CSPI Center for Science in the Public Interest
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 94P-0036

As the petitioner in this matter, the Center for Science in the Public Interest (CSPI) writes to comment on the recent proposal by the Food and Drug Administration (FDA) to require a symbol in the % DV column for *trans* fat and a corresponding footnote – "Intake of *trans* fat should be as low as possible" – when the amount of *trans* fat is listed on packaged foods.[1] While CSPI commends the FDA for trying to provide guidance to consumers to help them understand the amount of *trans* fat in a given serving of food in the context of a total daily diet,[2] we urge the FDA to modify the text of the footnote to "Combined total intake of saturated and trans fats should be as low as possible," and to place the asterisk (or other symbol) after the gram amounts of both saturated and *trans* fats.

We fear that the FDA's proposed footnote would distract some consumers from reducing saturated-fat intake, which is a well established goal of the U.S. Department of Health and Human Services and other health organizations. The clear conclusion of each of the three scientific reports relied upon by the FDA is that both saturated and *trans* fats increase LDL-cholesterol levels and the risk of coronary heart disease.[3] The Institute of Medicine (IOM) concluded that "Similar to saturated fatty acids, there is a positive linear trend between *trans* fatty

[1] 67 Fed. Reg. 69171 (November 15, 2002).

[2] For the reasons set forth in our August 14, 2002, letter, we continue to believe that the best way to provide guidance to consumers would be for the FDA to follow the label format proposed by Canada and use a single, combined % DV that would include both saturated and *trans* fats.

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[3] We note that a number of studies raise concerns that *trans* fat may cause other adverse health effects beyond coronary heart disease. We urge the FDA to hold a conference on emerging research and to catalyze research by federal agencies to further study the health effects of *trans* fat (similar to what the FDA has done on acrylamide). Depending on the outcome of the research, the FDA may need to take additional steps to regulate *trans* fat in the future.

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acid intake and LDL cholesterol concentrations, and therefore increased risk of CHD."[4] The IOM Macronutrient Dietary Reference Intake report also recommended keeping consumption of saturated fat as low as possible while maintaining a nutritionally adequate diet.[5] The *Dietary Guidelines for Americans* states: "If you need to reduce your fat intake ... do so primarily by cutting back on saturated and *trans* fats."[6] The National Institutes of Health concluded that a diet designed to reduce the risk of coronary heart disease "should contain less than 7 percent of total calories as saturated fatty acids " and "intakes of trans fatty acids should be kept low."[7]

In addition, Americans consume approximately five times more saturated fat than *trans* fat. Thus, limiting saturated fat is more important to reducing coronary heart disease risk in the U.S. (even if *trans* fat turns out to be more detrimental than saturated fat on a gram-for-gram basis). Any footnote should not lead consumers to limit *trans* fat at the expense of increasing saturated-fat intake. Labeling *trans* fat on a separate line with a cautionary footnote might lead a consumer to choose butter over a tub margarine that contains one gram of *trans* fat even if the combined total of saturated plus *trans* fat is significantly less in the margarine. A footnote reminding consumers to limit the intake of both saturated and *trans* fat would more accurately convey the advice of health authorities.

Additional examples indicate why it is important for the footnote to alert consumers about both *trans* and saturated fats. As with the butter/margarine example, a food with the least amount of *trans* fat may contain more saturated fat than similar foods. If *trans* fat were labeled as the FDA has proposed, consumers might think that Entenmann's All Butter French Crumb Cake, which would list 0 grams of *trans* fat but 5 grams of saturated fat per serving, is less damaging to their health than Entenmann's Crumb Coffee Cake, which would list 2.5 grams of *trans* fat and 2.5 grams of saturated fat per serving. A footnote that pointed out that both saturated- and *trans*-fat intake should be as low as possible would help consumers to understand that both products contain equal amounts of harmful fat.

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[4] *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (Food and Nutrition Board, Institute of Medicine, 2002) at 336. The FDA's proposal cites the part of this sentence dealing with the linear trend for *trans* fat, but omits the part saying that it is similar to saturated fat.

[5] *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (Food and Nutrition Board, Institute of Medicine, 2002), Chapter 8.

[6] *Dietary Guidelines for Americans, 2000* (United States Department of Agriculture and United States Department of Health and Human Services, 2000) at 30.

[7] *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)* (National Heart, Lung, and Blood Institute, National Institutes of Health, 2001) at V-9.

A consumer shopping for a snack food and who reads the label of Newman's Own Popcorn with Natural Butter Flavor might have a difficult time determining whether its 4.5 grams of saturated fat and 0 grams of *trans* fat is worse or better than a serving of Oreos cookies that has 1.5 grams of saturated fat and 2 grams of *trans*. The cookies are better with regard to saturated fat, while the popcorn is better with regard to *trans* fat. The FDA-mandated footnote should advise consumers to compare the sum of saturated and *trans* fats: 4.5 grams in the popcorn compared to 3.5 grams in the cookies.

Results from a national survey CSPI recently 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.[8] Participants were shown pairs of mock Nutrition Facts labels and asked to indicate which food they thought was more healthful.[9] (See appendix for the survey questions and results.) 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**

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[8] 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 (demographic information is attached). 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.

[9] 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.[10]

National Survey Results

	Mock label	Responses*
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%.

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[10] We conducted a similar survey on November 21-24, 2002. In the November survey, the questions were asked in a different order. The question regarding the labels with the saturated-plus-*trans*-fat footnote was asked prior to the question comparing the labels with the FDA-proposed *trans*-fat footnote. Also in the November survey, the introduction to the questions focused on *trans* fat (in the December survey, *trans* fat was not mentioned in the introduction). In the November survey, the answers to the questions comparing the labels without a footnote (57% correct) and comparing the labels with the FDA-proposed footnote (41% correct) were similar to those in the December survey. However, when the question comparing the labels with the saturated-plus-*trans*-fat footnote was asked last, only 39% answered correctly. We suspect that the inexplicable responses to that question were biased by respondents' reading of the second question.

Because the November and December surveys had identical first questions (though somewhat different introductions), we can compare the answers to the first two questions of the two surveys and avoid the order effects. In both surveys, 57% of respondents answered question 1 (labels with no footnote) correctly. When question 2 depicted the FDA- proposed *trans*-fat footnote (November survey), the percentage of respondents who answered correctly dropped to 41%. When question 2 depicted the saturated-plus-*trans*-fat footnote (December survey), the percentage of respondents who answered correctly jumped to 69%. This analysis gives us further confidence that the inexplicable results for the third question in the November survey was an artifact of the survey design.

A footnote that addresses only *trans* fat might lead to food reformulations that increase saturated-fat content. Since, even without any footnote, *trans* fat will be labeled on a separate line from saturated fat, food manufacturers may have greater incentive to reduce the amount of *trans* fat in foods, even if that results in increased amounts of saturated fat. A footnote that emphasized the need to limit only *trans* fat could further exacerbate such changes. A footnote that addressed both saturated and *trans* fat should increase the incentive to reduce both saturated and *trans* fats. And for foods with no *trans* fat, the asterisk and footnote would remind consumers to consider saturated-fat content.

Placement of the asterisk (or other symbol). If the FDA amends its proposal and uses 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). 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. Similarly, if the FDA moves forward with the label format in its November 2002 proposal, we suggest that the asterisk be placed after the gram amounts of *trans* fat rather than in the % DV column.

CSPI supports the FDA's proposal to use the term *trans* fat, rather than *trans* fatty acids both in the line containing the gram amount of *trans* fat and in the footnote. Use of the term *trans* fatty acid should not be allowed on food labels. First, use of multiple terms for the same nutrient could be confusing to consumers. In addition, the term *trans* fatty acid is more technical and is inconsistent with the terms used for other fatty acids on food labels. Although the technical term for saturated fat is saturated fatty acids, labels use the easier-to-understand term "fat" rather than "fatty acid." The FDA should keep the term for *trans* fat consistent with the labeling for other fatty acids and keep it easy to understand.

In conclusion, we urge the FDA to refine its *trans*-fat-labeling proposal to reflect continued concerns about saturated fat, minimize the possibility that labeling would lead consumers to limit *trans* fat at the expense of increasing saturated-fat intake, and encourage consumers to more fully protect their health by consuming less of both saturated and *trans* fats.

Respectfully submitted,

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Attachment