UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BEFORE TH E
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 S taff 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.

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 products(4) and 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 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

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 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 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 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 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 that. pora

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Endnotes:

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).

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.

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.

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.

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.

16. AHA 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.

19. Id. at S-4 (emphasis added).