

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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. 2003N-0076

COMMENTS OF
THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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April 15, 2004

03N-0076

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0076
Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider
Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

On October 9, 2003, the Center for Science in the Public Interest (CSPI)¹ submitted extensive comments on the FDA's advanced notice of proposed rule making regarding trans fat labeling pursuant to the agency's *Federal Register* notice on July 11, 2003 (see attached).² Those comments addressed many of the questions raised by the FDA in the *Federal Register* notice on March 1, 2004,³ including:

- criteria for trans fat claims;
- disqualifying levels for trans fat for saturated fat, cholesterol, lean, health, and other claims;
- the need for a combined DV for saturated plus trans fat; and
- the lack of a need for a trans fat footnote on the label if the FDA establishes a combined DV for saturated plus trans fat.

CSPI supports the IOM's recommendation for a combined DV for saturated plus trans fat.

The Institute of Medicine's report, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*, reinforces and provides further justification for the labeling approach advocated by CSPI in our October 9, 2003, comments. As outlined in those comments, we continue to believe that a combined DV for saturated plus trans fat would be most useful to consumers and would provide an appropriate incentive for the food industry to reduce both saturated and trans fat in its products. That approach is recommended in the IOM report, which stated, "the committee recommends that SFA and TFA amounts be listed on separate lines, but that one % DV be included in the Nutrition Facts box for these two nutrients together."⁴

¹ CSPI, a nonprofit consumer organization supported by approximately 800,000 members and subscribers to its *Nutrition Action Healthletter*, has worked since 1971 to improve national health policies and conduct education programs in the areas of nutrition and food safety.

² 68 *Fed. Reg.* 41507 (2003).

³ 69 *Fed. Reg.* 9559-9560 (2004).

⁴ Institute of Medicine, National Academies. *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Washington, D.C.: National Academies Press, 2003.

The FDA should develop a new DV for saturated plus trans fat.

CSPI strongly supports the recommendation in the IOM report to use “food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes (of trans and saturated fat) consistent with nutritionally adequate and health-promoting diets.”⁴ From what we could surmise from the last meeting of the Dietary Guidelines Advisory Committee, it sounded as if that approach is being pursued to allow the committee to make a quantitative dietary recommendation for trans fat intake. We suggest that HHS instead use that approach to develop a recommended intake level/DV for saturated plus trans fat combined.

The FDA either should 1) use the current DV for saturated fat as a combined DV for saturated plus trans fat as described in our October 9, 2003, comments and in the FDA’s 1999 proposed regulations for trans fat labeling⁵ or 2) use menu modeling, food composition data, and dietary survey data to develop a new recommended intake level for saturated fat in combination with trans fat. A menu modeling approach should determine the minimal intake of trans and saturated fat possible on health-promoting, nutritionally adequate diets and should take into consideration the following:

- Meat and dairy choices should be low in fat.
- Trans fats from partially hydrogenated oils used in processed and restaurant foods are unnecessary in the diet since they can (and should) be replaced with oils that are very low in trans fat.
- Since most Americans are sedentary, the DV should be based on the calorie needs of sedentary individuals.
- The new DV should protect more vulnerable populations (i.e., the DV should be based on the calorie and dietary needs of postmenopausal women rather than men and older adults rather than younger adults because postmenopausal women and older adults have lower calorie needs and are at greater risk for heart disease).

We urge the FDA to consider the recommendations above and those in our October 9, 2003, comments regarding trans-fat labeling. The FDA should move quickly to propose regulations to limit the amount of trans fat in foods that make nutrient content or health claims that currently have limits on saturated fat and should put the gram amounts of trans fat into the context of a day’s diet by developing a combined DV for saturated plus trans fat.

Respectfully submitted,



Margo G. Wootan, D.Sc.
Director, Nutrition Policy

⁵ 64 *Fed. Reg.* 62746 (November 17, 1999).

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October 9, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03N-0076
Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider
Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

As the petitioner in this matter, the Center for Science in the Public Interest (CSPI)¹ submits the following comments on the FDA's advanced notice of proposed rule making regarding *trans* fat labeling pursuant to the agency's *Federal Register* notice on July 11, 2003.²

I. Introduction

CSPI congratulates the Food and Drug Administration (FDA) for finalizing the regulations for quantitative disclosure of *trans* fat on food labels.³ *Trans* fat labeling will be an important tool to help protect the public's health and reduce heart disease in the United States.

However, CSPI is disappointed that the final rule did not include several important components of *trans* fat labeling that were included in the proposed rule. The failure of the FDA to put *trans* fat into the context of a daily diet, as required by the Nutrition Labeling and Education Act,⁴ and the failure to address claims is inexcusable, given the strength of the FDA's rationale and proposed labeling rules in the proposed *trans* fat labeling regulations in 1999, and the fact that the FDA has had ten years to address CSPI's petition on *trans* fat labeling. Retreating to the

¹ CSPI, a nonprofit consumer organization supported by approximately 800,000 members and subscribers to its *Nutrition Action Healthletter*, has worked since 1971 to improve national health policies and conduct education programs in the areas of nutrition and food safety.

² 68 Fed. Reg. 41507 (2003).

³ 68 Fed. Reg. 41434 (2003).

⁴ Section 2(b)(1)(A) of the Nutritional Labeling and Education Act of 1990 (NLEA), 21 U.S.C. section 343 note. Congress presumably expected this requirement to be met both for the original nutrients specified in the NLEA, as well as nutrients later added to the label.

stage of an advanced notice of proposed rule making sets several important aspects of the process back ten years.

Since the early 1990s, CSPI has been concerned about the health effects of *trans* fat. As outlined in our 1994 petition, a number of studies published in the early 1990s demonstrated that *trans* fat increases LDL cholesterol levels and the risk of heart disease. Studies published after our petition was filed provide further evidence for the need for *trans*-fat labeling.

In addition, the National Academies' Institute of Medicine report, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids* (the IOM macronutrient report), provided yet another confirmation that *trans* fat increases LDL cholesterol levels and the risk of coronary heart disease. Further, it found that the effect of *trans* fat on the LDL:HDL ratio is greater than for saturated fat. It also concluded that there is no known requirement for *trans* fat for specific physiologic functions. We will not summarize in these comments the science base regarding the health effects of *trans* fat, because the FDA has described it well in the proposed rule and final rule, and CSPI has summarized it in our petition and supplemental comments, letters, and meetings with the agency.

II. Health or nutrient content claims that limit saturated fat also should limit *trans* fat, similar to the limits in the FDA's *trans* fat labeling proposed rule.

A. In the absence of a Daily Value for *trans* fat, the FDA should use the same disqualifying and disclosure levels for *trans* and saturated fat combined as for saturated fat given that *trans* fat raises LDL cholesterol at least as much as saturated fat. Current evidence suggests at least gram-for-gram equivalency for saturated and *trans* fat.

In its review of the science for the *trans* fat labeling proposed rule, the FDA wrote that "studies do not conclusively show whether, on a gram-for-gram basis, the rise in LDL cholesterol from *trans* fatty acids is as great as the rise that results from saturated fatty acids." We urge the FDA to re-examine several of the studies cited as the basis for this conclusion. **All but one of the appropriately controlled studies show that, gram-for-gram, *trans* fat raises LDL cholesterol as much as saturated fat.**

As the FDA noted, several studies, such as Nestel, et al⁵ and Zock and Katan,⁶ show that, gram-for-gram, *trans* fat has a similar effect on LDL cholesterol levels as saturated fat. Those studies were designed to allow for a direct comparison of *trans* to saturated fat by making sure that the *trans* fat diets and the saturated fat diets had similar amounts of saturated plus *trans* fat, as well as similar amounts of cis-unsaturated fats.

⁵ Nestel P, Noakes M, Belling B, et al. J Lipid Research 1992;33:1029-1036.

⁶ Zock PL, Katan MB. J Lipid Research 1992;33:399-410.

About a half dozen studies were cited by the FDA as evidence that *trans* fat raises LDL cholesterol levels less than does saturated fat, on a gram-for-gram basis. However, many of those studies do not allow for a direct comparison of the gram-for-gram effects of *trans* and saturated fat. Several were designed to compare the effects of different fats (oil-versus-margarine or oil-versus-margarine-versus-shortening-versus-butter) rather than the effects of categories of fatty acids.^{7,8} While the results of those studies answer interesting questions, the levels of saturated plus *trans* fat, polyunsaturated fat, and/or dietary cholesterol vary between the diets. Too many variables differ between the test diets to allow for gram-for-gram comparisons between saturated and *trans* fat.

The FDA also cited the 1994 Judd study as showing that *trans* fat, on a gram-for-gram basis, does not raise LDL cholesterol as much as does saturated fat.⁹ The authors of that study did write that *trans* fat raises LDL cholesterol to a slightly lesser degree than does saturated fat. However, the results of the study do not support that conclusion. The study showed no statistically significant difference between LDL cholesterol levels for the diets providing 6% of energy as either saturated or *trans* fat.

Thus, of the studies cited by the FDA as the basis for its conclusion that *trans* fat is a less potent cholesterol raising fat than saturated fat, only the Mensink and Katan study supports the FDA's conclusion.¹⁰ Furthermore, a study published after the publication of the *trans* fat proposed rule by Roos et al shows that, gram-for-gram, *trans* fat and saturated fat have the same effect on LDL cholesterol levels.¹¹

More research needs to be conducted to compare the gram-for-gram ability of *trans* fat to raise LDL cholesterol relative to saturated fat. However, given the current evidence that suggests gram-for-gram equivalency of *trans* and saturated fat on LDL cholesterol levels and the possibility that *trans* fat lowers HDL cholesterol¹² and raises LP(a) (which both need more

⁷ Lichtenstein AH, Ausman LM, Carrasco W, et al. *Arteriosclerosis and Thrombosis* 1993;13:154-161.

⁸ Lichtenstein AH, Ausman LM, Jalbert SM, et al. *NEJM* 1999;340:1993-1940.

⁹ Judd JT, Clevidence BA, Muesing RA, et al. *Am J Clin Nutr* 1994;59:861-868.

¹⁰ Mensink RP, Katan MB. *NEJM* 1990;323:439-445.

¹¹ Roos NM, Bots ML, Katan MB. *Arteriosclerosis and Thrombosis* 2001;21:1233-1237.

¹² The FDA notes [68 Fed. Reg. 41482 (2003)] that the Dietary Guidelines 2000 Advisory Report, the National Cholesterol Education Program 2001, Institute of Medicine/National Academy of Sciences, and American Heart Association all state that substituting *trans* fats for saturated fats lowers HDL cholesterol levels.

study), it seems prudent to treat *trans* fat as equivalent to saturated fat, on a gram-for-gram basis, for the purpose of food labeling. Furthermore, various saturated fatty acids have different effects on LDL cholesterol yet the food label treats them as identical. The agency should feel especially comfortable using an approximate equivalency for *trans* and saturated fat given that groups as diverse as CSPI, the American Dietetic Association,¹³ and the Grocery Manufacturers of America¹⁴ have expressed a similar view.

B. Limits on *trans* fat for cholesterol, saturated fat, health and other claims are a more consumer-friendly and less deceptive approach than requiring disclosure statements.

Supermarkets often contain 35,000 or more items, and food packages contain considerable amounts of information on all surfaces. While shopping, the large volume of products and information consumers need to sift through to identify healthy choices makes it more likely that they will notice and read a prominent nutrient or health claim than a smaller disclosure statement.

A prominent claim coupled with a less prominent disclosure statement would be misleading on a food containing significant amounts of *trans* fat. For example, a “no cholesterol” claim on a product is more than a factual statement that a product lacks this particular sterol. It is a signal to consumers that the product is heart healthy. If such a product contained a significant amount of heart-unhealthy fat (*trans* or saturated), the label would be misleading. A “no cholesterol” claim on a stick margarine with 2 grams of saturated fat and 2 grams of *trans* fat would contain 20% of a day’s worth of heart-unhealthy fat in just one tablespoon. A disclosure stating that the margarine contains 2 grams of *trans* fat could easily go unnoticed by a busy shopper, and would be unlikely to prevent such a deception.

C. The FDA should not assume that its proposed label changes will spur companies to replace *trans* fat with equal or greater amounts of saturated fat.

We disagree with the comments by some food industry groups that functional considerations will require them to replace *trans* fat with equal or greater amounts of saturated fat. A number of alternatives to hydrogenated shortening are available on the market. While some of those may still be more expensive than the products that companies are currently using, the price will come down as more companies switch to these more healthful alternatives.

There are a number of low or no *trans* alternatives available for commercial deep fat frying, such as peanut oil (used by Boardwalk Fries restaurants), Cargill’s Clear Valley canola and sunflower

¹³ ADA comment, April 25, 2000, page 1. “Clinical studies demonstrate that partially hydrogenated unsaturated fat (or, *trans* fat) also raises blood cholesterol and presents relative risks for coronary heart disease (CHD) that are similar to those for saturated fat.”

¹⁴ GMA comment, April 17, 2000, page 3. “Because of the evidence that *trans* fat is roughly comparable to saturated fat in its effect on serum LDL cholesterol, ...”

oils, NuSun Sunflower Oil, and Wesson All-Purpose Canola Oil. Frito-Lay recently removed *trans* fat from its Cheetos, Doritos and Tostitos, while at the same time reducing the saturated fat content of those chips.

In addition, lower *trans* semi-solid shortenings are available for margarine, cookies, cakes, frostings and other commercial applications from Cargill and Bunge Foods. The combined total of saturated plus *trans* fat in those shortenings is approximately 35% compared to 65% for a typical commercial shortening. Also, a number of margarine manufactures have removed *trans* fat without increasing saturates. For example, Promise stick margarine had 2 grams of saturated and 2 grams of *trans* fat before being reformulated, and now has 2.5 grams of saturated fat and virtually no *trans* fat.

D. The FDA should continue to base the *trans* fat limits for claims on science and on the amounts of *trans* fat that would result in a misleading claim, rather than on amounts that would allow an industry to continue to use a claim on a certain product.

Any consideration of providing incentives for reformulation should have as a goal reducing the total amount of saturated and *trans* fat combined. For example, the amount of *trans* fat allowed in foods with a “no cholesterol” claim should not be increased just to allow more margarines to use “no cholesterol” claims. If “no cholesterol” claims were allowed on foods with 2 grams of saturated fat and 2 grams of *trans* (as proposed by the Grocery Manufacturers of America, the National Association of Margarine Manufacturers and others), a food could contain 20% of a day’s worth of heart-unhealthy fat and still qualify for a claim (“no cholesterol”) that implies that it is heart healthy.

While claims can provide incentives for companies to reformulate products, criteria should not be weakened to the point that claims could be made on foods that add significant amounts of saturated and/or *trans* fat to a person’s diet.

E. CSPI strongly supports *trans* fat limits for claims as proposed by the FDA in the *trans* fat labeling proposed rule.

1. **“Saturated fat free” claims:** CSPI continues to support the FDA’s original proposal for a limit of 0.5 grams of saturated fat plus 0.5 grams of *trans* fat for foods that make “saturated fat free” claims until the current detection limits for fatty acid analysis improve. Ideally, foods labeled “saturated fat free” should have less than 0.5 grams of saturated and *trans* fat combined.

2. **“Low saturated fat” claims:** CSPI supports the FDA’s proposal that foods that make “low saturated fat” claims contain 1 gram or less of saturated fat and less than 0.5 grams of *trans* fat and no more than 15% of calories from saturated and *trans* fat combined.

3. **“Reduced saturated fat” claims:** CSPI supports the FDA’s original proposal that foods that make “reduced saturated fat” claims contain at least 25% less saturated fat and at least 25% less saturated and *trans* fat combined per reference amount customarily consumed than an appropriate reference food.

4. **“*Trans* fat free” claims.**

a. **We continue to support the FDA’s proposed definition of a “*trans* fat free” claim.** Foods bearing a “*trans* fat free” claim should contain less than 0.5 grams of *trans* fat and less than 0.5 grams of saturated fat per reference amount customarily consumed and per labeled serving. The claim would help consumers to easily identify foods that would help them to reduce their risk of CHD.

The FDA should not increase the amount of saturated fat allowed in foods that make a “*trans* fat free” claim, as some comments on the *trans* proposed rule suggested.¹⁵ Some health experts proposed such an increase to allow liquid vegetable oil to carry “*trans* fat free” claims. While the presence of a “*trans* fat free” claim seems reasonable on a bottle of vegetable oil, a 2-gram limit on saturated fat also would allow “*trans* free” claims on some cookies, frostings, crackers, and other foods that are not low in saturated fat.

Alternatively, the FDA could provide a limited and specific exemption for unhydrogenated, liquid vegetable oils with no more than 2 grams of saturated fat per serving, and allow them to use “*trans* fat free” claims. “*Trans* fat free” claims would not be misleading on heart-healthy vegetable oils. The saturated fat in most oils would probably be neutralized by the unsaturated fat.

b. **The limit on saturated fat for foods that make “*trans* fat free” claims is as important as the limit on *trans* fat in foods that make “saturated fat free” claims.** The FDA stated that consumers expect foods with the label claim “saturated fat free” to be “free” of components that significantly raise serum cholesterol.¹⁶ The same logic applies to “*trans* fat free” claims. If a consumer chooses a product that is labeled “*trans* fat free,” that product should be free of saturated fat, which like *trans* fat, raises blood cholesterol. Such a strict limit on the saturated-fat content of foods with “*trans* fat free” claims would reduce the number of products that are eligible to use them, but would provide greater protection to consumers, reduce the possibility of consumer confusion, and

¹⁵ A number of comments supported that “*trans* fat free” claims be allowed on foods with 2 grams of saturated fat per serving or 20% saturated fat to allow claims on vegetable oils.

¹⁶ 58 Fed. Reg. 44020, 44027 (1993).

provide an incentive to manufacturers to reformulate their products to reduce the amount of both *trans* and saturated fat.

c. “*Trans* fat free” and “no hydrogenated oil” claims already are being used on products including margarines, liquid vegetable oils, flax oil supplements, cereal bars, chips, cookies, and breads. As consumer interest in and knowledge about *trans* fat increases, the number of claims likely will increase. Currently, the amount of saturated fat in foods that use “*trans* fat free” and “no hydrogenated vegetable oil” claims varies. Some products meet the proposed criterion (they have less than 0.5 grams of saturated fat) but others contain more saturated fat. Manufacturers need a definition for a claim that already is used in the market place.

d. Explanatory footnotes for ingredients that contain *trans* fat. CSPI supports the FDA’s proposal not to allow a food that bears a “*trans* fat free” claim to contain any ingredient that is generally understood by consumers to contain *trans* fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk (or other symbol) that refers to a statement below the list of ingredients that states, “adds a trivial amount of *trans* fat” or other synonymous phrase. CSPI has gotten numerous questions from consumers who are confused about a product that claims to be “free of *trans* fat” or that we have recommended in our newsletter as being low in *trans* fat that lists hydrogenated oil, margarine, or shortening in the ingredient list. An explanatory footnote would help reduce consumer confusion.

e. Hydrogenated oil claims. CSPI strongly supports the FDA’s proposal to consider statements such as “no hydrogenated oils” or “hydrogenated fat free” to be implied claims that a product is free of *trans* fat and that such statements only would be allowed on foods that meet the criteria for a “*trans* fat free” claim.

f. CSPI supports the FDA’s proposal to require disclosure statements about total fat and cholesterol in immediate proximity to “*trans* fat free” claims.

5. CSPI supports the FDA’s preliminary decision not to allow the use of “low *trans* fat” or “reduced *trans* fat” claims on labels. Such claims have the potential to be misleading since Americans consume more saturated fat than *trans* fat and the amounts of *trans* fat in many packaged foods are low to moderate (approximately 1-4 grams per serving).¹⁷ (The amounts in many restaurant foods are higher, since portion sizes are

¹⁷ Wootan MG, Liebman B, Rosofsky W. *Trans: The Phantom Fat*. Nutrition Action Healthletter 1996;23(7):1, 10-13.

larger.¹⁸) The problem with *trans* fat is that it is in many commonly eaten foods, so that the amounts add up to levels that have adverse health effects. As a result, claims that a product contains a 25% or even a 50% reduction in *trans*-fat content might lead consumers to believe that the product has been greatly improved when the improvement is actually minor. Consider a cracker that typically contains 2 grams of *trans* fat and 2 grams of saturated fat per serving. If a company wanted to market a version of that cracker with “25% less *trans* fat,” the reduced product would have only 0.5 fewer grams of *trans* fat, a very small reduction, and it would have only 12.5% less heart-unhealthy fat (*trans* plus saturated) than the reference product (assuming that the fat was not replaced by saturated fat).

6. Cholesterol claims: We strongly support the FDA’s 1999 proposal that “cholesterol free,” “low cholesterol,” or “reduced cholesterol” claims be allowed only on foods that contain 2 grams or less of saturated and *trans* fat combined per reference amount; meal products or main dish products should contain 2 grams or less per labeled serving. As mentioned above, the FDA has written that consumers expect foods that have the label claim “saturated fat free” to be “free” of all components that significantly raise serum cholesterol.¹⁹ We believe the same logic applies to cholesterol claims.

Consumers expect that foods with “no, low, or reduced cholesterol” claims will be low in heart-unhealthy fats (*trans* and saturated). If such a product contained a significant amount of heart-unhealthy fat (*trans* or saturated), the label would be misleading. The proposed criteria would prevent the use of “no cholesterol” claims on most stick margarine and many full-fat tub margarines. However, the claims would be allowed on most lower-fat tub margarines, which contain less saturated fat and fewer calories.

7. Lean claims: CSPI supports the FDA’s 1999 proposal to include *trans* fat in the current limits on the amount of saturated fat for both “lean” and “extra lean” claims.

8. Disqualifying and disclosure levels: We support the FDA’s 1999 proposal that the disqualifying nutrient levels for health claims and the general disclosure requirements for nutrient content claims be changed from “4 grams of saturated fat” to “4 grams of saturated fat and *trans* fat combined.”

9. Vegetable oil claims: Limits on the amount of *trans* fat in foods that use “made with vegetable oil” claims would be addressed by the 1999 proposed change to the definition of “low saturated fat” claims, which we support (see above).

¹⁸ Liebman B, Wootan MG. *Trans* Fat. Nutrition Action Healthletter 1999;26(5):9-11.

¹⁹ 58 Fed. Reg. 44020, 44027 (1993).

III. The FDA is required by law to put *trans* fat into context of a day's diet on food labels.

A. The best way to put *trans* fat into context of a day's diet is to label *trans* fat using a similar format to that proposed by Canada.

We continue to urge the FDA to require a *trans* fat labeling format similar to that proposed by Canada (with the grams of saturated and *trans* fat labeled on separate lines but clustered together without an intervening rule and with a combined percent Daily Value). The key advantage of the Canadian format is that it provides consumers with some context about how the combined amount of saturated and *trans* fat fit into a day's diet. Saturated and *trans* fat should be considered – and lowered – together to reduce the risk of heart disease. It would be counterproductive if the labeling format led consumers to increase their saturated fat intake while they reduced their consumption of *trans* fat, especially given that Americans consume approximately five times more saturated than *trans* fat. Combined labeling also should provide a greater incentive for food manufacturers to reduce the total amount of saturated plus *trans* fat if they reformulate products. Finally, the Canadian format would make it easier to compare products. A consumer would not have to add up two separate lines (saturated and *trans* fat) on several different products to compare the total amounts of fats that promote heart disease.

The FDA should use the current DV for saturated fat as the combined DV for saturated and *trans* fat. While the FDA laid out a strong rationale for such an approach in the proposed rule for *trans* fat labeling, that approach is bolstered by the IOM macronutrient report. Since the IOM concluded that the upper limit for *trans* fat *should be zero*,²⁰ the combined total of zero grams of *trans* fat plus 20 grams of saturated fat adds up to 20 grams of saturated and *trans* fat combined.

The American Heart Association reached a similar conclusion in 2000, when it issued a revised set of dietary guidelines that recommended that consumers try to limit their total intake of *trans* and other cholesterol-raising fatty acids to 10 percent of energy.²¹

Health Canada explained that “incorporating *trans* fat with saturated fat under the same DV is justifiable in view of the fact that the two dietary components have the same effect on LDL cholesterol, a risk factor for CHD [coronary heart disease]. The DV for the sum of saturated and *trans* fat is 20 g based on approximately 10% of energy for a 2000 calorie diet. This DV is

²⁰ The IOM concluded that the data suggest that the Upper Limit for *trans* fat should be zero. However, because eliminating all *trans* fat from the diet would be difficult and could have unintended, negative effects on diet quality, no Upper Limit was set. The IOM instead recommended that *trans* fat intake be as low as possible.

²¹ American Heart Association (AHA). AHA Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals from the Nutrition Committee of the American Heart Association. *Circulation* 2000, vol. 102, pp. 2296-2311.

justifiable since recommendations are to decrease the dietary intake of saturated and *trans* fats as any increase in intake increases CHD risk.”²²

We agree with the staff of the Federal Trade Commission that “the FDA’s concern about the lack of a DRI value estimate for *trans* fats in the IOM/NAS reports 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.”²³ The FDA should follow the rationale of Health Canada when it established a combined DV of 20 grams for saturated and *trans* fats. Health Canada quoted the findings of the IOM/NAS report on the similar effect of *trans* and saturated fats on CHD and noted that the IOM/NAS did not establish a recommended intake level for either *trans* or saturated fats.²⁴

Health Canada’s rationale is similar to that of the FDA’s in its 1999 proposed *trans* fat labeling regulations. The FDA explained that it had tentatively concluded that it would require *trans* fat to be included in the %DV for saturated fat because “Evidence has accumulated that *trans* fatty acids have physiologic effects similar to saturated fats and *trans* fatty acids in food are used functionally to replace saturated fat....If *trans* fatty acids are not considered, consumers who make food choices on the basis of saturated fat content with the intention of reducing their risk of CHD may be misled by the declared %DV [for saturated fat].”²⁵

The American College of Cardiology (ACC), the American Public Health Association (APHA), American Dietetic Association, American Association for Retired Persons, and more than 75 health professionals and scientists supported the FDA’s proposed regulations to have a combined DV for saturated and *trans* fat. Even the National Food Processors Association and one of the camps within the Grocery Manufacturers of America²⁶ supported a combined DV for saturated and *trans* fat.

A combined %DV for *trans* and saturated fat is the best way for the FDA to comply with the Congressional mandate that the FDA “shall require the required [nutrition] information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and *to understand its relative significance in the context of a total daily diet*”

²² *Canada Gazette Part II* (January 1, 2003) at 394.

²³ Comments of the staff of the Federal Trade Commission (December 16, 2002) at 4.

²⁴ *Canada Gazette Part II* (January 1, 2003) at 394.

²⁵ 64 Fed. Reg. 62746 (November 17, 1999) at 62756.

²⁶ In their April 17, 2000 comments, one group of GMA members supported labeling *trans* fat with a footnote to the declaration of saturated fat and the other group supported a footnote to the total fat declaration.

(emphasis added).²⁷ A national consumer survey that CSPI commissioned in August 2002 found that 80% of consumers think that labels should indicate the percent of a maximum daily intake of *trans* fat that a serving of food contains.

Without putting the number into context, the gram listing of *trans* fat will be confusing and misleading. Numbers that consumers perceive to be low could represent meaningful amounts of *trans* fat. For example, a consumer might think that five grams of *trans* fat in a doughnut is not significant. However, that amount represents a quarter of the DV for heart-unhealthy fat (i.e., of the current DV for saturated fat).

A national survey conducted by CSPI in August 2002 found that few people know how much *trans* fat is a lot or a little. Seventy percent of respondents said they did not know if 4 grams of *trans* fat was a small, moderate or large percentage of the amount of heart damaging fat that they should eat in one day. Only 15 percent of respondents correctly identified it as a large percentage.

B. If the FDA decides to require a footnote in place of a combined DV for saturated and *trans* fat, that footnote should address both saturated and *trans* fat but not cholesterol.

In December 2002, CSPI recommended that if the FDA decides against using a label format for *trans* fat similar to that of Canada, the FDA should modify its proposed *trans* fat footnote to read “Combined total intake of saturated and *trans* fat should be as low as possible” and place the asterisk (or other symbol) after the gram amounts of both saturated and *trans* fat.

While some industry groups commented that the footnote would add clutter to the label, the law requires and consumers need a means of interpreting the gram amounts of *trans* fat listed on labels. A footnote may add more information to the Nutrition Facts panel, but it is information that is essential to helping Americans’ choose more healthful products and reduce their risk of heart disease.

We disagree that the phrase “while maintaining a nutritionally adequate diet” needs to be added to that statement. While that is a part of the conclusion of the IOM macronutrient panel, the advice is obvious and unnecessary. People, of course, should strive to maintain a nutritionally adequate diet. That is true of any recommended dietary change, and is not unique to reducing *trans* and saturated fat intake. That phrase only makes the statement longer, adding useless and trite advice.

We also disagree that the footnote is a warning statement. A clarifying footnote buried in the Nutrition Facts panel to put the gram amounts of *trans* fat into context is more subtle than a

²⁷ Section 2(b)(1)(A) of the Nutritional Labeling and Education Act of 1990 (NLEA), 21 U.S.C. section 343 note. Congress presumably expected this requirement to be met both for the original nutrients specified in the NLEA, as well as nutrients later added to the label.

prominent warning statement on the front or back panel of a food package. In addition, the language in the proposed footnote is straight forward, scientifically-based *dietary* advice. It does not warn consumers about any adverse health outcomes from consuming either *trans* or saturated fat.

As we discussed in our December 2002 comments, it is important that the FDA's proposed footnote for *trans* fat also address saturated fat. The footnote should not distract consumers (or food manufacturers) from reducing saturated-fat intake (or content) or overemphasize the importance of *trans* fat. People consume far more saturated fat than *trans* fat, and consumers should consider both saturated and *trans* fat when assessing a product's impact on cardiovascular health.

As we also previously described, **results from a national survey CSPI commissioned suggest that the footnote as proposed by the FDA may lead some consumers to overemphasize the importance of *trans* fat relative to saturated fat.** CSPI commissioned a national on-line survey that was conducted on December 5-8, 2002.²⁸ Participants were shown pairs of mock Nutrition Facts labels and asked to indicate which food they thought was more healthful.²⁹ For all three mock-label pairs, there were 14 grams of saturated fat plus 0 grams of *trans* fat listed on the first label and 7 grams of saturated fat plus 2 grams of *trans* fat listed on the second label of the pair. In the first question, *trans* fat was listed on a separate line with no Daily Value and no footnote. In the second question, an asterisk was placed after the gram amounts of both saturated and *trans* fat, indicating a footnote that read, "Combined total intake of saturated and *trans* fat should be as low as possible." In the third question, the two simulated labels had the footnote as proposed by the FDA, in which an asterisk was placed in the % DV column for *trans* fat tied to a footnote that read, "Intake of *trans* fat should be as low as possible."

For question one, when asked to compare the labels with no footnotes, 57% of respondents answered correctly (i.e., they chose the food lower in saturated plus *trans* fat). In question 2, when respondents were shown the label pair with the saturated-plus-*trans*-fat footnote, 69% of respondents answered correctly – a better result than for the labels without a footnote. In question three, when the labels included the FDA-proposed *trans*-fat footnote, only 45% answered correctly, significantly lower than when no footnote was included or when both saturated and *trans* fat were included in the footnote. **The results suggest that the FDA's**

²⁸ The survey was conducted by TNS Intersearch. It included 1,000 respondents (18 years or older) who were randomly drawn from a national panel of 1.25 million Internet households. The results are weighted to be representative of Internet households. For the survey, participants see a question and any accompanying visuals on their computer screens. They select an answer and then are presented with the next question.

²⁹ The simulated labels were simplified and included only nutrition information for saturated and *trans* fat.

proposed footnote could mislead some consumers into choosing less healthful foods – that is, foods with more saturated plus *trans* fat.

National Survey Results

	<u>Mock label</u>	<u>Responses*</u>
No Footnote	Food 1: 14 g sat + 0 trans	22%
	Food 2: 7 g sat + 2 g trans	57%
Saturated-Plus- Trans-Fat Footnote	Food 1: 14 g sat + 0 trans	17%
	Food 2: 7 g sat + 2 g trans	69%
Trans-Fat Footnote	Food 1: 14 g sat + 0 trans	39%
	Food 2: 7 g sat + 2 g trans	45%

* Percentage of respondents who identified product as more healthful. Percentages are +/- 3.1%.

The results also show that the combined saturated-plus-*trans* footnote helped people to identify the more healthful product compared to the label without a footnote. The footnote did not confuse consumers, rather this research suggests that the presence of a footnote could be a helpful addition to the Nutrition Facts label.

Placement of the asterisk (or other symbol). If the FDA decides to use a footnote that addresses both saturated and *trans* fat, we suggest that the asterisk (or other symbol) that indicates the presence of the footnote should be placed after the number of grams of saturated fat and *trans* fat as shown below:

Saturated fat 5g*	25%
Trans fat 1g*	—

*Combined total intake of saturated and trans fats should be as low as possible.

The asterisk would be more visible to the right of the number of grams (which label readers are more likely to look at) than next to the name of the nutrients (which readers might gloss over after they become accustomed to which nutrients are listed on labels) or in the % DV column. In addition, an asterisk might not be very visible squeezed into the small space between the words “saturated fat” and the number of grams. There is a larger space between the number of grams and the % DV.

Addressing cholesterol in the footnote. Limiting cholesterol intake is also important to reducing heart disease risk. However, cholesterol differs from saturated and *trans* fats in a number of ways that would make it confusing to include in the footnote. Cholesterol and fatty

acids are measured in different units: fatty acids are measured in grams and cholesterol is measured in milligrams. A footnote that directs a consumer to compare saturated fat, *trans* fat and cholesterol *together* might make a comparison between a piece of apple pie with 3 g of saturated fat, 4 g of *trans* fat and no cholesterol with piece of custard pie with 4 g saturated fat, no *trans* fat and 35 mg of cholesterol confusing. The high number of 35 (for cholesterol) might seem less healthful than the pie with lower numbers of 3 and 4 (for saturated and *trans* fat), yet the custard pie has less heart-damaging fat.

Saturated and *trans* fat are fatty acids. Cholesterol is a sterol. There is no concern that food companies would/could reduce *trans* fat and replace it with cholesterol. Such trade offs are not possible because *trans* fatty acids have different functional properties than cholesterol. In addition, comparing the amounts of three nutrients is more complicated than comparing two nutrients. (Comparing two nutrients is more complicated than comparing just one number, which is, again, why a combined % DV for saturated and *trans* fat is a preferable labeling format.)

A footnote that prompts consumers to limit saturated fat, *trans* fat and cholesterol also might be confusing to consumers trying to follow the *Dietary Guidelines*' advice to choose lean meats, poultry and fish.³⁰ The primary objective of that advice is to reduce saturated fat intake. However, choosing leaner cuts of meat or poultry or fish in place of higher-fat cuts of meat would not reduce cholesterol intake. Such a footnote might distract a consumer from choosing frozen shrimp (3 oz.), which has 0 g of saturated fat and 165 mg cholesterol, in place of prime rib (3 oz.), which has 13 g saturated fat and 74 mg of cholesterol. While seafood is generally low in saturated fat, its cholesterol content is often similar to that of fatty meats. (Seafood also has other beneficial nutrients like omega-3 fatty acids, which are not listed on food labels.) A footnote that includes cholesterol might lead consumers to conclude that seafood is less healthful than it really is. Yet, numerous studies show that eating seafood can reduce heart disease risk.

IV. The FDA should use the same small business exemption for *trans* fat labeling as for other labeling required under the Nutrition Labeling and Education Act regulations.

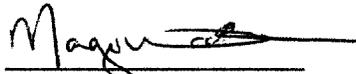
V. Conclusion

We urge the FDA to consider our recommendations regarding *trans* fat labeling and move quickly to propose regulations to limit the amount of *trans* fat in foods that make nutrient content or health claims that currently have limits on saturated fat and to put the gram amounts of *trans* fat into the context of a day's diet. Consumers have been waiting for many years for the agency to act, and they deserve an expeditious resolution of this matter.

³⁰ *Dietary Guidelines for Americans*, 2000, 5th Edition (U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2000) at 15, 29.

In addition, we encourage the FDA to consult with consumer, health and industry representatives before conducting its own consumer research on these issues. Stakeholder consultation could help to ensure that the FDA's research is well focused and better accepted by interested parties, and in the long run would save taxpayers' money and speed up the rule making process. The FDA also should conduct educational programs to help consumers understand and use the new *trans* fat information that is gradually being added to food labels as a result of the final *trans* fat labeling regulations issued in July 2003.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Margo G. Wootan", written over a horizontal line.

Margo G. Wootan, D.Sc.
Director, Nutrition Policy