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January 5, 2000

Jane Henney, MD  
FDA Commissioner  
FDA Dockets Management Grant (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 94P-0036, Food Labeling: Trans Fatty Acids in Nutrition Labeling,  
Nutrient Content Claims, and Health Claims; Proposed Rule

Dear Dr. Henney:

We are writing to express our strong support for the proposed labeling requirements for trans-fatty acids. We believe that the requirement to add the trans fat content to that of saturated fat, with the crucial requirement of the asterisk referring consumers to a footnote for the trans content, represents a major step forward in providing information to consumers and enhancing public health. The FDA has provided a thoughtful review of alternative strategies for improving the labeling for trans fat, and in our view, has devised the optimal solution which provides a good balance between scientific accuracy and ease of understanding. In particular, we regard the asterisk next to the saturated fat heading, as the simplest and best way to identify food products that are important sources of trans fat. This distinction is essential for scientific accuracy and is critical for consumers and dietitians because trans fat has adverse metabolic effects not shared by saturated fat. For example, the net effect of trans fat on the LDL/HDL ratio is approximately double that of saturated fat, a significant difference in each of the six studies that allowed a direct comparison (overall  $p < 0.00001$ ).

The text of the proposed rules provides a detailed review of the scientific basis for the regulations. We believe the adverse effects of trans fat on LDL and HDL in controlled feeding studies provide sufficient justification themselves for the proposed regulation. As the FDA notes, findings from prospective epidemiologic studies consistently find that the association of trans fat with coronary disease is considerably stronger than what would be predicted based on the changes in LDL and HDL alone. Inaccuracies in these observational studies could contribute to part of this apparently higher risk. However, a more likely explanation is that trans fat has other adverse health effects apart from its influence on LDL and HDL levels. Metabolic studies show that trans fat increases triglycerides and Lp(a). In addition, emerging evidence suggests that trans fat increases insulin resistance in short term feeding studies, and raises risk of diabetes. Because trans fats have a different physical shape than the cis form, it is

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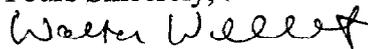
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plausible that they may affect many different physiologic functions. Thus, the estimates for the health effect of trans fatty acid based solely on LDL, or LDL and HDL, most likely represent substantial underestimates of the true effect. For these reasons, we strongly support efforts to improve consumer knowledge about trans fat, with the aim of reducing their consumption.

An increasingly important source of trans fat is from its use in frying, particular at fast food restaurants. We strongly urge that the FDA consider ways to improve consumer knowledge regarding intake of trans from restaurant meals.

The new labeling regulations for trans have the potential for a substantial public health impact which will require little effort on the part of consumers. Although nutrition experts differ in their views as to the magnitude of the adverse health impact of trans fats, there is widespread agreement that health would be improved if intake of trans fat could be reduced. The first step toward this goal is to provide consumers the information that they need. We applaud the FDA's efforts in this regard.

Yours Sincerely,



Walter Willett, MD

Chair, Department of Nutrition  
Harvard School of Public Health



Meir Stampfer, MD, DrPH  
Professor of Nutrition and Epidemiology  
Harvard School of Public Health

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Associate Professor of Nutrition and Epidemiology  
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