

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

**In the Matter of Food Labeling:
Trans Fatty Acids in Nutrition Labeling,
Nutrient Content Claims and Health Claims; Reopening of the Comment Period**

Docket No. 94P-0036

**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**

December 16, 2002*

*** 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.**

94P-0036

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I. INTRODUCTION

The Food and Drug Administration (FDA) reopened the comment period for the agency's proposed rule on Trans Fatty Acids in Nutrition Labeling¹ (2002 FDA proposal) to request comments on a new proposal for listing *trans* fatty acids (*trans* fats) on the Nutrition Facts panel of food labels. Under the new proposal, the listing would be accompanied by a footnote informing consumers that "Intake of *trans* fat should be as low as possible." The FDA seeks comments on only this footnote and not on the proposed rule in general. The FDA's proposal also notes that, pending publication of a final rule, it would, as an exercise of its enforcement discretion, allow truthful *trans* fat declarations that are accompanied by the proposed footnote.

The FTC enforces the Federal Trade Commission Act,² which prohibits deceptive or unfair acts or practices in or affecting commerce.³ 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 food products⁴ and

¹ 67 Fed. Reg. 69,171 (Nov. 15, 2002).

² 15 U.S.C. § 45, *et seq.*

³ *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).

⁴ See *Conopco, Inc.*, C-3706 (Jan. 23, 1997) (consent); *Grey Advertising, Inc.*, C-3691 (Oct. 30, 1996) (consent); *The Dannon Co.*, C-3643 (Mar. 18, 1996) (consent); *Eggland's Best, Inc.*, C-3520 (Aug. 15, 1994)(consent); *Pompeian, Inc.*, C-3402 (Oct. 27, 1992)(consent); *Campbell Soup Co.*, D. 9223 (Aug. 18, 1992)(consent); *Bertolli U.S.A., Inc.*, C-3396 (Aug. 17, 1992)(consent).

dietary supplements.⁵ In implementing its law enforcement mandate, the FTC has developed considerable expertise in understanding the role of advertising and labeling in providing information to consumers.

The Commission's staff also has experience examining the effects of advertising regulation on market performance, including performance of the food market.⁶ 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 information about diet and health are likely to lead to better informed consumers, more competition on the health attributes of food, and the formulation of more healthful products.⁷

We believe that our experience has a bearing on the FDA's new proposal for the provision of *trans* fat content information on the Nutrition Facts panel. Accordingly, the staff

⁵ See *Home Shopping Network*, Civil Action No. 99-897-CIV-T-25C (Apr. 15, 1999) (Complaint for Civil Penalties, Injunction, and Other Relief and Proposed Consent Decree); *Amerfit, Inc.*, C-3747 (Jun. 16, 1997) (consent); *KCD Inc.*, C-3752 (June 16, 1997) (consent); *Schering Corp.*, D. 9232 (Sept. 16, 1991)(Initial Decision), (Oct. 30, 1994)(consent); *U.S. v. General Nutrition, Inc.*, No. 94-686 (W.D. Pa. April 28, 1994)(consent); *Miles, Inc.*, 114 F.T.C. 31 (1991)(consent); *General Nutrition, Inc.*, 111 F.T.C. 387 (1989)(consent); *FTC v. PharmTech Research, Inc.*, 576 F. Supp. 294 (D.D.C. 1983)(preliminary injunction), 103 F.T.C. 448 (1984)(consent).

⁶ Relevant prior comments regarding food labeling issues include: *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 (2000) and *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). Relevant FTC staff research includes: 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); and J. Calfee and J. Pappalardo, *How Should Health Claims for Foods be Regulated? An Economic Perspective* (1989).

⁷ *Id.*

of the FTC's Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning submit their views on the new proposal for the provision of *trans* fat content information on the Nutrition Facts panel.

II. BACKGROUND

In 1999, the FDA proposed a rule to allow *trans* fatty acid information on food labels.⁸ The proposal described several labeling options and explained the FDA's preference for the option of adding *trans* fats to the saturated fats entry on the Nutrition Facts panel on food labels.⁹ The FDA proposed this alternative because, even though *trans* fats technically are not saturated fats, the agency believed that *trans* fats and saturated fats both have adverse effects on serum cholesterol and heart disease risks. 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.¹⁰

FTC staff filed a comment on the 1999 proposal in April 2000 (2000 FTC Staff Comment). In the comment, the staff:

- supported efforts to allow truthful *trans* fat information on food labels;
- recommended that *trans* fats not be included in the saturated fat category because such a grouping was technically inaccurate and potentially confusing;

⁸ 64 Fed. Reg. 62,746 (Nov. 17, 1999) at 62,753-754.

⁹ Products containing *trans* fatty acids would have included an asterisk that would refer to a footnote declaring "Contains _____ g *trans* fat."

¹⁰ The 1999 proposal included the following suggested changes: (1) mandatory *trans* fatty acid labeling on the Nutrition Facts Panel of foods and dietary supplements that contained 0.5 or more grams of *trans* fat per serving; (2) stricter saturated fat thresholds for nutrient content claims and health claims, which would be based on the **sum** of saturated fat and *trans* fat content; and (3) definition of a "*trans* fat free" descriptor. Additional descriptors and health claims about *trans* fat and Coronary Heart Disease [CHD] would have still been prohibited.

- supported the definition of “Trans Fat Free” claims;
- recommended consideration of a “Reduced Trans Fat” claim; and
- recommended that the FDA consider allowing health claims that would inform consumers of the potential relationship between *trans* fatty acids and heart disease risks, based on staff’s conclusion that such claims were likely to promote consumer knowledge of *trans* fat risks, lead to more healthful food choices, and promote the development of more healthful products.

III. THE NEW PROPOSAL

The FDA now proposes to list *trans* fats separately from saturated fats. We support this proposal for the reasons described in the 2000 FTC Staff Comment. We have reservations, however, about the unique treatment that *trans* fatty acids will receive under the proposal. We therefore recommend that the FDA conduct consumer research to determine if the current proposed footnote will inadvertently confuse consumers about the relative risks of saturated fat, cholesterol, and *trans* fat. Given the significant effect of *trans* fats on heart disease risks, we support the FDA’s proposal to allow *trans* fat information in labeling prior to issuance of a final rule. Moreover, in light of mounting scientific conclusions emphasizing the effect of various fats on heart disease risks, we reiterate our 2000 recommendation that the FDA consider allowing truthful messages about the effects of *trans* fats on health. Information about the effects of various fats on heart disease can help consumers make more healthful product choices and promote competition on the heart-health dimensions of foods.

Under the current proposal, *trans* fats would have a unique position among fats on food labels. Unlike the entries for total fat, saturated fat, and cholesterol, a Percentage Daily Value (% DV) will not be listed for *trans* fats. Lack of a % DV alone would not necessarily be a

concern because consumers may still find the content information useful even without a recommended daily intake. For example, % DV is not listed for polyunsaturated fats or other monounsaturated fats, and the % DV entry for polyunsaturated and other monounsaturated fats is currently left blank. In contrast, the proposed % DV entry for *trans* fats would not merely be blank but would include a symbol leading to the following footnote: “Intake of *trans* fat should be as low as possible.”

The FDA derives the suggested footnote from the conclusions of a recent report by the Institute of Medicine of the National Academies of Science (NAS/IOM), “Dietary Reference Intakes.”¹¹ According to the FDA, this report found “‘a positive linear trend’ between *trans* fatty acid intake and total and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of coronary heart disease.”¹² The FDA proposal further notes that:

The report summarized that the scientific evidence would suggest a tolerable upper intake level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended “that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.”¹³

Accordingly, the FDA’s proposal suggests that *trans* fats should be treated differently from saturated fats on the nutrition label largely because the IOM/NAS report, while recognizing potential risks from *trans* fats, “did not provide a dietary reference intake (DRI) value for *trans*

¹¹ Institute of Medicine, National Academies of Science (IOM/NAS), *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids*, Chapter 8, National Academy Press, Washington, DC, (<http://www.nap.edu>), 2002 (IOM/NAS report) at 335-432.

¹² 67 Fed. Reg. at 69,171.

¹³ *Id.*

fat or information that the agency believes is sufficient to support its establishing a daily reference value (DRV) to assist the agency in providing other information on the label, such as a % DV for *trans* fat.”¹⁴

IV. SCIENTIFIC EVIDENCE LINKING *TRANS* FATS AND HEART DISEASE

As discussed in the 2000 FTC staff comment, scientific opinion about the health effects of *trans* fatty acids has shifted considerably during the past two decades. Since the FDA’s 1999 proposal was published, researchers and research organizations have continued to examine the effects of *trans* fats. A review of the literature in 2002 concludes:

Compelling evidence from metabolic studies, epidemiologic investigations, and clinical trials in the past several decades converges to indicate that at least 3 dietary strategies are effective in preventing CHD [coronary heart disease]: substitute unsaturated fats (especially polyunsaturated fat) for saturated and *trans*-fats; increase consumption of omega-3 fatty acids from fish oil or plant sources; and consume a diet high in fruits, vegetables, nuts, and whole grains and low in refined grains. A combination of these approaches can confer greater benefits than a single approach. However, simply lowering the percentage of energy from total fat in the diet is unlikely to improve lipid profiles or CHD incidence.¹⁵

In 2000, the American Heart Association issued a revised set of dietary guidelines.

Among other things, the guidelines conclude that:

It has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol . . . The AHA recommends limiting the intake of *trans*-fatty acids, the major contributor of which is hydrogenated fat. Future inclusion of *trans*-fatty acid content on food labels, as well as the increasing availability of *trans*-fatty acid-free products, will aid consumers in reducing current intake (average

¹⁴ *Id.* Because of a lack of a daily reference intake, the agency has not established a % DV for *trans* fats.

¹⁵ Frank B. Hu & Walter C. Willett, *Optimal Diets for Prevention of Coronary Heart Disease*, 288 JAMA, 20 (Nov. 27, 2002) at 2575.

2% to 3% of total energy) to achieve a total intake of cholesterol-raising fatty acids that does not exceed 10% of energy.¹⁶

As noted above, the 2002 FDA proposal relies heavily upon the IOM/NAS recommendation “that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.” Notably, however, the same report reaches a similar conclusion about saturated fatty acids and cholesterol:

There is a body of evidence suggesting that saturated and trans fatty acids and cholesterol increase blood total and LDL cholesterol concentrations, and therefore the risk of coronary heart disease . . . Because the intake of each of these three nutrients and risk of coronary heart disease is a positive linear trend, even very low intakes of each may increase risk.¹⁷

More specifically, the IOM/NAS report notes a similar problem setting Dietary

Reference Intake (DRI) values for saturated fats:

There is a positive linear trend between total saturated fatty acid intake and total and LDL cholesterol concentration and increased risk of coronary heart disease. A UL is not set for saturated fatty acids because any incremental increase in saturated fatty acid intake increases CHD risk. It is neither possible nor advisable to achieve 0 percent of energy from saturated fatty acids in typical whole-food diets.¹⁸

According to another section of the report, similar problems were encountered for other fats:

There were insufficient data to use the model of risk assessment to set a UL for total fat, monounsaturated fatty acids, n-6 and n-3 polyunsaturated fatty acids, protein, or amino acids. While increased serum low density lipoprotein (LDL) cholesterol concentrations, and therefore risk of coronary heart disease, may increase at high

¹⁶AHA Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association, 102 *Circulation* (2000), <http://circ.ahajournals.org/cgi/content/full/102/18/2284> at 10, (citations omitted).

¹⁷ Institute of Medicine, National Academies of Science (IOM/NAS), *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids*, National Academy Press, Prepublication Copy, Washington, DC, (<http://www.nap.edu>), 2002 at 11- 46.

¹⁸ *Id.* at 8-50.

intakes of saturated fatty acids, trans fatty acids or cholesterol, a UL is not set for these fats because the level at which risk begins to increase is very low and cannot be achieved by usual diets and still have adequate intakes of all other required nutrients. *It is thus recommended that saturated fatty acid, trans fatty acid, and cholesterol consumption be as low as possible while consuming a nutritionally adequate diet.*¹⁹

V. ANALYSIS OF FDA'S PROPOSED DISCLOSURE AND RECOMMENDATIONS

The FTC staff's review of recent recommendations leads us to three general conclusions, which provide a basis for our analysis of the FDA's proposed disclosure. First, scientific understanding regarding the effects of various fats on heart disease risks continues to evolve. Second, although the base of knowledge is changing, there is currently general agreement that: (i) consumers would benefit from reductions in *trans* fat, saturated fat, and dietary cholesterol consumption; (ii) substituting polyunsaturated or *cis*-monounsaturated fats for cholesterol-raising fats is likely to be beneficial; and (iii) holding calories constant, any heart-health benefit from reductions in total fat consumption will depend on the type of fat substitution made. Third, recommendations about saturated fats tend to be qualitatively similar to recommendations about *trans* fats, even though there are some differences between the two.

In light of FTC staff research on the role of nutrition and health information in markets, we believe that the recommendations from the National Academies of Science, the American Heart Association, and others suggest that consumers would benefit from knowing more about the role of *trans* fats and other fats in the diet. We therefore support the FDA's efforts to allow more truthful information about fats in food labeling.

We are concerned, however, that the unique treatment proposed for *trans* fats on the Nutrition Facts panel may suggest to consumers that there is a significant qualitative difference

¹⁹ *Id.* at S-4 (emphasis added).

between saturated fats and *trans* fats, and such a conclusion appears to be inconsistent with current dietary advice. Moreover, we note that the FDA's concern about the lack of a DRI value estimate for *trans* fats in the IOM/NAS report seems an insufficient basis on which to conclude that *trans* and saturated fats should be treated differently, given that the report indicated similar problems for saturated fat.

Without consumer testing, we do not know the extent to which the proposed footnote, in the context of the current label, might lead consumers to conclude that *trans* and saturated fats have significantly different effects on health. The footnote might encourage consumers to focus more on *trans* fats than on saturated fats, or vice versa. Although there is some evidence to suggest that *trans* fats may be somewhat more harmful than saturated fats, because *trans* fats represent a relatively small proportion of current fat consumption, a more prominent focus on *trans* fats, at the possible expense of attention to saturated fats, might inadvertently lead consumers to make food choices based on an incorrect understanding of the health consequences.

We recommend that the FDA conduct research on the proposed footnote, similar to some of the research undertaken by the FDA to develop the Nutrition Facts panel. For example, the FDA may wish to conduct a series of controlled copy tests comparing the effects of alternative formats and disclosures on consumer knowledge. The proposed format could be tested against other alternatives. One alternative would be to disclose *trans* fats, saturated fats, and dietary cholesterol in as close to identical formats as feasible since such treatment appears consistent with the overall recommendations in the IOM/NAS report. For example, the FDA could copy test a label that applies the proposed footnote not only to *trans* fats (with or without

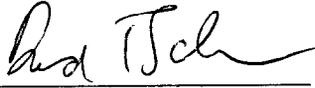
a % DV) but also to saturated fats and dietary cholesterol (with or without % DVs) to determine which format is most informative for consumers and runs the least risk of inadvertently confusing them about the relative risks of saturated fat, cholesterol, and *trans* fat.

Research on *trans* fat and saturated fat disclosures would be particularly helpful if health messages about the effects of various fats on heart disease risks are also studied. As discussed in the 2000 FTC Staff Comment, we believe it important to allow companies to fashion health claims to explain the significance of different types of fats to consumers. For example, producers of foods with relatively healthful fat profiles may wish to convey the findings of recent reports in food labeling. Truthful information on health effects can help consumers understand why fat choices matter, and their improved understanding can lead to more healthful diets, competition based on heart-health attributes, and innovation of more healthful foods. *Trans* fat content listings alone may not be meaningful to consumers who are not aware of the science that underlies the concern.

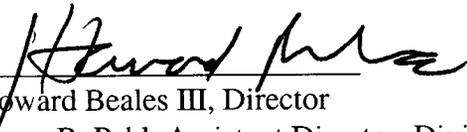
VI. CONCLUSION

FTC staff believes that the FDA's proposal to list *trans* fats on the Nutrition Facts panel separate from the listing for saturated fats will help to achieve the FDA's goal of informing consumers about *trans* fatty acids. We also recommend that the FDA engage in consumer research on the proposed footnote, such as conducting a series of controlled copy tests comparing the effects of alternative formats and disclosures on consumer knowledge. In addition, in evaluating the proposed footnote, it would be valuable to determine whether health messages about the effects of various fats on heart disease risks would improve consumer understanding.

Respectfully submitted,



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