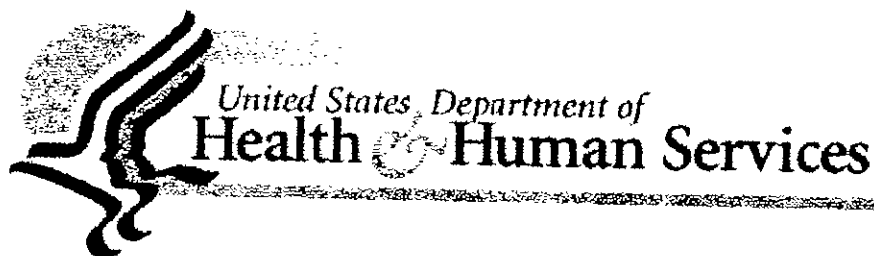


Declaration of Erich O. Grosz

Exhibit 3

Case No. 1:07-CV-01092 (RJL)



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Press Release

FOR IMMEDIATE RELEASE
Friday, March 12, 2004

FDA Press Office
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HHS UNVEILS FDA STRATEGY TO HELP REDUCE OBESITY New "Calories Count" Approach Builds on HHS' Education, Research Efforts

HHS Secretary Tommy G. Thompson today released a new Food and Drug Administration (FDA) report outlining another element in HHS' comprehensive strategy for combating the epidemic of obesity that threatens the health of millions of Americans with a focus on the message, "calories count."

The report by FDA's Obesity Working Group includes recommendations to strengthen food labeling, to educate consumers about maintaining a healthy diet and weight and to encourage restaurants to provide calorie and nutrition information. It also recommends increasing enforcement to ensure food labels accurately portray serving size, revising and reissuing guidance on developing obesity drugs and strengthening coordinated scientific research to reduce obesity and to develop foods that are healthier and low in calories.

"Counting calories is critical for people trying to achieve and maintain a healthy weight," Secretary Thompson said. "This new report highlights FDA's overall strategy for getting consumers accurate, helpful information that allows them to make wise food choices at home, at supermarkets and in restaurants. Taking small steps to eat a more balanced diet and to stay physically active can go a long way to reversing the epidemic of obesity that harms far too many Americans."

The FDA report comes on the heels of a new study from HHS' Centers for Disease Control and Prevention (CDC) that shows poor diet and inactivity are poised to become the leading preventable cause of death among Americans – causing an estimated 400,000 deaths in 2000. CDC estimates that 64 percent of all Americans are overweight, including more than 30 percent who are considered obese. About 15 percent of children and adolescents, aged 6 to 19, are overweight – almost double the rate of two decades ago.

Secretary Thompson on Tuesday unveiled a new national education campaign to encourage Americans to take small steps to fight obesity and a new obesity research strategy at the National Institutes of Health. Today's report builds on those initiatives by highlighting actions that FDA, which regulates many foods and their labels, can take to enable consumers to make smart choices about their diet and maintain a healthy weight.

"Our report concludes that there is no substitute for the simple formula that 'calories in must equal calories out' in order to control weight," said FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D. "We're going back to basics, designing a comprehensive effort to

attack obesity through an aggressive, science-based, consumer-friendly program with the simple message that "Calories Count."

The report's recommendations include:

- Evaluating how the "Nutrition Facts" panel on food labels can be revised to highlight the critical role calories play in consumers' diets -- such as increasing type size and adding a column to list quantitative amounts of calories as a Percent Daily Value for the entire package. The report recommends FDA issue an advance notice of proposed rulemaking to gain public input on approaches to effectively revise food labels.
- Considering the authorization of health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of such a health claim might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers." The report recommends an advance notice of proposed rulemaking to obtain public input on the approach.
- Encouraging manufacturers to use dietary guidance statements, such as, "To manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; or have cherry yogurt, not cherry pie."
- Defining such terms as "low," "reduced," or "free" carbohydrates, as well as providing guidance for the use of the term "net" in relation to carbohydrate content of food, in light of increasing consumer interest in low carbohydrate diets and in response to petitions asking FDA to define these terms.
- Focusing FDA's consumer education strategy on influencing behavior and promoting healthy eating choices with the basic message that "Calories Count." FDA will work with private and public sector partners, including youth-oriented organizations, to give consumers a better understanding of the food label and how to use it to make healthier food choices.
- Encouraging the restaurant industry to launch a national, voluntary effort to include nutritional information for consumers at the point of sale. Such information would help consumers make healthier and lower-calorie choices outside the home, where Americans now spend nearly half their total food budget. The report recommends that FDA seek restaurants to participate in a pilot program to study effective options for simple, voluntary, standardized nutritional information at the point of sale in restaurants.
- Increasing FDA's focus on enforcing accurate serving size declarations on food labels and advising manufacturers when the agency identifies apparent errors in declared serving sizes. FDA is issuing a letter to encourage the food industry to review its nutrition information and ensure that the serving size declared is appropriate for the food product in question.
- Revising and reissuing FDA's 1996 draft Guidance for the Clinical Evaluation of Weight-Control Drugs. This action item reflects the fact that some obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. FDA would issue this revised guidance for public comment.
- Strengthening the coordination of research into obesity and the development of foods that are healthier and lower in calories with other HHS agencies, the U.S. Department of Agriculture, and other public and private sector partners. Specific target areas include research related to information to facilitate consumers' weight management decisions; the relationship between overweight and obesity and food consumption patterns; incentives for product reformulation; the potential for FDA-regulated products to contribute unintentionally to weight gain; and the extension of basic research findings to the regulatory environment.

The full report from the FDA's obesity working group is available at <http://www.fda.gov/oc/initiatives/obesity/>. More information about HHS' new anti-obesity campaign and NIH's obesity research agenda is available at <http://www.hhs.gov/news/press/2004pres/20040309.html>.

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