FDA Can Help Advance the Administration’s “Prevention” Strategy
by Bruce Silverglade

The Food and Drug Administration (FDA) should be tapped to play a significant role in advancing the President’s “prevention” agenda to improve health. Diet-related disease, including heart disease, diabetes, cancer and other chronic illnesses represent the leading causes of death in the United States, and claim hundreds of thousands of lives each year. In addition, overweight and obesity rates in the United States have been soaring. Obesity often increases the risk of chronic disease. Childhood obesity levels are especially alarming. Health conditions such as type II diabetes (previously known as “adult-onset diabetes”) are now prevalent in children.

The Administration should reinvigorate FDA’s nutrition mission and the agency should be instructed to develop and implement a series of initiatives that would help Americans improve their diets and protect their health.

The blueprint for such an initiative has already been laid out by the World Health Organization (WHO), in its 2004 Global Strategy on Diet, Physical Activity and Health. The WHO identified policy initiatives that should be undertaken by national authorities to help reduce the incidence of obesity and diet-related disease; they include efforts to reduce the salt, trans fat and sugar content of processed foods, improve food labeling and set guidelines for foods that should or should not be advertised to children.

While such steps were either off-the-table or not seriously considered under the previous administration, the Obama Administration should direct FDA to undertake action in these areas. Other countries, most notably the United Kingdom (UK), have already done so and have successfully implemented regulatory and policy initiatives. FDA should closely examine efforts by the UK’s Food Standards Authority (FSA) to persuade companies to reformulate processed foods, use standardized front-of-pack symbols to communicate nutritional values, and set nutritional guidelines for limiting food advertising to children. Such steps can serve as a model for actions here in the United States.

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Product Reformulation

One of the most direct ways that the processed food industry can facilitate improvements in diet and health is to lower the salt, trans fat, saturated fat and added sugar content of their products. The WHO has recommended that national governments consider working with industry to achieve these objectives. The FSA has successfully conducted a sodium reduction program in the UK, and is presently conducting a similar effort to reduce saturated fat in processed food products.

High sodium levels are the single most harmful aspect of the American diet. According to a 2004 paper co-authored by the director of the National Heart, Lung and Blood Institute, cutting sodium (mostly from salt) in half would prevent about 150,000 fatal heart attacks and strokes annually. FDA should set sodium targets or limits for various categories of processed foods and insist companies meet those goals according to a specified timetable. FDA should simultaneously commence a proceeding to revoke the generally recognized as safe (GRAS) status of sodium chloride or to stipulate that salt (or the cumulative level of sodium from various ingredients) is not GRAS if present in amounts that exceed specified levels.

FDA should conduct a similar effort aimed at eliminating artificial trans fat from processed foods. The presence of artificial trans fat from partially hydrogenated vegetable oil (another substance currently considered to be GRAS despite a finding by the National Academy of Sciences Institute of Medicine that there is no known safe level of trans fat consumption) has been a cause of cardiovascular disease in the United States. While adding trans fat to the Nutrition Facts label in 2006, which resulted in national publicity, spurred many manufacturers and restaurants to switch to healthier oils, a substantial amount of artificial trans fat still remains in the food supply. FDA should initiate rulemaking to revoke the GRAS status of partially hydrogenated vegetable oil.

Such steps are clearly feasible. The State of California recently limited the amount of artery-clogging trans fatty acids in restaurant foods, following the lead of New York, Philadelphia and other cities. Denmark did the same back in 2004 on a national level.

Food Labeling

Improvements in food labeling are also key elements of a comprehensive strategy to help consumers improve their diets and reduce their risk of disease. FDA has recognized the importance of mandatory nutrition labeling. The Nutrition Labeling and Education Act (NLEA), however, is almost 20 years old and many of FDA’s implementing regulations need to be updated to bring the law into the 21st Century.

Under the current scheme, information for fat, saturated fat, cholesterol, sodium and fiber is disclosed only by amount and as a percentage of the “Daily Value” (DV) for each nutrient. Studies have shown that the use of this format is not understood by most Americans. According to FDA’s Counting Calories: Report of the Working Group on Obesity (FDA Obesity Report), this shortcoming results in too few consumers choosing a healthy diet. According to one leading study cited in the FDA report, just 20 percent of Americans accurately calculated the contribution of a food to a daily diet. Other studies have shown similar problems.

Thus, while mandatory nutrition labeling has been a valuable source of information for many consumers, its complexity has been an impediment to its effectiveness. To realize the full potential of food labeling, DVs need to be supplemented by easily understood symbols that appear on the fronts of food packages.

FDA has held two public meetings on the issue, and conducted some focus group research. The UK has made much greater progress. The FSA has developed a set of nutrition criteria and established a system of “traffic lights” that can be used on the fronts of food packages to communicate nutritional value. The red, amber, and green dots indicate whether a food contains, high, moderate or low levels of fat, saturated fat, salt, and sugars. At least one North American manufacturer, McCain’s (the frozen potato company), uses the traffic lights on packages of french fries and other products in the UK.

Multiple Nutrient Traffic Light

The UK traffic light system is voluntary, but may be made mandatory in the future—despite food manufacturers’ objections.

The legislative history of the NLEA specifically called on FDA to consider the use of “universal symbols” to communicate nutritional content. The House Report to the NLEA states: In order to present nutrition information in a manner that facilitates the public’s understanding, the Secretary may choose among a variety of options. For example, one way
that this could be accomplished would be to include information about the recommended daily intake on the label. This could include the use of descriptive terms such as “high,” “medium,” and “low” or use of universal symbols to indicate desirable or undesirable levels of particular nutrients.¹⁵ (emphasis added)

That was almost 20 years ago. Given that research has shown that the DV framework is inadequate, Congress or the Administration should direct FDA to conduct research in cooperation with the Institute of Medicine of the U.S. Academy of Sciences to develop symbols for use on the fronts of food packages that communicate nutritional quality at a glance.

The development of a standard set of symbols to communicate nutrition information should be only the beginning of FDA’s efforts to modernize the food label. The agency should also support efforts by states and localities to require chain restaurants to post calorie information for all standard food items on menu boards, and to require that calories, saturated fat, trans fat, sodium and sugar content be disclosed on menus. FDA should also require health warning statements on high calorie soft drinks, improve ingredient labeling by requiring quantitative disclosure of key ingredients,¹⁶ and require ingredients to be printed more clearly (in easy to read typeface, using upper- and lowercase lettering).

**Food Marketing to Children**

The WHO,¹⁷ as well as the U.S. Institute of Medicine,¹⁸ has recognized that food marketing can adversely affect children’s health. The UK has addressed this problem by prohibiting the broadcast advertising of low nutrition foods on television and radio programs that appeal to children under the age of 16. The FSA played an essential role in that program by using its scientific expertise to establish criteria for foods of low nutritional value that should not be advertised to children. (The UK Office of Communications, which is responsible for broadcast regulation, defined which programs appeal to children and youth.)¹⁹

The new rules have reduced the broadcast advertising of foods of low nutritional value to British children by about one-third,²⁰ thus helping remedy the vast imbalance that exists between the information provided in food advertisements and the information provided in government sponsored nutrition education programs.²¹ American food companies like Kellogg, Coca-Cola and McDonald’s comply with the new UK law, yet continue to expose American children to advertisements now banned in that country.

The Administration should convene an inter-agency task force to address the matter. The task force should include FDA, other agencies within the Department of Health and Human Services (HHS) such as the Centers for Disease Control (CDC), the Federal Trade Commission (FTC) and the Federal Communications Commission (FCC).

**The Way Forward**

Eating better is not simply a matter of personal responsibility, and willpower has proven to be inadequate to solve the enormous problems at hand. The government has an important role in mitigating the toxic food environment created by food manufacturers and restaurant chains promoting huge servings of soft drinks, snacks and “value” meals that are literally penny-wise and pound foolish.

No one public health initiative by itself can solve the obesity problem and eliminate diet-related disease. However, if taken together, product reformulations, improved food labeling and limits on food advertising to children can form the basis of a comprehensive public health program. Other elements include changes in agricultural policy and fiscal measures to make fruits and vegetables more affordable and accessible, as well as the development of aggressive media advocacy campaigns encouraging healthful eating and physical activity. Programs based on the WHO’s Global Strategy on Diet, Physical Activity and Health have been under way in other countries such as the UK, and U.S.-based multinationals and other companies are complying. It is now time for such programs to be instituted in the United States. FDA can play an important role in this effort, and in so doing, help advance the Administration’s preventative health strategy. △

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2. According to the CDC, approximately 17 percent of children between the ages of 6-11 in the U.S. are overweight or obese; and 17.6 percent for children ages 12-19. This data was obtained from a series of surveys conducted by the National Center for Health Statistics at the CDC, available at http://www.cdc.gov/nccdphp/dnpa/obesity/childhood/index.htm, (accessed Dec. 2008).
Opportunities and Challenges

7 The 2002 report: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids said that because they are not essential and provide no known health benefit, there is no safe level of trans fatty acids and people should eat as little of them as possible while consuming a nutritionally adequate diet, available at http://www.nationalacademies.org/headlines/20060109.html, (accessed Jan. 26, 2009).
8 A complete listing of all state and local menu labeling laws in the United States can be found at http://www.cspinet.org/ menulabeling/.
11 Levy, Patterson, & Kristal, How well do consumers understand percentage daily values on food labels? American Journal of Health Promotion, (2000), 14:157-60. Given the confusion with %DV, the authors suggested a set of criteria be developed for evaluating foods using %DV.
12 In the 1996 Food Marketing Institute/Prevention Magazine Survey, 82 percent of 1000 shoppers claimed to have seen the %DV information on nutrition information panels, FMI/Prevention, (1996). However, only 43 percent understood the meaning of a DV for fat of 5 percent. Even among the “healthy” eaters, only 50 percent could accurately interpret %DV for fat. The use and understanding of food label information amongst 27 women with non-insulin dependent diabetes mellitus was investigated, Miller et al., (1997). Focus groups and face-to-face interviews were carried out. Participants did not consider %DV to be useful because of the belief that the figures did not apply to them and that percentages were confusing. Misconceptions relating to %DV include: 1) %DV relating to the nutrient in the entire package; and 2) that the product with the highest %DV is the nutrient that is present in the highest amount in the product.
13 FDA has held two public meetings at which the potential usefulness of front-label nutrition symbols has been reviewed. The most recent was on Dec. 12, 2008 at an FDA “Nutrition Roundtable.” See presentation of Dr. Barbara Schneeman, Director, Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, Wiley Building, 5100 Paint Branch Parkway, College Park, MD.
16 Much of Europe, Australia, New Zealand and Thailand require percentage ingredient labeling of processed foods. For example, in the UK, Kellogg’s Strawberry Nutri-Grain bars must state that they contain only 5 percent strawberries by weight. Such requirements provide valuable information to consumers, prevent misleading labeling and might lead companies to market more healthful foods.
21 The FTC estimates that food companies spend about $1.6 billion per year on advertisements that target children. Marketing Food to Children and Adolescents: A review of Industry Expenditures, Activities, and Self-Regulation, FTC, (2008). The U.S. Institute of Medicine estimates the total figure may be as high as $10 billion per year, infra, n. 7. Both figures outweigh the amount of money spent by the U.S. government on nutrition education programs directed at children.