abilities to label voluntarily other desirable nutrients so long as such additional information is presented in a truthful and nondeceptive manner.[66]

In order to keep nutrition labels relatively current, the FDA should consider developing some means to ensure periodic review of which nutrients must be included on labels. The costs to consumers associated with any delay in revising the label will be partly alleviated by allowing the manufacturers to volunteer information about their products as new discoveries arise. Substantial delay in revising labels, however, may still be costly for consumers.

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[65] For further discussion, see Calfee & Pappalardo, supra note 3, at 45-48.

[66] FDA should, of course, pursue effective enforcement against deceptive or misleading additions to the label.

B. Ingredient Labeling

Another possible method for communicating the nutritional composition and quality of food products to consumers would be to allow or mandate percentage disclosures on the ingredient label. The present ingredient labeling regulations only require that manufacturers list ingredients in descending order of predominance; this list does not need to specify actual quantities or percentages. The lack of quantification may make it impossible for consumers to judge the amounts of particular ingredients in the products they eat. Sugar provides a good example of this problem. Most nutrition labels provide information for "carbohydrates" without distinguishing between simple sugar and complex carbohydrates. The ingredient list does not improve on this. It simply names various sugars -- "sugar," "honey," "dextrose," "high fructose corn syrup," etc. -- without providing specific quantities or percentages.

As a means of identifying both negative and positive nutrients, the FDA may wish to consider whether manufacturers should be required to disclose specific quantities of the major or characterizing ingredients[67] in terms of percentages of total weights in lieu of, or in addition to, nutrition labeling. This could make it easier for consumers to determine whether a particular product has a desired amount of a given ingredient. Furthermore, this also could enable consumers quickly to determine the major characteristics and composition of food products. This might be particularly helpful if the FDA

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[67] We defer to the FDA to determine what is considered "major" or "characterizing."

were to adopt a "common names" approach to naming food products instead of continuing the present use of identity standards for food products.[68]

C. Serving Sizes

1. Present System

a. Discretion created by broad definition

The FDA presently defines a "serving" as a "reasonable quantity of food suited for . . . consumption as part of a meal by an adult male engaged in light physical activity . . . ."[69] As a practical matter, this definition allows food manufacturers considerable discretion in choosing serving sizes and varying them among products.[70] This flexibility raises the possibility that companies may choose serving sizes deceptively, perhaps by increasing serving sizes when consumers are concerned about nutrient deficiencies or decreasing serving sizes to diminish the per-serving amounts of calories and ingredients that are perceived by consumers as undesirable or harmful.[71]

There is some evidence that serving sizes for the same type of food items vary. Heimbach et al. studied whether food manufacturers changed

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[68] See Part III of this comment for further discussion of identity standards.

[69] 21 C.F.R. § 101.9 (b)(1) (1988). For food products to be consumed by infants or children under 4 years old, a serving must be a "reasonable quantity of food suited for . . . consumption as part of a meal . . . by an infant or child under 4 years of age." Id.

[70] Heimbach, Levy, & Schucker, Declared Serving Sizes Packaged Foods: 1977 to 1986 (1989) FDA Staff Paper. For example, one soup manufacturer is reported to have changed the serving sizes of some of its soups to 8 ounces, while retaining 10 3/4 ounce and 11 ounce serving sizes for others.

[71] Heimbach, Levy & Schucker, supra note 70; Pondering Portions, Ounce by Ounce, Washington Post, Feb. 25, 1987, at E-1 (citing Marilyn Stephenson, a nutritionist at the FDA's Center for Food Safety and Applied Nutrition).

serving sizes over the period 1977-1986 to reflect changes in consumers' concerns regarding diet and health.[72] It was found that "nineteen of the 44 product classes . . . and both bread categories moved toward smaller declared serving sizes in the period 1977-1986." The authors note that once changes were initiated, the majority of the manufacturers of the products surveyed adopted similar changes rapidly. It also was found that although many changes appear to be towards what the authors called more reasonable sizes, some changes simply "represent a redefinition of . . . a 'serving' from the original idea of an amount actually likely to be consumed at a single sitting to that of a standard unit used to communicate nutrition information to consumers."[73]

b. Variations within product categories

i. Variations among large multi-serving packages

Although serving sizes for large multi-serving packages are not uniform, there is some evidence suggesting that there is not a wide range of variation within most product categories. Most firms within a food category appear to use roughly the same serving size.

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[72] Heimbach, Levy & Schucker, supra note 70. This study analyzed the FDA FLAPS database which consists of label data collected by the FDA about every two years from 1977 to 1986. Each year's survey includes approximately 30 product classes with six individual products within each class, 3 most popular brands and 3 brands at random.

[73] Heimbach, Levy & Schucker, supra note 70. The authors use diet sodas as one example of this change in a concept of serving size. They further commented that "[i]f the manufacturer allowed the serving size to vary with the container size by labeling each as one serving, then the amount of (for example) sodium per serving [of diet sodas (for example)] would be 50% higher in 12-oz. cans than in 8-oz. bottles; 16-oz. bottles would contain 100% more sodium per serving. This in turn could lead to the situation of a diet soft drink sold in a 10-oz. bottle being a 'low sodium' product . . . , while the same product sold in a 16-oz. bottle would not be a 'low sodium' product."

For instance, for their recent study of the cereal market, Ippolito and Mathios collected label information for 113 cereals available in the Spring of 1988.[74] Of these 113 cereals, 103 used a serving size of 1.0 ounce on multi-serving packages regardless of whether or not the cereals contained dried fruits or nuts.[75] Three cereals used a smaller than 1.0 ounce serving size: Shredded Wheat gave its nutrition data per biscuit, which weighs only 0.83 ounce, and Quaker puffed cereals, which are high-volume, low-weight cereals, used 0.5 ounce as serving size. With the exception of one Swiss imported cereal, all of the cereals with serving sizes larger than 1.0 ounce contained dried fruits or nuts. Thus, the cereal evidence for multi-serving packages shows a high degree of standardization.[76]

ii. Variations among small-sized packages

Unlike the variations among the serving sizes used for large multi-serving packages, the variation seems substantially greater among serving

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[74] Ippolito & Mathios, supra note 3.

[75] One major food company's marketing of its cereal provides a concrete example of within class variation. This food company presently markets a variety of cereals and has uniformly used 1.0 oz. as the serving size for all of its cereals, regardless of whether or not the cereals contain dried fruits. This company has recently marketed a new dried fruit cereal claiming that it provides "100% daily allowance of 12 vitamins and minerals." Although this cereal has the same density (i.e., mass per unit volume) and the same kind of dried fruit as certain other of the company's cereals, the serving size for the new cereal is 50% larger (1.5 oz. instead of 1.0 oz.). This variation in serving size may make comparisons among products more difficult for consumers. In addition, by using different serving sizes for basically the same cereals in making different nutritional claims, the manufacturer may have somewhat lessened the value intended by the FDA in requiring nutritional disclosure, i.e., informing consumers of the nutritional composition of foods they plan to ingest.

[76] This finding is consistent with the study conducted by Heimbach et al., which found substantial uniformity of serving sizes within product categories and rapid adoption of new serving sizes whenever the serving sizes changed. Heimbach, Levy & Schucker, supra note 70.

sizes for single-serving or small multi-serving packages. For example, we found serving sizes of single-serving packages of various cereals of 9/16 ounce, 11/16 ounce, 13/16 ounce, 15/16 ounce, 1 1/16 ounces, 1 1/8 ounces, 1 1/4 ounces, 1 7/16 ounces, and 1 1/2 ounces.[77] Similarly, we found serving sizes of single-serving packages of various snack foods of 1/2 ounce, 9/16 ounce, 5/8 ounce, 3/4 ounce, 1 ounce, and 1 1/4 ounce.[78] The serving sizes of single-serving packages of cereals appear to be based on the use of a uniform single-serving package size and the diverse volume/weight ratios of cereals. The differences for snack foods may reflect variation in consumer demand for different size packages of snack foods for different purposes (e.g., children's snacks, adults' snacks, etc.).

While our limited investigation of labels leads us to believe that variations in the serving sizes for small-sized packages are substantial, these variations may not be easy to eliminate without creating confusion for consumers and, therefore, standardization may not be desirable. If producers were required to use the same serving size for all of their packages, then small packages would sometimes contain a fractional number of "servings." For example, most potato chip producers appear to use a 1 ounce serving size for their larger packages. However, if this serving size is retained for all small packages, they will contain "3/4 serving," "1 1/8 serving," "1 1/4 serving," or "2 servings" despite the likelihood that such packages will usually be consumed by a single consumer at one sitting. If uniformity is

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[77] These numbers reflect both the serving sizes and the content of the packages.

[78] The serving sizes for multi-serving packages (both large and medium-size packages) are usually 1 ounce.

mandated, serving size would be uniform across package sizes but might be less informative in terms of what the consumer is likely to eat.

Conversely, if the serving size is required to be the full amount in the package or a whole number of servings per package, which is the approach used by some producers, then serving size will necessarily vary according to package sizes. A serving for existing small packages of potato chips would then be "3/4 ounce," "1 1/8 ounces," or "1 1/4 ounces," while a serving for larger packages would be 1.0 ounce. Although providing nutritional information in terms of the entire package may well be an informative way to communicate the nutritional composition of products to consumers, this method could also create confusion. Uniformity would be sacrificed, and without uniformity, comparisons across products typically become more difficult.

We conclude by noting that it is not possible to make serving sizes uniform across package sizes and, at the same time, require that serving sizes reflect the amount a consumer is likely to eat at one sitting. One or the other must be sacrificed.

c. Variations across product categories

Unlike serving sizes within product categories, serving sizes across product categories vary significantly. For example, the serving sizes of some products are expressed as 4 ounces, while others are expressed as 2 cookies or 8 fluid ounces. This variation stems from the fact that foods have different density and composition and are consumed differently. Although it is unclear whether consumers often compare the nutritional compositions of products which are not in comparable units (or of products that are not reasonable substitutes), the present serving size system does not facilitate

such comparisons. This difficulty simply reflects the complex nature of the nutritional compositions of food products and the varied nature of consumption patterns.

d. Effect of variable serving sizes on FDA-defined terms

The fact that serving sizes may vary means that they can affect the usefulness of certain defined nutritional terms, such as "low sodium" or "low cholesterol." For example, while a serving of most multi-serving or single-serving packages of peanut snacks is usually chosen to be 1.0 ounce, a serving of peanuts served by one airline contains only 1/2 ounce of salted peanuts (50% smaller). The small serving size enables the airline to indicate on the package that its peanuts are "low" in sodium, because a "serving" of its peanuts has only 85 milligrams of sodium. The FDA regulations define "low sodium" as 140 milligrams or less of sodium per serving. Planters' salted peanuts have less sodium per ounce than the peanut snacks used by the airline (160 mg. versus 170 mg., respectively). But, Planters cannot make a "low sodium" claim, because a serving of its peanuts (1.0 ounce) has 160 milligrams of sodium, more than the allowable minimum per serving that would allow the "low sodium" claim to be made.

This example illustrates that variable serving sizes for products within the same product categories may interact with other FDA regulations to produce anomalous and, from the consumers' standpoint, confusing results.

e. Variations in serving sizes may cause inconvenience not intended by the nutrition labeling regulations

Assuming that providing nutritional information in terms of amounts per serving is the most useful way to convey this information to consumers, it is important that serving sizes accurately reflect the "amount actually likely

to be consumed at a single sitting"[79] by an average person. This will facilitate comparisons within product categories and possibly also across product categories.

There is, at present, only limited empirical evidence on the extent to which serving sizes within product categories vary or whether such variations may become greater over time. If the serving size issue is pursued further, additional information and evidence to answer the following questions could be very helpful:

(1) Are there in fact significant and systematic variations in serving size within product classes?

(2) Do the variations occur primarily in small-sized packages?

(3) What accounts for the variations other than package size?

(4) Do the variations make information processing and product comparisons more or less difficult?

(5) What is the likelihood that the variations would be constrained by market forces?[80] and

(6) What are the costs and benefits of regulation to reduce the degree of variation in serving size within and across product classes?

If there is evidence to suggest that the present serving size system warrants review, it may then be appropriate to reexamine whether the serving size system is adequately serving the FDA's original goal of

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[79] Heimbach, Levy & Schucker, supra note 70 at 7.

[80] In other words, would firms match the serving sizes used by their competitors to make the same, or better, claims than those made by their competitors?

providing a simple and easy unit of measure to communicate nutrition information to consumers.

2. Standardizing Serving Sizes May Not Be the Appropriate Solution to the Problem

There may be no "perfect" serving size for any given product because consumption patterns may vary too significantly among individuals and across different eating occasions. Furthermore, consumption patterns also may vary directly with package sizes, because package sizes themselves are likely to influence how much an individual consumes in a sitting. Thus, recognizing potential problems raised by the discretionary nature of the present serving size system does not necessarily lead to the conclusion that serving sizes should be standardized by regulation.

There also are potential problems associated with standardizing serving sizes which, at least to some extent, are avoided by the discretion under the present system. For example, as a general matter, adult men eat more than adult women, and adults eat more than children. The consumption patterns of health conscious consumers may differ from those of consumers who are less conscious of health issues. Consumption patterns change over time, especially as health concerns change, and standardized serving sizes may be very hard to change (witness the difficulty in changing identity standards). Standardized serving sizes may lead to the anomalous result of food packages designed to be consumed at a single sitting being labeled as containing more than a single serving. Finally, products within the same product class may differ in serving size for legitimate reasons. Standardized serving sizes simply cannot reflect these types of differences.

D. Format of Nutrition Label

The manner in which mandated or voluntary nutritional information is presented on labels is important. Dietary recommendations are of marginal use if consumers cannot implement them easily through the information contained on labels. Two prime examples of potential problems are the fat consumption recommendation that most public health organizations have adopted and the recent National Research Council (NRC) sodium recommendation. The current dietary recommendation for fat consumption made by a number of public health bodies[81] is that 30% or less of one's daily caloric intake should come from fat. But the nutrition label provides the information for fat in terms of weight, e.g., 4 grams of fat. How the 4 grams of fat fits in the "30% or less" dietary recommendation requires the following analysis. Each gram of fat has about 9 kilocalories, so

$$4 \times 9 \text{ kilocalories} = 36 \text{ kilocalories.}$$

The percentage of the calories from fat per serving is given by

$$\frac{\text{36 kilocalories per serving}}{\text{total kilocalories per serving}} = \text{\% of kilocalories from fat per serving.}$$

Having to make this type of computation does not make it easy for consumers to implement the dietary recommendations.

There is also a significant discrepancy between the NRC's sodium recommendation and the current sodium information on nutrition labels. While the NRC makes the sodium recommendation in terms of "salt" (sodium chloride), nutrition labels provide the salt content of the products in terms of "sodium." "Salt" and "sodium" are not interchangeable. One gram of salt

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[81] See, e.g., National Research Council, Recommended Dietary Allowances, 10th Edition (1989).

has 0.4 grams of sodium and 0.6 grams of chloride. Unless a consumer knows this relationship, the NRC's recommendation that salt consumption be limited to 4-6 grams per day may be difficult to implement.

For this reason, whichever format the FDA chooses, it should consider the utility of the label in light of the dietary recommendations. In particular, the FDA should make the label as accessible as possible for consumers attempting to follow recommended consumption levels for various ingredients. It also is important for the FDA to try, as much as possible, to take an active role in encouraging other public health organizations to consider the way products are labelled in making dietary recommendations. This might be best accomplished by encouraging these public health organizations to make dietary recommendations and guidelines in a way that is consistent with labeling that covers the broadest possible range of products.

E. Predefined Terms

The FDA on various occasions has defined terms used by the food industry to communicate certain information to consumers. For example, the FDA has promulgated regulations defining the terms "sodium free," "very low sodium," "low sodium," "reduced sodium," "unsalted," "no salt added," and "without salt."[82] Although these definitions provide a useful common point of reference for both manufacturers and consumers, the regulations leave open the possibility that serving sizes may be varied to fit predefined terms. Because of the inherently flexible nature of the serving size system, any

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[82] 21 C.F.R. § 101.13 (1988). The FDA is presently in the process of defining the terms "cholesterol free," "low cholesterol," and "cholesterol reduced." The FDA has proposed that cholesterol content be declared only in terms of milligrams per serving.

definition that uses serving size as the basis for determining whether a predefined term is met may not accomplish the intended purpose of providing a useful common point of reference. The salted peanut snack example discussed above is illustrative. Given the problems associated with the flexible nature of serving sizes (assuming that the present serving size system is retained), the FDA may wish to consider defining terms by using a basis other than, or in addition to, serving size (e.g., amount per number of ounces, amount per number of calories, or amount per percent of the package).

In addition to terms used to convey the amount of a particular nutrient in a food, manufacturers also have used descriptive terms, such as "light," "natural," or "organic" to market their products. By their nature, providing a specific definition of these terms inevitably involves some degree of arbitrariness. In addition, given the complexity of food composition, it may perhaps be impossible for each descriptive term to be defined in such a way that the definition can provide the same useful information for all products across all food categories. Many descriptive terms have no consistent meaning and are used to describe different aspects of a food product. For example, companies can use the term "light" to mean reduced calories, fat, sodium, or sugar, or a food that is lighter in texture, flavor, or color. A 1982 FDA survey shows that 70% of consumers who had seen "light" claims on labels thought that the claim meant lower in calories, 15% thought lower in sugar, 11% lower in salt or sodium, 6% lower in fat or cholesterol, and 6% lower in weight.[83] However, even if the FDA had the resources to define

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[83] Center for Science in the Public Interest, supra note 59, at 23 citing FDA, Familiarity With and Perceived Meaning of 'Light' (telephone interview survey of 1,000 adults in a national probability sample, conducted

terms as they are introduced in the market, new terms would continuously be invented.

We recognize that undefined terms can cause confusion and can be used deceptively, and that at some point it may be desirable to adopt uniform definitions for such terms. However, we have not seen evidence to date sufficient either to recommend that manufacturers be prohibited from using such descriptive terms or to recommend the imposition of arbitrary definitions for such terms. Instead, to reduce the possibility of deception, mandatory disclosure of how the terms are used, such as "light colored" or "light in calories," and providing nutritional information might well be a preferred alternative to the general problem. Such an approach would not only lessen the FDA's burden in defining terms, but it may also increase the flow of information to consumers. This flow of information, in turn, may be likely to police manufacturers' behavior by strengthening the incentives to make accurate claims as well as improve their products on these dimensions.

Oct.-Nov. 1982).