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An FAO Center of Excellence for Food and Nutrition Policy

November 21, 2003

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

**RE: Docket No. 2003N-0338: Obesity Issues
68 Fed. Reg. 03-25645 (October 8, 2003)**

The Center for Food and Nutrition Policy (“Center” or CFNP) at Virginia Tech in Alexandria is an independent, non-profit research and education organization that is dedicated to advancing rational, science-based food and nutrition policy. It is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization (FAO) of the United Nations. The Center uniquely operates like an independent “think-tank,” while maintaining its academic affiliation with Virginia Tech, a major land-grant university. The research, education, outreach, and communication activities of the faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy process on food and nutrition issues.

Encompassed in the Center’s activities on nutrition policy are its interests in policy and regulatory issues involving dietary guidance, food labels, labeling, and obesity.

The Center recognizes and respects the difficult task that the Food and Drug Administration (FDA) faces in expending finite resources on the numerous and diverse issues that affect public health. As such, the Center respectfully submits the following comments in response to the FDA’s request for comment on obesity issues, docket no. 2003N-0338 as published in the *Federal Register*.¹

The comments contained herein address FDA’s question #6: “Based on the scientific evidence available today, what are the most important things that FDA

¹ Federal Register: Notices. October 8, 2003, Volume 68, Number 195, pages 58117-58118.

could do that would make a significant difference in efforts to address the problem of overweight and obesity?”

Rigorous “Weight of the Evidence” Process for Obesity Initiatives Is Needed

On January 16, 2003, Food and Drug Administration Commissioner Mark McClellan announced the formation of an internal task force—Consumer Health Information for Better Nutrition—to develop scientific guidance for establishing standards in making qualified health claims on food and supplement labels.²

The charge to the task force was to:

- “Report on how the agency should apply the ‘weight of the evidence’ standard established under the consumer health information initiative for qualified health claims on conventional foods.
- Develop a framework of regulations that will give these principles the force and the effect of law.
- Identify procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of health claim petitions.
- Develop a consumer studies research agenda designed to best present scientifically based information to consumers in a truthful and non-misleading way, and to identify the kinds of information known to be misleading to consumers.”

On July 10, 2003, FDA issued industry guidance and interim procedures for making qualified health claims on human foods and dietary supplements.³ In like fashion, the Center for Food and Nutrition Policy urges FDA to establish a similar rigorous framework for evaluating the “weight of the evidence” in establishing regulations, guidance, educational campaigns, or research agendas that are within FDA’s scope of responsibility in addressing the issue of overweight and obesity in the American population.

Few reasonable scientists disagree that excess body weight is the result of an imbalance between energy (calories) consumed and energy expended. But there are many factors—non-modifiable and modifiable—that contribute to one’s risk of becoming overweight. Non-modifiable risk factors for overweight include genetics (that may include race/ethnicity), age, and gender. Modifiable risk factors include lifestyle habits, such as levels of physical activity at work and during leisure time, sedentary behaviors, and diet.

² <http://www.cfsan.fda.gov/~dms/nutfftoc.html>

³ <http://www.cfsan.fda.gov/~dms/hclmgui3.html#intro>

Non-Modifiable Factors Are Strongest Determinants of Overweight

Genetics, Race and Ethnicity. Research shows that some people may have a genetic predisposition to becoming overweight, but this susceptibility may not be expressed phenotypically. Modifiable lifestyle factors are also important variables in whether a genetically predisposed individual becomes overweight.⁴ The strength of genetics has been shown in elegant studies conducted by Bouchard and colleagues in identical twins.⁵

Race/ethnicity also appears to be a significant factor in becoming overweight; evidence suggests that race/ethnicity affects the timing and rate of weight gain. Williamson and his colleagues found that African-American women tended to gain more weight during perimenopause than did white women.⁶ This is in contrast to the findings of Hamman and co-workers who noted no extra weight gain among Pima Indian women at the time of menopause.⁷ However, this may be due to the fact that the Pimas tend to gain weight at a much earlier age.

Age and Gender. Advancing age appears to be related to increased body weight even among healthy, active men and women. Increased body weight, however, is related to changes in resting metabolic rate (RMR), which comprises about 60-75 percent of daily energy expenditure.^{8,9} Poehlman and colleagues found that the age-related decline in RMR among healthy women was not an independent effect of age, but rather was strongly related to a decline in fat-free weight accounting for 72 percent of the variance in RMR. These investigators predicted that in healthy women, there would be a 0.6 percent decline per decade in RMR between ages 18-50 and a 4.0 percent decline per decade between 51-81 years of age. A re-analysis of a similar study conducted among men showed the same curvilinear relationship between RMR and age. The declines in RMR among men occurred at a younger age (41 years) than women, and at nearly double the rate of decline seen in women.^{6,10}

⁴ Leibel RL, Chung WK, Streamson CC Jr. The molecular genetics of rodent single gene obesities. *J Biol Chem* 1997; 272: 31937-31940.

⁵ Bouchard C, Tremblay A. Genetic influences on the responses of body fat and fat distribution to positive and negative energy balances in human identical twins. *J Nutr* 1997; 127: 943S-947S.

⁶ Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in U.S. adults. *Arch Intern Med* 1990; 150: 665-672.

⁷ Hamman RF, Bennett PH, Miller M. The effect of menopause on serum cholesterol in American (Pima) Indian women. *Am J Epidemiol* 1975; 102: 164-169.

⁸ Poehlman ET, McAuliffe TL, Van Houten DR, Danforth Jr. E. Influence of age and endurance training on metabolic rate and hormones in healthy men. *Am J Physiol* 1990; 259 (Endocrinol Metab 22): E66-E72.

⁹ Heymsfield SB, Gallagher D, Poehlman ET, Wolper C, Nonas K, Nelson D., Wang ZM. Menopausal changes in body composition and energy expenditure. *Experim Gerontol* 1994; 29: 377-389.

¹⁰ Poehlman ET, Goran MI, Gardner AW, Ades PA, Arciero PJ, Katzman-Rooks SM, Montgomery SM, Toth MJ, Sutherland PT. Determinants of decline in resting metabolic rate in aging females. *Am J Physiol (Endocrinol Metab)* 1993; 264: E450-E455.

Loss of fat-free weight significantly influenced RMR among men and women, but men experienced the decline in fat-free weight at an earlier age than did women. Men began to lose fat-free weight around age 35 years, whereas women experienced this loss around 48 years of age. The rate of decline in fat-free weight was similar between men and women, however. These studies and others suggest that strategies to increase physical activity may mitigate losses of fat-free mass leading to the age-related decline in RMR.^{11,12} Thus, Williams recommended that guidelines targeting older adults should urge substantially greater levels of physical activity, or develop weight standards that are adjusted for older age groups if physical activity does not increase over time.

Non-modifiable risk factors appear to be the strongest determinants of overweight among children and adolescents as well as adults. The Centers for Disease Control and Prevention (CDC) have developed gender-specific “growth” charts for children showing increases in body mass index (BMI) with age.¹³ A study conducted by Forshee and his colleagues showed that gender, age, race/ethnicity were better predictors of overweight than lifestyle habits of 6-11 year old children and 12-19 year old adolescents. These investigators also noted that among lifestyle habits, sedentary behavior—as measured by hours of television/video watched—predicted body mass index more strongly than did dietary components.¹⁴ The relationship of physical activity, or the lack of it, with overweight among children and adolescents is consistent with the studies among adults that are cited here.

As noted in the previous section, physical activity is an important lifestyle component that may help prevent, or at least slow, unhealthy weight gain among children, adolescents, and adults. The CDC, a “sister” agency of FDA, developed the Youth Media Campaign (YMC) to encourage greater physical activity among 9-13 year old school children.¹⁵ The CDC conducted a longitudinal survey of this age group and the children’s parents. The report found that among the group of 9-13 year olds surveyed, 61.5 percent did not participate in any organized physical activity, and 22.6 percent did not participate in any physical activity during their non-school hours. Striking disparities in organized physical activity were observed among non-Hispanic black and Hispanic children compared with non-Hispanic white children. Nearly 47 percent of white children

¹¹ Van Pelt RE, Jones PP, Davy KP, DeSouza CA, Tanaka H, Davy BM, Seals DR. Regular exercise and the age-related decline in resting metabolic rate in women. *J Clin Endocrinol Metab* 1997; 82: 3208-3212.

¹² Williams PT. Evidence for the incompatibility of age-neutral overweight and age-neutral physical standards from runners. *Am J Clin Nutr* 1997; 65: 1391-1396.

¹³ Centers for Disease Control and Prevention, National Center for Health Statistics, www.cdc.gov/growthcharts/

¹⁴ Forshee RA, Storey ML, Weaver AR, Sansalone WR. Demographic and lifestyle factors associated with body mass index among children and adolescents. *Intl J Food Sci Nutr* 2003; 54: 491-503.

¹⁵ Centers for Disease Control and Prevention. Physical activity levels among children aged 9-13 years—United States, 2002. *MMWR* 2003; 52: 785-788.

reported participating in organized physical activity during the preceding seven days, but only 24 and 26 percent of black and Hispanic children, respectively, reported similar activity. There was much less difference in reported free-time physical activity, however. For example, 79 percent of white children reported participating in free-time physical activity, while 75 percent of black and Hispanic children reported participation.

This suggests that physical activity is a must for all consumer communications if FDA and other federal agencies responsible for public health are to succeed in stemming rising obesity.

Few Changes Are Needed to the Nutrition Facts Panel to Combat Obesity

Some groups have suggested that FDA require additional labeling to combat the problem of overweight and obesity. As previously stated above, energy expenditure must be balanced with energy (calorie) intake to maintain a healthy weight. In so doing, consumers must have the information to properly assess caloric intake from foods consumed. In 1978, less than half of foods provided nutrient information on the package. But as more research suggested an important link between diet and health, there was greater demand for nutrition information on food packages. The Nutrition Labeling and Education Act of 1990 (NLEA; Public Law 101-535) mandated that nearly all FDA-regulated food packages display nutrient content—including calorie content—per serving of food. Regulations implementing NLEA took effect on May 8, 1994. Three years after implementation, research conducted by FDA showed that 96.5 percent of foods displayed a Nutrition Facts label and caloric content.¹⁶ One objective of NLEA—nutrition labeling—was therefore achieved. Hence, consumers can access the necessary information to calculate how many calories they are consuming in a serving of food.

Information, however, does not necessarily mean that consumers will have the education to make healthy decisions or that they will choose to do so. Another objective of NLEA was to help consumers improve dietary habits through education, yet this objective has not been achieved in the 13 years since the law was enacted, or in the decade since the regulations were implemented. One of the key assumptions behind the NLEA was that policymakers presumed that consumers placed significant importance on nutrition when deciding which foods to purchase, and that reading the nutrition label would induce food choices that would lead to a healthier diet.

It should be recognized that some consumers do use the nutrition label. Consumers who use the Nutrition Facts panel tend to be 1) white, 2) female, 3)

¹⁶ Brecher SJ, Bender MM, Wilkening VL, McCabe NM, Anderson EM. Status of nutrition labeling, health claims, and nutrient content claims for processed foods: 1997 Food Label and Package Survey. J Am Dietetic Assoc 2000; 100: 1057-1062.

older, 4) more affluent, 5) already eating healthfully, and/or 6) have an important health concern.^{17,18,19}

Analysis of the FDA's Food Label Use and Nutrition Education Survey (FLUNES) showed that the Nutrition Facts panel was used most often to assess the level of a certain characteristic of the food product and to avoid a specific ingredient.²⁰ This analysis suggested that the nutrition label was not used in making first-time purchases, comparing brands, preparing meals, or deciding how much of the product to eat. Surprisingly, in this survey consumers did not use the Nutrition Facts panel to determine the nutritional content of the food, or to confirm the truth of an advertising or packaging claim.

Even people with serious health problems do not fully utilize information on food labels. For example, a study conducted in four family medicine clinics in southwest Missouri showed that patients with high blood pressure were 63 percent more likely to look for sodium content on the food label than patients with normal or low blood pressure; and patients with high blood cholesterol were more likely to look for saturated fat content. Neither of these groups of patients, however, was more likely than others to look for additional nutrition information on the label.

Adolescents also appear to limit their use of the nutrition label. For example, a study conducted among 90 high-school aged adolescents showed that they are more likely to attend to information presented on the principal display panel (the front) of food packages than they are to information in the Nutrition Facts panel.²¹ The top three reasons these adolescents gave for choosing certain foods were preference/taste, custom/habit, and price/cost. The front label/nutrition claim, nutrient label, and television advertising ranked fifth, twelfth, and thirteenth, respectively, among their reasons for selecting certain food items.

This strongly suggests that other factors determine consumers' food choices regardless of the availability of nutrition information that is easily accessed on the food label. The Center therefore finds little rationale for making major changes to the nutrition label to address the problem of overweight and obesity.

¹⁷ Kreuter MW, Brennan LK, Scharff DP, Lukwago SN. Do nutrition label readers eat healthier diets? Behavioral correlates of adults' use of food labels. *Am J Prev Med* 1997; 13: 277-283.

¹⁸ Neuhouser ML, Kristal AR, Patterson RE. Use of food nutrition labels is associated with lower fat intake. *J Am Diet Assoc* 1999; 99: 45-53.

¹⁹ Papakonstantinou E, Hargrove JL, Huang CL, Crawley CC, Canolty NI. Assessment of perceptions of nutrition knowledge and disease using a group interactive system: the Perception Analyzer. *J Am Diet Assoc* 2002; 102: 1663-1668.

²⁰ Brooks KC. The nutrition facts panel: who uses it and how is it used? Practicum for the Master of Public Policy degree, Georgetown University, May 2000.

²¹ McCullum C, Achterberg CL. Food shopping and label use behavior among high school-aged adolescents. *Adolescence* 1997; 32: 181-197.

Summary of Comments

In summary, the Center urges FDA to:

1. use an evidence-based evaluation of the currently available science to determine the most important factors in the development of overweight and obesity;
2. establish regulations or amend regulations based on the strength of the evidence and that are within the scope of FDA's mission and responsibility;
3. begin an education campaign in collaboration with the food industry to help consumers understand the nutrition label; and
4. collaborate with the Department of Education to institute age-appropriate nutrition education curricula in elementary, middle, and high schools.

Respectfully submitted,

A handwritten signature in black ink, reading "Maureen L. Storey". The signature is written in a cursive style with a large initial "M".

Maureen L. Storey, PhD
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