

Lester M. Crawford, DVM
Deputy Commissioner
Food and Drug Administration

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RE: Comments to FDA Obesity Working Group [HFA-305]

Dear Dr. Crawford,

I want to commend the U.S. Food and Drug Administration for recognizing the critical nature of America's obesity epidemic and for getting involved in addressing this important and timely issue. Thank you for providing an opportunity for individuals in the nutrition research community to offer evidence of best practices that help people lose weight and maintain a healthful lifestyle.

My name is Donald K. Layman and I am professor of nutrition in the Department of Food Science and Human Nutrition at the University of Illinois at Urbana-Champaign. My research focuses on protein-energy requirements, the interaction of nutrition and exercise, and obesity. Results of my research have been published in the *Journal of Nutrition*, the *American Journal of Clinical Nutrition*, and the *American Journal of Physiology*. FDA's Obesity Working Group has asked for comment on a variety of questions related to understanding what is needed to better understand how to address obesity in the United States. I will address various aspects of FDA's inquiries based on recent research conducted by myself along with my research team at the University of Illinois.

Studies suggest that today's consumer is more successful with weight loss programs that focus on **energy balance** - a simple way of saying that to lose or maintain a healthy weight, individuals must match appropriate food intake with their level of physical activity. Critical to this approach is helping people make healthful food and fitness choices.

Consumers benefit from programs that allow flexibility to choose **from a variety of foods** both for nutritional value and personal enjoyment. Studies show that diets focusing on the extremes of high-protein/high-fat or very low fat/high carbohydrate are usually unsuccessful because they impose too many limits on food choices. Recent research presented at the American Heart Association's November meeting, shows that compelling people to adhere to restrictive, nutrient-specific diets is unsuccessful. Data is now becoming clear, that to lose weight, diets must be individualized, along with the right amount of physical activity to match energy intake. The Institute of Medicine's (IOM) 2002 Macronutrient Report indicated for the first time that there is a range of good nutrition - or Average Macronutrient Distribution Range (AMDR). The AMDR allows for the flexibility to adjust an individual's diet within established ranges for protein, carbohydrates, and fat, but still meet micronutrient recommendations.

The research is also clear that for long-term success with weight management, consumers must increase their daily level of physical activity. Unfortunately, in many of the efforts to address the obesity epidemic, there seems to be an uneven focus on the "energy in" side of the equation, but not enough on "energy out." According to the Institute of Medicine (IOM) Macronutrient Report 2002, a critical step to a healthy lifestyle is "adopting an active lifestyle." There are exponential health benefits related to regular physical activity. Research shows that exercise induces a small increase in energy expenditure even after the activity itself is completed. In addition, regular physical activity results in chronic changes in energy expenditure as a result of change in body composition, alterations in the metabolic rate of muscle tissue, and spontaneous physical activity associated with higher levels of fitness.

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My own research shows that for successful weight reduction, individuals should choose diets that enable them to eat foods that are naturally high in vitamins, minerals, and high quality protein with controlled levels of fat and refined carbohydrates. Most recently, my team and I conducted three research studies that demonstrate that a moderate increase in protein in a well-balanced diet can contribute greatly to weight reduction and loss of body fat with muscle maintenance. In these studies participants were given a diet consisting of a variety of healthy foods, including high quality protein sources, such as beef, dairy products, poultry, fish, and eggs. In addition, they ate vegetables, fruit, and limited levels of whole grains. These studies were designed to increase the amount of high quality protein in the diet and specifically the level of the essential amino acid, leucine, which helps to maintain muscle mass and targets loss of body fat.

After 10 weeks, study participants lost an average of 16 pounds and after 16 weeks they lost an average of more than 21 pounds - almost exclusively from fat, while maintaining lean muscle mass. Maintaining muscle is critical to weight management because muscle helps burn calories. These dieters were successful, in part because they found the eating plan easy to follow and used foods from all the food groups. The results were so significant that a long-term study has been launched by the University of Illinois and Penn State University.

The role of high-quality protein in a diet is even more important as we consider actual consumption patterns in the U.S. According to national surveys, only 30 percent of adult Americans are eating the recommended amount of high quality protein that the Food Guide Pyramid recommends (USDA Healthy Eating Index). Additionally, the National Health and Nutrition Examination Survey (NHANES) suggests that adult women in America only consume 68 grams of protein each day – thus barely meeting the minimum RDA of 60 – 70 grams. **This is an inadequate intake of protein necessary to maintain adult muscle mass throughout the lifecycle.** With the incidence of sarcopenia (loss of muscle) among American adults increasingly prevalent, and with today's sedentary lifestyles, American adults need to consume high quality protein, specifically proteins providing the amino acids available from animal sources.

Unfortunately, American consumers remain confused about what constitutes a high quality diet because of ongoing contradictions about good nutrition in the media and in nutrition education tools, as well as the ongoing pre-occupation about fats. In fact, less than one percent of American adults and between one and three percent of children actually follow the Food Guide Pyramid recommendations. Americans overeat refined carbohydrates and sugars (fructose), the top of the pyramid, and are very limited in high quality proteins. What is important in educating consumers about healthful lifestyle and eating is to develop an educational structure or tool that provides guidelines that utilize the AMDR ranges set by the IOM, thus allowing flexibility in choices.

It may seem like common sense, but a majority of American consumers do not fully recognize the importance of a diet consisting of a variety of naturally nutritious foods. In the past, weight loss strategies have focused on low-fat – and still, our nation is fighting an obesity epidemic. History and controlled research studies have proven that focusing on dietary fat is no magic bullet to weight loss. New research is showing that the *quality and balance* of the diet – along with physical activity – are the keys to maintaining overall healthful lifestyles.

Any effort to combat obesity should help individuals choose foods that pack more high quality proteins, vitamins, and minerals into fewer calories. This means eating a variety of lean meats, low fat dairy foods, vegetables, fruits, and whole grains first, and including high-calorie, nutrient poor snacks and desserts as energy output will allow. This ensures that people are getting the right nutrients, including important micronutrients, and that all foods fit in a healthy and enjoyable diet. It does not imply that there are “good” and “bad” foods, rather there are foods that have higher nutritional value and thus, should be consumed first.

In summary, my recommendations are for the FDA to:

- **Educate consumers about the importance of energy balance** and provide them with guidance and information to help them understand the level of physical activity necessary to balance the energy that they bring in through their diet.
- Begin to acknowledge that **one diet doesn't fit all** and develop criteria that allow for flexibility of food choices to meet individual needs. Most of public debate centers around diets at the extremes of very high or very low levels of protein, carbohydrates, or fat. As discussed above, my own research, published in the February 2003 issue of the *Journal of Nutrition* suggests that moderate high-quality protein intake is more effective in preserving optimal body composition – more muscle mass. I found what I call a “Sensible Solution” to weight loss and management. The protein range used in this approach fell within the AMDR established by the Institute of Medicine (IOM) - recognizing allowance for flexibility among individuals for macronutrient needs.
- We need new guidelines that help consumers understand **the importance of high quality proteins** found in dairy, meats, and eggs, and the problems associated with high carbohydrate diets using high levels of refined carbohydrates and sugars. Dietary recommendations that provide consumers with information about food *quality* will enable them to choose a variety of food to fit their individual nutrient needs, tastes, cultures, and economic environments. It is important to develop national nutrition guidance that educates consumers about healthful lifestyles and eating in a manner that allows for flexibility and variety in food choices. Guidelines need to recognize the AMDR ranges set by the IOM, which would allow a more individualized approach.

The evidence is clear. Successful programs to fight obesity include nutrition approaches that enable consumers to choose from a variety of nutritious foods, including high-quality protein such as beef, dairy products, poultry, fish, and eggs, and vegetables, fruits, and whole grains. Physical activity is a critical component to helping people maintain the appropriate energy balance for the food they consume. And, evolving nutrition information tools to reflect the AMDRs set by the IOM and allow for flexibility and individualized nutrition will be most useful for consumers in making sensible food choices.

Thank you for this opportunity to share findings from my research on moderate protein intake and weight management. As you continue to develop programs and policies to address issues of obesity, please feel free to contact me at dlayman@uiuc.edu or 217-333-1616.

Sincerely,

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