



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

Re: Docket No. 94P-0036

Dear Sir or Madam:

The Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA) appreciate this opportunity to comment on the Food and Drug Administration's (FDA) amended proposed rule on labeling of trans fatty acids. 67 Fed. Reg. 69171 (Nov. 15, 2002). CMA and NCA are strongly opposed to the proposal to require a footnote in the nutrition label reading "Intake of *trans* fat should be as low as possible."

CMA is the national, not-for-profit trade association representing the majority of chocolate manufacturers in the United States. CMA members produce over 90 percent of all chocolate manufactured in this country. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture and market a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market. NCA is the national, not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers.

CMA and NCA believe that the proposed *trans* fat footnote would be viewed by consumers as a warning statement. By singling out *trans* fat for a message of avoidance, it would go beyond the nutritional recommendation on which it is based and would unconstitutionally compel commercial speech. The proposed footnote would stigmatize products with low levels of *trans* fat, while many of the foods with the highest levels of *trans* fat, because they are generally consumed in foodservice establishments, would escape its coverage.

- 1. The footnote would be viewed by consumers as a warning that would stigmatize foods with even low levels of *trans* fat.**

The proposed footnote (*i.e.*, "Intake of *trans* fat should be as low as possible") would be required to appear in the nutrition label of any food containing 0.5 or more grams (g) of *trans* fat

94P-0036

C2294

per serving.¹ CMA and NCA believe that consumers would view the footnote as a warning that the labeled food contains an unhealthy nutrient. While the current requirement to declare percent Daily Values (“% DV’s”) for total fat, saturated fat, cholesterol, and sodium imply that intakes of those nutrients should be limited, the proposed footnote would single out *trans* fat for an explicit message of avoidance. Because this warning statement is required for no other nutrient, we believe consumers would interpret it as a recommendation to eliminate, or virtually eliminate, *trans* fat from their diets, contrary to the express precaution that *trans* fat consumption not be reduced at the expense of adequate intake of other nutrients.

The proposed footnote would have the effect of stigmatizing products that contain even low levels of *trans* fat.² At the same time, many of the foods with the highest levels of *trans* fat (e.g., french fries, doughnuts) that are primarily sold in foodservice establishments, and therefore are not required to bear nutrition labeling, would escape coverage. As a result, the proposed rule does not provide for communication of the nutritional message to consumers in the context where they most need it.

2. Singling out *trans* fat in this way is not supported by the Institute of Medicine report on which the proposed footnote is based.

The proposed footnote is based on the conclusions of the National Academy of Sciences’ Institute of Medicine (IOM) in its recently released report on dietary reference intakes (DRI’s) for macronutrients.³ However, in two respects, the proposed footnote is inconsistent with the IOM conclusions.

First, the IOM Macronutrient Report does not support singling out *trans* fat for special attention. The IOM report’s recommendations regarding *trans* fat are essentially the same as its

¹ It is not entirely clear whether a food containing less than 0.5 g of *trans* fat per serving would be required to declare *trans* fat as zero. CMA and NCA request that, in its final rule, FDA clarify that declaration of *trans* fat, as zero, is optional for foods with less than 0.5 g of *trans* fat per serving, absent a triggering claim. In this regard, we note that FDA’s original Regulatory Impact Analysis for this rulemaking posited that only some, and not all, food labels would need to be changed to comply. See 64 Fed. Reg. 62746, 62775 (Nov. 17, 1999). If all food products are required to change their labels, the original economic analysis is no longer valid.

² There is remarkably little solid scientific evidence that *trans* fat at low intake levels increases serum total or LDL cholesterol. Although the Institute of Medicine report on which the proposed footnote is based found a “positive linear trend” between *trans* fat intake and total and LDL cholesterol levels, this finding was apparently based on a single chart. That chart, in turn, was based on surprisingly little data for *trans* fat at low intake levels (*i.e.*, less than 3 percent of total energy) and does not appear to have been peer-reviewed.

³ National Academy of Sciences, Institute of Medicine, “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids” (IOM Macronutrient Report) (2002).

recommendations regarding intake of saturated fat and cholesterol. The report recommends that “saturated fatty acid, *trans* fatty acid, and cholesterol consumption be as low as possible while consuming a nutritionally adequate diet.”⁴ The IOM report provides no basis that we can discern for highlighting only *trans* fat with a footnote.⁵

Moreover, the IOM Macronutrient Report specifically cautions against total avoidance of *trans* fat. It states that eliminating *trans* fat from the diet would “introduce undesirable effects... and unknown and unquantifiable health risks” by reducing intake of protein and certain micronutrients present in foods that also contain *trans* fat.⁶ This is why the IOM recommended that “*trans* fatty acid consumption be as low as possible *while consuming a nutritionally adequate diet.*”⁷ Singling out *trans* fat for a footnote/warning, especially one that omits the qualifying phrase “while consuming a nutritionally adequate diet,” would be seen by consumers as a recommendation to avoid *trans* fat, rather than the more nuanced advice contained in the IOM Macronutrient Report.

3. The footnote would be difficult to fit on the labels of confectionery products, many of which have very small packages.

Many confectionery products have very little label space on their packages. Adding new mandatory information is always a particular challenge for the confectionery industry. In the case of *trans* fat labeling, manufacturers are being asked to add not one, but two, new mandatory items of information: the declaration for the amount of *trans* fat and the *trans* fat footnote. This will be very difficult for some confectionery products to accommodate. CMA and NCA request that FDA require new mandatory label information only when there is a compelling reasons for doing so. We do not believe there is a compelling justification for the proposed footnote.

As discussed in footnote 1 above, CMA and NCA request that FDA’s final rule clarify that no label change is required for products that contain less than 0.5 g of *trans* fat per serving and that make no triggering health claim or nutrient content claim.

4. The footnote is inconsistent with FDA’s expressed desire to adhere to First Amendment requirements.

⁴ IOM Macronutrient Report, p. S-4.

⁵ FDA states that the nutrition label is required by statute to include information that explains the significance of each declared nutrient in the daily diet. 67 Fed. Reg. at 69171. However, some nutrients (*e.g.*, sugars) now declared in Nutrition Facts have neither a % DV nor a footnote explaining their significance in the daily diet. CMA and NCA also believe that the proposed footnote would exaggerate the significance of *trans* fat in the daily diet.

⁶ IOM Macronutrient Report, p. 8-66.

⁷ IOM, “Letter Report on Dietary Reference Intake for *Trans* Fatty Acids” (July 10, 2002), p. 14 (emphasis added).

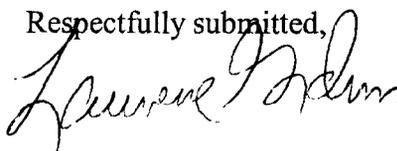
Under the First Amendment, government regulation of commercial speech, including regulations that compel commercial speech, must directly advance a substantial government interest and must be no more extensive than is necessary to achieve their purpose. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980). FDA recently expressed an intention to bring its existing regulations into compliance with the First Amendment. 67 Fed. Reg. 34942 (May 16, 2002).

CMA and NCA believe the proposed *trans* fat footnote is not consistent with prevailing case law on regulation of commercial speech. Even assuming the proposed footnote directly advances a substantial government interest (*i.e.*, the public health benefit derived from informing consumers about the amounts and significance of nutrients that may increase their risk of heart disease), it clearly fails the final prong of the *Central Hudson* test. The footnote is more extensive and burdensome than is necessary to achieve its purpose. By singling out *trans* fat as the only nutrient to carry an explicit message of avoidance, the proposed footnote amounts to the "functional equivalent of a warning." See *International Dairy Foods Association v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996). Yet, for the reasons discussed above, this warning is not supported by the IOM recommendations on which it is based.

* * * * *

For the foregoing reasons, CMA and NCA urge FDA to omit the proposed footnote from its final rule on labeling of *trans* fat. Rather, nutrition labeling of *trans* fat should parallel that required for sugars (*i.e.*, declaration of a quantitative amount per serving without a % DV) and other nutrients (*e.g.*, monounsaturated fat, polyunsaturated fat, soluble fiber) that also have a relationship to risk of chronic disease. CMA and NCA further urge FDA to undertake a consumer education campaign about *trans* fat.

Respectfully submitted,



Lawrence T. Graham
President