BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

In the Matter of Food Labeling:
Trans Fatty Acids in Nutrition Labeling;
Consumer Research to Consider Nutrient Content
and Health Claims and Possible Footnote
or Disclosure Statements

Docket No. 03N-0076

Comments of the Staff of
the Bureau of Economics,
the Bureau of Consumer Protection,
and the Office of Policy Planning
of the Federal Trade Commission

October 9, 2003*

*** These comments represent the views of the staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission. They are not necessarily the views of the Federal Trade Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to submit these comments.**

I. INTRODUCTION

Consumption of *trans* fatty acids (or "*trans* fats") increases serum cholesterol levels, thereby increasing the risk of cardiovascular disease. To provide consumers with more information about the amount of *trans* fats in foods, on July 11, 2003, the Food and Drug Administration (FDA) issued a final rule mandating that *trans* fats be listed as a separate line item on the Nutrition Facts panel (*Trans* Fat Final Rule or Final Rule).[1] On that same date, the FDA issued an advance notice of proposed rulemaking seeking consumer research regarding a proposed footnote to accompany the listing of *trans* fats on the Nutrition Facts panel, as well as comment on other issues related to nutrient content[2] and health claims[3] related to *trans* fats (*Trans* Fatty Acid ANPR or ANPR).[4]

The Federal Trade Commission has considerable expertise in food advertising and labeling issues. The FTC enforces the Federal Trade Commission Act,[5] which prohibits

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[1] 21 C.F.R. Part 101; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434 (July 11, 2003).

[2] A nutrient content claim is a claim on a food product that directly or by implication characterizes the level of a nutrient in the food (*e.g.*, "low fat" or "high in oat bran"). Nutrient content claims are also known as descriptors. *See* 21 C.F.R. § 101.13(b).

[3] A health claim is a claim on a food product that represents, suggests, or implies that the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. *See* 21 C.F.R. § 101.9(k)(1).

[4] Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements, 68 Fed. Reg. 41507 (July 11, 2003) ("ANPR").

[5] 15 U.S.C. § 45 *et seq*.

deceptive or unfair acts or practices in or affecting commerce.[6] The FTC considers the prevention of deceptive health-related advertising claims to be one of its highest priorities and has taken action in numerous cases involving deceptive health-related claims about foods and dietary supplements. Through implementing its law enforcement mandate, the FTC has developed considerable expertise in understanding the role of advertising and labeling in providing information to consumers.[7]

The Commission's staff also has experience examining the effects of advertising regulation on market performance, including the performance in markets for foods.[8] FTC staff research suggests that labeling and advertising regulations have a strong effect on the type and amount of health information that consumers receive. Specifically, labeling and advertising regulations that permit sellers to disseminate truthful and nonmisleading information about diet and health are likely to lead to better informed consumers, more

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[6] *Id.* The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for ensuring that their advertising is truthful and not misleading. Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971).

[7] *See Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission in the Matters of Nutrition Labeling: Nutrient Content Claims: Health Claims; Ingredient Labeling Proposed Rules Before the Department of Health and Human Services Food and Drug Administration*, Docket Nos. 91N-0384, 84N-0153, 85N-0061, 91N-0098, 91N-0099, 91N-0094, 91N-0096, 91N-0095, 91N-0219 (1992).

[8] *See* P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977 - 1997* (2002); P. Ippolito & A. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996); P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* (1989); J. Calfee and J. Pappalardo, *How Should Health Claims for Foods be Regulated? An Economic Perspective* (1989).

competition on the health attributes of food, and the formulation of healthier products.

The FTC staff has followed the regulatory developments relating to *trans* fats and has submitted comments to the FDA on two previous occasions.[9] To assist the FDA, we provide this comment in response to the questions presented in the ANPR. The FTC staff supports the FDA's decisions to list *trans* fats as a separate line item on the Nutrition Facts panel and to solicit consumer research before mandating that any footnote disclosure accompany that listing. The FTC staff also encourages the FDA to adopt regulatory and law enforcement policies that would encourage truthful, nonmisleading nutrient content and health claims related to *trans* fats.

II. BACKGROUND

In 1993, the FDA issued final regulations on nutrition labeling for foods that it regulates.[10] These rules require that marketers list a food's total fat and saturated fat content on the Nutrition Facts panel. In addition, the FDA required marketers that make claims about fatty acids and cholesterol to list the monounsaturated fat and polyunsaturated fat content. The FDA, however, concluded that it was premature to require the listing of *trans* fat

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[9] *See Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims*, Docket No. 94P-0036 (Dec. 16, 2002), *available at* http://www.ftc.gov/be/v030003.htm; *Comments of the Staff of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission In the Matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims; Proposed Rule Before the Food and Drug Administration*, Docket No. 94P-0036 (Apr. 17, 2000), *available at* http://www.ftc.gov/be/v000003.htm.

[10] Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, Part IV, 58 Fed. Reg. 2079 (Jan. 6, 1993).

information on the Nutrition Facts panel, because of a lack of consensus on the dietary implications of *trans* fat intake.[11]

In 1999, the FDA reviewed additional scientific evidence and concluded that it "consistently indicate[d] that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL-C [low density lipoprotein cholesterol] compared with consumption of diets containing cis-monounsaturated or cis-polyunsaturated fat sources."[12] The FDA therefore proposed that marketers disclose *trans* fat information on food labels.[13] The FDA considered several labeling options; its preferred option was to add *trans* fats to the saturated fats entry on the Nutrition Facts panel on food labels.[14] The FDA also proposed a "*Trans* Fat Free" claim (and several synonyms) for foods that contain less than 0.5 grams of *trans* fat and less than 0.5 grams of saturated fats per serving.

In April 2000, the FTC staff filed a comment on the FDA proposal (2000 FTC Staff Comment).[15] In that comment, the staff: (1) supported efforts to allow truthful and nonmisleading *trans* fat information on food labels; (2) recommended that *trans* fats not be

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[11] *Id.* at 2091.

[12] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, Part II, 64 Fed. Reg. 62,746, 62753-754 (Nov. 17, 1999).

[13] *Id.*

[14] Products containing *trans* fats would have included an asterisk that would refer to a footnote: "Contains _____ g *trans* fat."

[15] *Comment of the Staff of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission in the Matter of Trans Fatty Acid in Nutrition Labeling*, Docket No. 94P0036 (Apr. 17, 2000).

included in the saturated fat category; (3) supported the definition of "*Trans* Fat Free" claims; (4) recommended consideration of a "Reduced *Trans* Fat" claim; and (5) recommended that the FDA consider allowing health claims to inform consumers of the relationship between *trans* fats and heart disease risks.

In November 2002, the FDA reopened the comment period (2002 FDA proposal).[16] The FDA specifically requested comment on a new proposal for listing *trans* fats separately from saturated fats on the Nutrition Facts panel. Under that proposal, the listing would be accompanied by a footnote informing consumers that "Intake of *trans* fat should be as low as possible." The FDA's proposal also noted that, pending publication of a final rule, it would, as an exercise of its enforcement discretion, allow truthful *trans* fat listings that are accompanied by the proposed footnote.

In December 2002, FTC staff filed a comment on the new FDA proposal (2002 FTC Staff Comment).[17] In that comment, the staff: (1) supported the FDA's proposal to list *trans* fats separately from saturated fats; (2) recommended that the FDA conduct consumer research, such as a series of controlled copy tests, to determine if the proposed footnote would confuse consumers about the relative risks of saturated fat, cholesterol, and *trans* fat; (3) supported the FDA's proposal to allow *trans* fat information in labeling prior to issuance of a final rule, given the significant effect of *trans* fats on heart disease risks; and (4)

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[16] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period, 67 Fed. Reg. 69,171 (Nov. 15, 2002).

[17] *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims*, Docket No. 94P-0036 (Dec. 16, 2002).

reemphasized that the FDA should consider allowing truthful and nonmisleading nutrient content and health claims related to *trans* fats.

The 2002 FTC Staff Comment's analysis was based on certain conclusions that are relevant here. Scientific understanding regarding the effects of various fats on heart disease risks continues to evolve. Despite this evolution, there is general agreement that: (1) consumers would benefit from reductions in *trans* fat, saturated fat, and dietary cholesterol consumption; (2) substituting polyunsaturated or *cis*-monounsaturated fats for saturated or *trans* fats is likely to be beneficial; and (3) holding calories constant, any heart-health benefit from changes in total fat consumption will depend on the type of fat substitution made.

III. THE 2003 *TRANS* FAT FINAL RULE

The *Trans* Fat Final Rule requires manufacturers of foods and dietary supplements[18] to list *trans* fat separately on the Nutrition Facts panel beginning in 2006. *Trans* fats will be listed immediately under saturated fat. The amount of *trans* fat is to be listed without a % Daily Value (DV) or an accompanying footnote statement.

FDA's *Trans* Fat Final Rule is a salutary step. The required disclosure of *trans* fat separately from saturated fat on the Nutrition Facts panel reflects the fact that *trans* fats are chemically distinct from saturated fats and may have different effects on cholesterol levels. This disclosure will increase accuracy of the Nutrition Facts panel and help avoid consumer confusion between the two types of fat. Once the rule is implemented, this information as to the amount of *trans* fat in a food will make it easier for consumers to identify the foods that

[18] The *Trans* Fat Final Rule requires dietary supplement manufacturers to list *trans* fat on the Supplement Facts panel if their products contain 0.5 gram or more of *trans* fat.

best meet their dietary goals.

IV. THE 2003 *TRANS* FATTY ACID ANPR

1. Nutrition Facts Panel Information

As discussed above, the *Trans* Fat Final Rule requires that manufacturers list *trans* fats on the Nutrition Facts panel. The FDA, however, has withdrawn the proposed accompanying footnote that would have stated, "Intake of *trans* fat should be as low as possible." The agency withdrew the footnote requirement pending the completion of additional consumer research.

The FDA's decision is consistent with our suggestions in the 2002 FTC Staff Comment. Our concern was that the "unique treatment" of *trans* fat in the form of the proposed footnote "may suggest to consumers that there is a significant qualitative difference between saturated fats and *trans* fats, and such a conclusion appears to be inconsistent with current dietary advice."[19] We encouraged the FDA to conduct research such as copy tests comparing alternative formats, disclosures, and health messages to determine consumers' take-away.[20] In the ANPR, the FDA recognizes the importance of consumer testing "to

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[19] *See* 2002 FTC Staff Comment, Section V. In a recent study conducted for the International Food Information Council Foundation, for example, Cogent Research suggests that the proposed footnote statement may lead consumers to place inordinate weight on foods' *trans* fat content rather than considering *trans* fats in context with saturated fats and total fats. Cogent Research, *Impact of Trans Fat Label Information on Consumer Food Choices* (June 10, 2003), *available at* http://www.ific.org/research/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=1522.

[20] In the 2002 FTC Staff Comment, for example, we suggested that the FDA test disclosures of *trans* fats, saturated fats, and dietary cholesterol in as close to identical formats as feasible. The FDA could copy test a label that applies the proposed footnote not only to *trans* fats (with or without a % DV) but also to saturated fats and dietary cholesterol (with or without % DVs) to determine which format is most informative for consumers and runs the least risk of

ensure that any claim or footnote statement about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction."[21]

2. Nutrient Content Claims

When the FDA issued its *Trans* Fat Final Rule, it withdrew proposed rules that would have established nutrient content claims for "*Trans* Fat Free" and "Reduced *Trans* Fat" foods. The FDA withdrew these proposed rules "because the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat, such as a DRI [Daily Reference Intake] level, from which the agency could derive a DRV [Daily Recommended Value] for *trans* fat."[22]

As we suggested in the 2000 FTC Staff Comment,[23] nutrient content claims can be an important vehicle for health information. One example is a "Reduced *Trans* Fat" descriptor. For some foods, it may be feasible to reduce – but not eliminate – *trans* fats. Consumers' health may benefit if manufacturers who meaningfully reduce the *trans* fat content of a food can communicate that fact to consumers. A reduced *trans* fat descriptor would provide an incentive for manufacturers to make such a reduction, thereby spurring competition and innovation in such foods. Similarly, a "*trans* fat free" descriptor would help consumers identify healthier products more easily. These nutrient content descriptors may catch the

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confusing them about the relative risks of saturated fat, cholesterol, and *trans* fat.

[21] ANPR, *supra* note 4 at 41508.

[22] *Id*. at 41509.

[23] 2000 FTC Staff Comment at Section V, *Consumers Can Benefit from Trans Fat Descriptors*.

attention of consumers who might not otherwise read the Nutrition Facts panel.

The FDA recognizes the value of nutrient content claims to consumers, yet has decided not to adopt its proposed rules because it could not derive a DRV for *trans* fat. It could take years of research, however, to develop a sufficient understanding of *trans* fats to derive a DRV. In the interim, nutrient content claims may be particularly important to assist consumers in assessing the relative amount and significance of the *trans* fats in foods. Therefore, we encourage the FDA to authorize nutrient content descriptors such as "Reduced *Trans* Fat" and "*Trans* Fat Free."

We note that the FDA has limited the use of nutrient content claims to nutrients for which there are DRVs or Recommended Daily Intakes (RDIs), except for use of "sugar free" and terms related to caloric levels in foods.[24] One alternative would be to allow nutrient content claims related to *trans* fats without reference to a DRV, as the agency has done for sugar. Or, a food could be described as having "reduced *trans* fat" in comparison to a reference food rather than a DRV. Thus, a marketer could claim that its snack crackers were *trans* fat free, if they had no *trans* fat, or that its potato chips had reduced *trans* fat, if they had, for example, at least 25% less *trans* fat than regular potato chips.

3. Health Claims

Empirical evidence supports the conclusion that truthful and nonmisleading claims in food advertising and labeling can play a vital role in fostering well-informed consumer

[24] *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421 (Nov. 27, 1991).

dietary choices and in encouraging food marketers to develop and offer healthier products.[25] Thus, it is important to allow companies to fashion health claims to explain to consumers the significance of different types of fats. Truthful and nonmisleading information on health effects can help consumers understand why fat choices matter. In turn, their improved understanding can lead consumers to substitute heart-healthier foods for foods that are higher in *trans* fats, and spur food marketers to compete and innovate based on heart-health attributes.

In the ANPR, the FDA recognized the value of truthful and nonmisleading health claims in promoting consumer understanding of the impact of *trans* fats on health: "In addition to the information on the Nutrition Facts panel, nutrient content and health claims are important tools for providing consumers with information about the level of one or more nutrients in a food product."[26] Accordingly, the FDA announced that "if a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would have to consider the exercise of its enforcement discretion."[27]

We understand that the FDA has decided to use its discretion to allow marketers

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[25] *See generally* 2002 FTC Staff Comment, Section IV, *Empirical Evidence on Approaches to Commercial Speech*; 2000 FTC Staff Comment Section IV, *Consumers Can Benefit from Explicit Trans Fat Health Claims.* Key studies include P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989); P. Ippolito & A. Mathios, *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990*, FTC Staff Report (1996); P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997*, FTC Staff Report (2002).

[26] ANPR, *supra* note 4 at 41509.

[27] *Id.*

flexibility to make truthful, nonmisleading health claims relating to *trans* fats. We think that even greater consumer benefits could be realized if the FDA were to authorize specific health claims explaining the likely link between *trans* fats and heart disease. There is anecdotal evidence that many food marketers currently are reluctant to emphasize the *trans* fat profiles of foods.[28] Food marketers may also be hesitant to make health claims related to *trans* fats in light of FDA's general practice of prohibiting health claims unless specifically approved.[29] FDA authorization of health claims related to *trans* fats would eliminate this uncertainty, thus encouraging food marketers to spread this valuable information.[30] Given the significant effect of *trans* fats on heart disease risks, we think that the better alternative would be for the FDA

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[28] *See, e.g.*, S. Thompson, *Food Makers Keep Mum on* Trans *Fats*, Advertising Age (July 21, 2003), at 4 ("many food companies are steering clear of drawing attention to their efforts to reduce *trans* fat in their products, in part because they're not sure consumers actually care").

[29] The FDA's approach to regulating the marketing of health-related products frequently relies on prior approval. Over the course of the past decade, the FDA has considered but declined to approve health claims for *trans* fats. Given this history, an FDA announcement that it will exercise its enforcement discretion not to challenge some health claims for *trans* fats may not be enough to persuade food marketers to incur the financial cost and legal risks associated with reformulating their food products and making such claims in their marketing. FDA authorization of claims may be necessary to provide the needed impetus and assurance to food marketers in these specific circumstances.

[30] The FTC and the FDA share jurisdiction over the marketing of various health-related products. *See supra* note 6. An important goal of both the FDA and the FTC is to curb false or deceptive claims, whether in labeling or advertising, and to stop products from being marketed in a way that jeopardizes the safety of consumers. The agencies have overlapping but not identical mandates, however, and generally have used different approaches in their efforts to satisfy these objectives. For example, the FTC proceeds by identifying and prohibiting deceptive claims after they are made rather than engaging in the prior approval of claims. The FTC's approach and its emphasis on remedies that provide consumers with more information – rather than less – to prevent future deception, dovetail with First Amendment principles intended to promote the free flow of truthful and non-misleading commercial speech. *See* Comment of the Staff of the Federal Trade Commission to the FDA on First Amendment Issues (Sept. 13, 2002), *available at* <http://www.ftc.gov/os/2002/09/fdatextversion.pdf>.

to authorize health claims related to *trans* fats.[31]

We note that in the ANPR, the FDA announced that it "intends to promote consumer awareness and understanding of the health effects of *trans* fat as part of an educational program."[32] Such efforts can be helpful, given that many consumers appear to be unaware of the link between *trans* fats and health.[33] If consumers learn from the FDA that there are health benefits from decreasing the amount of *trans* fats in their diet, they might examine the *trans* fat content on the Nutrition Facts panels and make more healthful food choices.

Although public information campaigns can benefit consumers, we believe that consumers' knowledge could be further enhanced by authorizing food marketers to explain on food labels why *trans* fat is important to consumer health. Evidence from the economics, marketing, and nutrition education literatures suggests that explicit health claims in labeling could help to improve consumer awareness and knowledge about the potential links between

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[31] Evidence about advertising in the fats and oils market after enactment of the Nutrition Labeling and Education Act of 1990 indicates that once the FDA prohibited heart health claims for fats and oils (because they are not low in fat), firms stopped making those health claims in advertising. Once the health claims ended, nutrient content claims about saturated fat and cholesterol also fell substantially. By 1997, few fat and oil producers were competing on the nutritional characteristics of their products. *See* Ippolito and Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997*, p. 158, Figure 7-8. This evidence supports the premise that firms are less likely to highlight nutrition characteristics of a food if they cannot tell consumers why the characteristic is important to health.

[32] ANPR, *supra* note 4 at 41437.

[33] Consumer awareness of the relationship between *trans* fats and health may be low. A previous FDA *trans* fat rulemaking proposal noted that, at that time, few consumers were aware of the substantial evidence linking *trans* fats to an increase in serum cholesterol and heart disease. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, Part II, 64 Fed. Reg. 62,746, 62,754-55 (Nov. 19, 1999). This survey evidence, however, reflects a period during which *trans* fat labeling was prohibited.

trans fats and heart disease.[34] Food marketers often disseminate specific information on labels and in advertising concerning the presence and significance of nutrients in a particular brand of food.[35] The provision of such nutrient information can be very effective in getting a dietary message to consumers. Thus, consumers are likely to benefit the most if the FDA allows health claims and nutrient content claims for specific food products to complement[36] its proposed general consumer education initiative.[37] Health claims can help provide the critical motivation for consumers to make choices using the content information the Nutrition Facts panel will provide.

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[34] Consumer research suggests that consumers who know about diet-disease relationships or believe that diet is important for reducing disease risks are more likely to use nutrition labels. *See, e.g.*, Christine Moorman, *The Effects of Stimulus and Consumer Characteristics on the Utilization of Nutrition Information*, 17 J. Consum. Res. 362 (Dec. 1990); Marian L. Neuhouser *et al., Use of Food Nutrition Labels Is Associated with Lower Fat Intake*, 99 J. Am. Diet. Assoc. 45 (Jan. 1999); Lisa R. Szykman *et al., A Proposed Model of the Use of Package Claims and Nutrition Labels*, 16 J. Pub. Pol'y & Mktg. 228 (Fall 1997).

[35] For example, a study on the effects of the dissemination of health information in the ready-to-eat cereal market showed that marketers' dissemination of fiber/cancer claims for cereals benefitted consumers by providing important dietary guidance and by expanding the range of high fiber cereal choices available to them in the market. P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989).

[36] Advertising and labeling also generally complement one another. Consumers who see a nutrient content claim in a food ad may be reminded of the claim if they see similar information on the product's label in the grocery store. Consumers who see such a claim in labeling at the grocery store likewise may remember similar information they saw in an ad for the food.

[37] Nutrient content information in advertising and on labels also would be useful to consumers who do not normally pay attention to the health and nutrition issues discussed in government educational pamphlets or the popular press. For example, according to a 1996 survey of 4,200 food shoppers, 70% of brand purchase decisions are made in the store, the point at which consumers are being directly exposed to label information. Point of Purchasing Advertising Institute, *1996 POPAI Consumer Buying Habits Study* 8 (1996).

4. Disqualifying Levels for Health Claims

The FDA also seeks scientific information and consumer research data that would assist the agency in setting levels of other nutrients in a food that would disqualify a food marketer from making a health claim for *trans* fats.[38] For example, the FDA might prohibit a food marketer from making the health claim "reducing the consumption of *trans* fats in your diet may reduce your risk of heart disease" if the food for which the claim is proposed contains an amount of sodium that exceeds disqualifying levels. The FDA seeks comment on the specific issue as to whether the use of disqualifying levels to prohibit a health claim for *trans* fats is consistent with the First Amendment.

Marketers' health claims about a product are a form of commercial speech, and, therefore, the FDA's use of disqualifying levels to prohibit such claims would be analyzed under the Supreme Court's *Central Hudson* test.[39] Under *Central Hudson*, if the commercial speech concerns lawful activity and is not inherently misleading,[40] the court will ask "whether the asserted governmental interest is substantial."[41] If the government interest is substantial, the court "must determine whether the regulation directly advances the governmental interest asserted."[42] Next, the court must determine "whether [the regulation] is not more extensive

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[38] ANPR, *supra* note 4 at 41509.

[39] *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980); *see also Pearson v. Shalala*, 164 F. 3d 650, 656 (D.C. Cir. 1999).

[40] In *Pearson v. Shalala*, 164 F. 3d at 655-66, the court rejected the FDA's contention that health claims unsupported by significant scientific agreement are inherently misleading but agreed that such claims may be potentially misleading.

[41] 447 U.S. at 566.

[42] *Id.*

than is necessary to serve that interest."[43] To survive a First Amendment challenge, the government has the burden of proving that its restriction on commercial speech satisfies the *Central Hudson* test.[44] Courts have found that the FDA has a substantial government interest in preventing consumers from being misled, and that prohibiting a potentially misleading health claim would directly advance the FDA's interest in preventing deception.[45]

If the FDA finds that a health claim for *trans* fats is potentially misleading when a product contains a disqualifying level of another nutrient, it should first determine whether a disclosure would be sufficient to prevent consumers from taking away a misleading impression from the health claim for *trans* fats before it prohibits such a claim. This is because the First Amendment embodies a "preference for disclosure over outright suppression" as the method of advancing the government's substantial interest.[46] Consequently, the government "disregards a far less restrictive means" of advancing its interest "where it chooses a policy of suppression over disclosure – at least where there is no showing disclosure would not suffice to cure misleadingness."[47]

Consumer research data could provide critical information as to whether some sort of disclosure of the amount of the disqualifying nutrient or other information on the food label would be sufficient to prevent consumers from taking away a misleading impression from a

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43 *Id*.

44 *Id*.

45 *See, e.g., Pearson v. Shalala,* 164 F. 3d at 655-56.

46 *Id.* at 658; *see also Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

47 *Pearson*, 164 F. 3d at 658.

health claim for *trans* fats.[48] For example, consumers may get useful, accurate health information if the marketers of one type of margarine were able to make truthful, non-misleading comparative claims that it is lower in *trans* fat than another margarine, even though both products contained a disqualifying level of total fat. We therefore support the FDA's efforts to obtain more information, including consumer research data, on the particular issue of the efficacy of disclosing the amount of disqualifying nutrients or similar disclosures in preventing deception.

V. CONCLUSION

The FTC staff supports the FDA's decision to require marketers to disclose *trans* fats in a separate line item on the Nutrition Facts panel, to withdraw the proposal to require a footnote statement, and to solicit consumer research before mandating that any footnote disclosure accompany the listing of *trans* fats. We understand that the FDA had decided to consider the exercise of prosecutorial discretion in allowing truthful, nonmisleading health claims and nutrient content claims about *trans* fats. We think that consumers and competition would benefit if the FDA were to go further and authorize truthful, nonmisleading nutrient content and health claims related to *trans* fats, which may be necessary given the FDA's history of declining to grant approval of such claims.

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[48] Disclosures are most effective if they are clear and prominent, focusing on specific elements such as clarity of language, relative type size and proximity to the claim being qualified, and an absence of contrary claims, inconsistent statements, or other distracting elements. *See* Deception Policy Statement, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 180 (1984); *Thompson Med. Co.* 104 F.T.C. 648, 842- 43 (1984); *Figgie Int'l, Inc.*, 107 F.T.C. 313, 401 (1986), *aff'd*, 817 F.2d 102 (4th Cir. 1987); *see also FTC v. Brown & Williamson Tobacco Corp.*, 778 F. 2d 35 (D.C. Cir. 1985); *Katherine Gibbs, Inc. v. F.T.C.*, 612 F. 2d 658, 666 (2d Cir. 1979).

Respectfully submitted,

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