Docket Number 2004N-0463

Tab 1

Department of Health and Human Services
Food and Drug Administration

Calories Count

Report of the Working Group on Obesity

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date February 11, 2004

From Chair and Vice Chair, Obesity Working Group

Subject Working Group Report and Recommendations

To Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

We are pleased to transmit the final report and recommendations of the Food and Drug Administration's (FDA) Obesity Working Group (OWG). You established the OWG on August 11, 2003. The OWG met eight times from August 28, 2003, to January 22, 2004. In addition, the OWG held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups), and solicited comments on obesity-related issues. The public meeting examined FDA's role and responsibilities in addressing the major health problem of obesity, focused on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans, and obtained stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition. The science-based public workshop, which was co-sponsored and funded by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, collected data relevant to FDA efforts to help consumer make better-informed weight management decisions. In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (i.e., messages, education, food label, restaurants/industry, therapeutics, research, and stakeholder investment), each designed to focus on a particular aspect of the original charge to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report.

The report that follows provides, for your consideration, a range of short- and long-term recommendations that are responsive to the charge. The OWG believes that, if the report's recommendations are implemented, they will make a worthy contribution to confronting our Nation's obesity epidemic and helping consumers lead healthier lives through better nutrition. The report also contains a number of appendices, including your

original charge memo, the list of OWG members and subgroups, and other supporting material.

We appreciate the opportunity to have served FDA as leaders of the OWG, and we stand ready to facilitate the implementation of the OWG's recommendations.

Lester M. Crawford, D.V.M., Ph.D
Chair
Deputy Commissioner of
Food and Drugs

Robert E. Brackett, Ph.D.
Vice Chair
Director
Center for Food Safety and
Applied Nutrition

Calories Count
Report of the Food and Drug Administration
Working Group on Obesity

EXECUTIVE SUMMARY

Obesity is a pervasive public health problem in the United States. Since the late 1980s, adult obesity has steadily and substantially increased in the United States. Today, 64 percent of all Americans are overweight and over 30 percent are obese; in 1988 through 1992, fewer than 56 percent were overweight and fewer than 23 percent of American adults were obese. The trends for children are even more worrisome. Recent research by the U.S. Centers for Disease Control and Prevention[1] (CDC) shows that 15 percent of children and adolescents aged 6 to 19 are overweight –double the rate of two decades ago (CDC, 2003). As Americans get heavier, their health suffers. Overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers. According to some estimates, at least 400,000 deaths each year may be attributed to obesity (Mokdad, *et al.*, 2004).

To help confront the problem of obesity in the United States and to help consumers lead healthier lives through better nutrition, on August 11, 2003, Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs, created the Food and Drug Administration's (FDA) Obesity Working Group (OWG). He charged the OWG to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities.

This report reflects the work of the OWG to meet the Commissioner's charge and is organized largely around the specific elements of the August 11, 2003, charge.

The problem of obesity has no single cause. Rather, it is the result of numerous factors acting together over time. Similarly, there will be no single solution; obesity will be brought under control only as a result of numerous coordinated, complementary efforts from a variety of sectors of society. Nor can this problem be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

The OWG's recommendations are centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity (see Appendix B Text Boxes in the report for a fuller discussion). The recommendations contained in this report therefore focus on a "calories count" emphasis for FDA actions. The box on the next page contains the OWG's principal recommendations. The body of this report details the underlying rationale for each of these principal recommendations and additional recommendations. Taken together, they represent a plan of action, founded on science, FDA's public health mission and legal authorities, and the importance of considering consumer and other stakeholder views and needs in addressing obesity.

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[1] See Appendix A for a list of acronyms and abbreviations used throughout this report.

OWG PRINCIPAL RECOMMENDED ACTION ITEMS

Food Labeling

- ***Calories:*** *Issue an advance notice of proposed rulemaking (ANPRM) to solicit public comment on how to give more prominence to calories on the food label. As examples, increasing the font size for calories, including a percent Daily Value (%DV) column for total calories, and eliminating the listing for calories from fat.*
- ***Serving Sizes:*** *Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire content of the package can reasonably be consumed at a single-eating occasion. For example, a 20 oz bottle of soda that currently states 110 calories per serving and 2.5 servings per bottle could be labeled as containing 275 calories per bottle.*
- ***Carbohydrates:*** *File petitions and publish a proposed rule during summer 2004 to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.*
- ***Comparative Labeling Statements:*** *Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt – 29 percent fewer calories and 86 percent less fat").*

Enforcement Activities

- *Together with the Federal Trade Commission (FTC), increase enforcement against weight loss products having false or misleading claims.*
- *Consider enforcement action against products that declare inaccurate serving sizes.*

Educational Partnerships

- *As part of a larger DHHS effort, establish relationships with, among others, youth-oriented organizations such as the Girl Scouts of the USA and the National Association State Universities and Land Grant Colleges (4-H program), to educate Americans about obesity and leading healthier lives through better nutrition.*

Restaurants

- *Urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.*

Therapeutics

- *Convene a meeting of a standing FDA advisory committee to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.*
- *Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.*

Research

- *Support and collaborate, as appropriate, on obesity-related research with others, including NIH.*
- *Pursue research on obesity prevention with U.S. Department of Agriculture/Agricultural Research Service (USDA/ARS).*

CALORIES COUNT
REPORT OF THE FOOD AND DRUG ADMINISTRATION WORKING GROUP ON OBESITY

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I. Introduction

A. Public Health Impetus

The nation is currently facing a major long-term public health crisis. In recent years, unprecedented numbers of Americans of all ages have become either overweight or obese.[2] This trend toward overweight and obesity has accelerated during the past decade and is well documented (see Box 1) by numerous scientific analyses. (For convenience, future use in this document of the term obesity includes both overweight and obesity.) Unfortunately, this trend towards obesity shows no signs of abating. If it is not reversed, the gains in life expectancy and quality of life resulting from modern medicine's advances on disease will erode, and more health-related costs will burden the nation's healthcare systems. For these reasons, the trend toward obesity must be reversed.

Box 1 – Facts and Figures on Overweight and Obesity

The scope of the growing and urgent public health problem of obesity is outlined in the Surgeon General's Call to Action (DHHS, 2001). In 1999-2000, 64% of U.S. adults were overweight, an increase from 56% when surveyed in 1988-1994; 30% of adults were obese, an increase from 23% in the earlier survey (DHHS, 2003; Flegal *et al.*, 2002). In addition, among children and adolescents age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (CDC, 2003; Ogden *et al.*, 2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Mokdad, *et al.*, 2004). The total economic cost of obesity in the United States is up to $117 billion per year (DHHS, 2003), including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures (DHHS, 2001; DHHS, 2003).

The prevalence of overweight and obesity varies by gender, age, socioeconomic status, and race and ethnicity (DHHS, 2001). For example, although overweight has increased among all children, the prevalence of overweight and obesity is significantly higher among non-Hispanic black and Mexican-American adolescents than among non-Hispanic white teens (12-19 years old) (Ogden *et al.*, 2002). A majority of non-Hispanic black women over 40 are overweight or obese (Flegal *et al.*, 2002).

[2] National Institutes of Health (NIH) clinical guidelines (http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations) define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9, and "obesity" as a BMI of 30.0 or higher. BMI (see Text Box at Appendix B) is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters.

The problem of obesity in America has no single cause. Rather, obesity is the result of multiple factors acting together over time, including genetic (Loos and Bouchard, 2003) and environmental factors (Hill and Peters, 1998; Hill *et al.*, 2003).[3] Similarly, there will be no single solution to the problem of obesity; it will be brought under control only as a result of coordinated, complementary efforts from a variety of sectors of society. The obesity epidemic also will not be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

Obesity is associated with significant health problems in the pediatric age group and is an important risk factor associated with adult morbidity and mortality. The causes and mitigation of childhood obesity have been and continue to be the focus of much attention (Hill and Trowbridge, 1998; Barlow and Dietz, 1998; Ashton, 2004; Bowman, *et al.*, 2004). A policy statement of the American Academy of Pediatrics proposes strategies for early identification of excessive weight gain by using BMI,[4] for dietary and physical activity interventions during health supervision encounters, and for advocacy and research (AAP, 2003). According to Ritchey and Olson (1983), parental behavior is a dominant influence on children's eating habits. For adults, the literature discusses how having a specific behavior goal for the prevention of weight gain (e.g., increasing physical activity or eating less at each meal) may be key to arresting the obesity epidemic (Wyatt and Hill, 2002; Hill, 2004). In similar fashion, the *Dietary Guidelines for Americans* includes a chapter on physical activity, linking physical activity with nutrition.

The combined efforts of Federal, state and local governments, the packaged food industry, the restaurant industry (including both quickservice and other types of restaurants), the professional health community (including primary care physicians, nutritionists, dietitians, and others), consumer advocacy groups, schools, the media and, of course, committed individuals will all be required to contribute to the solution to the problem of obesity.

The current crisis has been recognized by many of these groups, including a number of our stakeholders, for some time, and many wide-ranging efforts to address and reverse the trends that lead to obesity are already underway. Within the DHHS, Secretary Tommy G. Thompson has led efforts to address the public health problem of obesity. On July 30, 2003, Secretary Thompson convened a roundtable on obesity/nutrition involving experts from academia, the health professions, industry, and government to consider the role that the Department can play in reducing or reversing the weight gain that leads to obesity (see Appendix C for the five questions presented at the roundtable). DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather additional information on this topic.

Each group now working on the problem of obesity brings unique resources and expertise to bear on it. Among the major Federal government entities with a responsibility and a capability to address the problem, FDA, within the broader context of DHHS, is bringing its own unique strengths to bear, including relevant legal authorities.

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[3] For additional information on factors contributing to obesity see CDC webpage (http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm)

[4] In children, the BMI is expressed as percentile growth that is based on gender-and age specific growth charts.

B. FDA Obesity Working Group

In a memorandum dated August 11, 2003 (see Appendix D for the August 11 memorandum), Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D., created the OWG and gave it its charge. FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., chairs the OWG; the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), Robert E. Brackett, Ph.D., is the vice-chair.[5] Other members of the OWG (see Appendix E for list of OWG members) were selected from across FDA to provide expertise and knowledge in a range of relevant scientific and other disciplines. The Commissioner requested that the OWG deliver, in six months, a report that outlines an action plan covering critical dimensions of the obesity problem as outlined in the charge and to help consumers lead healthier lives through better nutrition.

During its tenure, the OWG met eight times; received briefings from several invited experts from other government agencies; held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups); and solicited comments on obesity-related issues, directing them to the Docket that DHHS established in July 2003 (Docket No. 2003N-0338). In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (see Appendix F for list of OWG subgroups), each designed to focus on a particular aspect of the Commissioner's original charge. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report. This report presents the OWG's recommendations that are responsive to the Commissioner's charge, and that the OWG believes can contribute to confronting obesity in the United States.

II. Foundations of this Report

Any FDA effort to address obesity must be based on the following: (a) adherence to fundamental scientific principles; (b) conformance with FDA's public health mission and legal authorities; and (c) consideration of consumer and other stakeholder views and needs.

A. Scientific Principles

Fundamentally, obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity; see text box on Calorie (Energy) Balance at Appendix B). Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these

[5] When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.

macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, "calories count."[6]

1. Calories

Quite simply, the OWG's recommendations center on the scientific fact that weight control requires caloric balance. Food supplies the energy that provides fuel for the body and for rebuilding the "wear and tear" one is subjected to during the day. The traditional unit for expressing the energy value of foods is the *kilocalorie* (kcal). The term *calorie* is commonly used in place of kilocalorie. One calorie is equal to 4.184 kilojoules (kjoules) a common unit of energy used in the physical sciences and internationally in nutrition labeling. The caloric intake that is appropriate for an individual depends on a number of factors, including height, weight, gender, and age.

2. Calorie Contribution of Macronutrients

Attention to caloric intake is a key element of weight control (the other is caloric expenditure). The three macronutrients that provide energy in our diets are carbohydrate, protein, and fat (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value at Appendix B). (Alcohol is also a source of energy, yielding 7 calories per gram, but it is not a nutrient.[7]) These macronutrients yield different amounts of energy in the form of calories per unit weight.

- Carbohydrate = 4 calories per gram
- Protein = 4 calories per gram
- Fat = 9 calories per gram

To maintain a constant bodyweight over time, "energy in" from food must equal "energy out" as a result of resting metabolism plus physical activity. In other words, calories eaten should equal the calories expended on a daily basis. Bodyweight will change if one alters this basic balance. If one consumes even slightly more calories than one expends over time, one will eventually gain weight (Wright, *et al.*, 2004). Conversely, if one consumes fewer calories than one expends over time, one will eventually lose weight.

B. FDA's Public Health Mission and Legal Authorities

FDA's mission is to promote and protect the public health. It seeks to accomplish this mission by enforcing the laws it is charged with administering and by conducting educational and public information programs relating to its responsibilities.

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[6] For a further discussion of energy balance see, *Dietary Reference Intakes* – Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 2, Chapter 12 Physical Activity; 12:1-39 (Institute of Medicine of the National Academies, 2002) and references cited therein.

[7] Although alcoholic beverages are not a focus of this report, there is some interest in having calorie and other nutrition information declared on the label of such beverages, as evidenced by a recent petition from the Center for Science in the Public Interest (CSPI) submitted to the Tax and Trade Bureau of the Treasury Department. In a letter dated December 17, 2003, to DHHS Secretary Thompson, CSPI requested that DHHS support the petition.

The Federal Food, Drug, and Cosmetic Act (the Act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA, Public Law 101-535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of the total daily diet. The statute and the regulations were also intended to provide incentives to food manufacturers to improve the nutritional quality of their products.

The cornerstone of the NLEA is the Nutrition Facts panel (NFP), which lists the total number of calories derived from any source, as well as the total number of calories derived from total fat. The amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food are also listed in the NFP, both as the quantitative "amount per serving" (grams or milligrams) and, with the exception of sugars and protein, as the percent of a dietary reference value, called the "percent Daily Value" (%DV). FDA requires the declaration of nutrients as a %DV, in part to help consumers understand the role of individual foods in the context of the total daily diet. Also, to help consumers determine how their individual dietary needs compare with the reference daily values used on the label, the NFP includes a footnote that specifies that the reference daily values are based on a 2,000 calorie diet. On larger packages, the footnote goes on to list the daily values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for both a 2,000 and a 2,500 calorie diet.

As part of FDA's regulations implementing the NLEA, the agency established reference amounts customarily consumed (RACCs) for 139 food categories that manufacturers are to use in developing serving sizes that are then expressed in household measures (e.g., teaspoons, cups, pieces). These serving sizes become the basis for reporting the amount of each nutrient present and enable consumers to compare the nutritional qualities of similar food products.

Under the NLEA, FDA also has authority over health claims and nutrient content claims for foods. Appropriate health claims and nutrient content claims, like nutrition labeling, further the statutory objectives of enabling consumers to make more informed and healthier food product choices and encouraging manufacturers to improve the nutritional quality of their products.

A health claim is a claim that characterizes the relationship between a food, or a food component, and a disease or a health-related condition, and may only be made in accordance with an authorizing regulation issued by FDA. An example of a health claim is: "Although many factors affect heart disease; diets low in saturated fat and cholesterol may reduce the risk of heart disease." A nutrient content claim is a claim that characterizes the level of a nutrient in a food, and it, too, must be made in accordance with an authorizing regulation issued by the agency. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as "free," "high," and "low," or they compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," and "lite." More information on FDA's implementation of these authorities can be found at http://www.cfsan.fda.gov/~dms/hclaims.html.

Restaurants, unlike the manufacturers of packaged foods, are not required by the NLEA to provide nutrition information for a menu item or meal unless a nutrient content claim or a health claim is made for such item or meal. When such a claim is made, the restaurant need only

provide information on the amount of the nutrient that is the basis of the claim. Thus, for example, if a restaurant claims that a particular menu item is "low in fat" (i.e., makes a nutrient content claim with regard to fat) then this requirement is satisfied by adding: "low fat – provides fewer than 3 grams fat per serving" (i.e., the basis of the "low fat" claim). The restaurant may provide information about the nutrient for which the claim is made in various ways, including in brochures. In other words, restaurants need not provide such information on the menu or menu board.

A restaurant making such a claim also would not be required to provide complete nutrition information; its decision to provide nutrient content information about one nutrient does not trigger a requirement to disclose complete nutrition information for that item or meal.

C. Stakeholder Participation

From the outset, FDA asked stakeholders to identify obesity issues that FDA should address. Prior to the creation of the OWG, DHHS convened a round table discussion in late July 2003 (bringing together experts from academia, the health professions, industry, and government) to consider how best to address the obesity issue, as reflected in five questions presented to the round table for discussion (see Appendix C for the five questions). As noted above, DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather information on this subject.

Following the creation of the OWG, FDA provided several opportunities for stakeholder participation: a public meeting on October 23, 2003; a workshop on November 20, 2003, that was co-sponsored and funded by the DHHS Office of the Assistant Secretary for Planning and Evaluation (OASPE); roundtable meetings with health professionals/academicians and consumer groups respectively, on December 15 and 16, 2003; and meetings with representatives of the packaged food and restaurant industries. FDA used these opportunities to solicit public comments on the obesity issue, as reflected in six questions the agency asked (these questions are set out in section VI.A. of this report). FDA used the Docket established in July 2003 (Docket No. 2003N-0338) to gather additional comments; the OWG organized the comments to this docket into a searchable database that informed preparation of this report.

D. The OWG's Work

The remainder of this report reflects the work of the OWG subgroups:

- ***Obesity Knowledge Base:*** Gathered information on existing obesity, weight management, and nutrition related programs.
- ***Messages:*** Identified existing obesity-related messages in the public and private sectors; conducted focus groups to test five messages; recommended a calorie focus for FDA's action plan.
- ***Education:*** Explored and is initiating a number of new and enhanced private and public sector partnerships to focus on obesity education.
- ***Food Label:*** Explored options for enhancing the food label in relation to efforts to address obesity.

- ***Restaurants/Industry:*** Explored options for providing consumers with nutrition information on food consumed outside the home; considered the potential health consequences of using diet plans and related products.
- ***Therapeutics:*** Surveyed existing therapies for mitigating obesity; recommended next steps for updating the 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."
- ***Research:*** Identified gaps in obesity knowledge and areas for further biomedical and social sciences research.
- ***Stakeholder Investment:*** Held meetings and a workshop to solicit stakeholder views; and organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

III. Messages

The Commissioner charged the OWG to set out specific means for developing and implementing a "clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic." This part of the charge was expanded with an eye toward establishing a broader theme that focuses on calories[8] as a fulcrum for further action, in the context of an overall healthful diet as defined by the DHHS/USDA *Dietary Guidelines for Americans.*

A. Obesity Knowledge Base

Prior to considering obesity messages and to ensure that it was aware of the range of current public and private efforts to address obesity, the OWG formed a subgroup to collect information on existing and planned obesity-related activities in the United States; assemble a centralized repository of the information gathered; and report out to the full OWG on the scope/contents of the repository.

A majority of the activities listed in the repository and database are programs that provide advice on nutrition/diet and/or physical activity. Most associations, agencies, and organizations identified are sending out the message that diet and physical activity should be addressed together in the fight against obesity.

Many partnerships or collaborations exist between government agencies and/or private entities. There are several areas, however, where different groups manage similar programs. These similar programs, if merged into a larger partnership, could have a greater impact.

To determine whether various programs, activities and initiatives are effective in reducing and/or preventing overweight and obesity in the United States, program evaluation must improve. In addition, improvements are needed in educational outreach to convey the messages and implement the initiatives that government and non-government entities have developed.

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[8] As noted earlier in Section II.A.1., there is much discussion in the field of nutrition concerning the specific macronutrient source of calories, but given the charge to focus on obesity, the OWG believes that a primary focus on calories is appropriate.

B. Obesity Messages

Message Recommendation Highlight:

- ***Develop messages tied to a "calories count" focus...p. 10***

The OWG formed a subgroup to identify existing messages in the public and private sectors and to set out specific means for developing simple, clear, coherent, and effective FDA messages around the theme of "calories count" based on the scientific fact that net calorie gain or loss over time is the root cause of obesity.

1. Identifying Existing Messages

Today, consumers are inundated with a range of messages about food. Some of these messages are in the form of food advertisements or marketing efforts that focus on product convenience, taste and value. Other messages relate to weight-loss programs or products, or weight management. Some of the messages in each of these areas may not necessarily direct consumers toward wise dietary choices.

The Federal government tries to provide long-term sound nutrition advice to consumers (e.g., government-sponsored public health campaigns). For example, DHHS collaborates with the USDA to establish and promote the *Dietary Guidelines for Americans,* which provide guidance on choosing a lifestyle that combines sensible eating with regular physical activity. An important recent effort of DHHS is *Steps to a HealthierUS.*[9] In support of the President's *HealthierUS*[10] initiative, the DHHS effort emphasizes personal responsibility for the choices Americans make to ensure that policy makers support prevention programs that foster healthy behaviors.

[9] For more information on *Steps to a HealthierUS* see http://www.healthierus.gov/steps/index.html
[10] For more information on the *HealthierUS* Initiative see http://www.healthierus.gov/

2. FDA Focus Groups on Obesity Messages

Box 2 – FDA Focus Groups

FDA conducts its own consumer research to evaluate the appropriateness and effectiveness of its messages. For example, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the NFP format. Since NLEA, FDA and other researchers have studied how consumers use the NFP, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

In November-December 2003, FDA, with OASPE funding, conducted focus group research. There were 8 groups of 7-10 participants. Groups were segregated by gender and education level. All participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quickservice restaurant in the past month. The purpose of the groups was to explore (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quickservice restaurants; and (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the NFP and the principal display panel (PDP) on food packages and to various presentations of nutrition information at restaurants.

It is important to emphasize that the findings from these focus groups are based on qualitative research with small sample sizes. They should not be viewed as nationally representative or projectable. Quantitative experimental data are necessary to make reliable and verifiable conclusions. However, these focus group results shed some interesting light on the complex issues discussed in this report and are useful in identifying quantitative research needs.

The focus group findings discussed in this report are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers.

In November and December 2003, FDA focus groups were convened to evaluate, among other things: (1) how consumers use the nutrition information on food labels; and (2) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label (see Appendix G for FDA Division of Market Studies report, referenced in this report as FDA, 2003).[11] Appendix H contains a discussion on the development of effective consumer messages. The findings from the FDA focus group efforts are discussed below.

[11] In addition, the focus groups explored what type of nutrition information they would like to see in quickservice restaurants (see section V.B.1.of this report). Participants discussed and reacted to various presentations of nutrition information at restaurants.

FDA developed five NFP-based messages that the agency tested through its focus groups. The messages and materials were intended to remind people where to find the NFP, why it is there, and how to use the information; while at the same time reinforcing various "promises" (i.e., motivators) associated with regularly using the NFP.

The messages tested were as follows:

1. "Read it before you eat it - Always look at the Nutrition Facts"
2. "Calories count and fat matters - Always look at the Nutrition Facts"
3. "Do you know the serving size? - Always look at the Nutrition Facts"
4. "What you eat is what you are - Always look at the Nutrition Facts"
5. "If you read labels for things you put *on* your body, why wouldn't you read labels for what you put *in* your body?"

Overall, none of these "slogan-type" messages resonated particularly well with the FDA focus group participants. Nevertheless, FDA focus group participants believed that reminder messaging about the NFP would be helpful for them in making food choices. In addition, the results of other focus groups indicate that messaging should emphasize small, incremental steps versus major life changes with respect to weight management and obesity prevention, and should address the importance of "planning ahead" as a necessary step for eating right (Borra *et al.*, 2003; IFIC, 2003).

C. OWG Message Recommendations

The OWG recognizes that some focus group (Borra *et al.*, 2003; FDA, 2003; IFIC, 2003) and some quantitative data (Derby and Levy, 2000; Levy, 2004; Lin, 2004) indicate that not all consumers pay enough attention to calorie information in the NFP. Nevertheless, given the fact that obesity, at its most fundamental level, is a direct function of caloric imbalance, the OWG believes that "calories count" must be the focus for its recommendations. Accordingly, in relation to messages, the OWG recommends the development and testing of messages tied to this focus.

IV. Education Program to Deliver the Message

Education Recommendation Highlight:

- ***Establish partnerships to educate Americans about obesity and leading healthier lives through better nutrition… p. 13***

The Commissioner directed the OWG to outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent chronic diseases associated with it.

A. Need for Education Programs

Consumer perceptions regarding weight and dietary habits are significant in the fight against the obesity epidemic. Consumers who are not aware of their own weight status and its medical implications are unlikely to be receptive to public health efforts to alleviate obesity. This point extends to parental perceptions of children's weight status and dietary habits as well, given that parents have significant influence over their children's environment, habits, and health. Lack of knowledge about weight status and its health implications undermine consumers' "promise" or motivation, a key component of messaging; therefore the OWG identified education as a critical adjunct to effective messaging about caloric balance.

Recent focus group studies conducted by the International Food Information Council (IFIC)[12] suggest that consumers distinguish between "overweight" and "obesity," and consider the first to be of relatively little health significance (IFIC, 2003). Therefore, consumers who consider themselves to be merely "overweight" may have less incentive to take action. There is also evidence to suggest that both adults (Kuchler and Variyam, 2003) and teenagers (Kant, 2002) misperceive their weight status, although the form of misperception can vary with gender, socioeconomic status, age and race and ethnicity. For example, men were found to be more likely than women to underestimate the level of their weight status; healthy or underweight women were more likely to consider themselves overweight. Lower income and education were also associated with underassessment of weight status; higher income and education levels were linked to overestimation of weight status. Parents also appear prone to misjudge their children's weight status and its health significance (Borra *et al.*, 2003; Contento *et al.*, 2003; Maynard *et al.*, 2003). Many parents with overweight children consider their children to be at a healthy weight. In some cases this may be due to cultural perceptions of appropriate weight (Bruss *et al.*, 2003; Contento *et al.*, 2003). In some cases where parents do accurately judge their children's weight status, they may believe that the child will outgrow their overweight or obese status and, therefore, be less likely to take action.

Consumers may have difficulty accurately assessing the nutritional quality of their diet. Although consumers report in focus group studies that they understand what comprises a healthy diet (IFIC, 2003), approximately 40 percent of one sample (almost 3000 household meal preparers drawn from USDA 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) data) perceived the quality of their diets to be better than the calculated diet quality (Variyam *et al.*, 2001). Parents, in particular, do not always have a clear picture of their children's diets. In a recent series of focus groups and phone/Internet surveys conducted by the American Dietetic Association Foundation (Moag-Stahlberg *et al.*, 2003), parents significantly underestimated the frequency with which children ate outside of regular mealtimes, such as after

[12] IFIC states that its mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, government officials and others providing information to consumers. IFIC states that its purpose is to bridge the gap between science and communications by collecting and disseminating scientific information on food safety, nutrition and health and by working with an extensive roster of scientific experts and through partnerships to help translate research into understandable and useful information for opinion leaders and ultimately, consumers. IFIC is supported primarily by the food, beverage and agricultural industries.

dinner and while engaged in sedentary activities like television viewing. A recent report by the Kaiser Family Foundation discusses the role of media in childhood obesity (KFF, 2004).

Qualitative research by Borra and colleagues (Borra *et al.*, 2003) also suggests that children (aged 8-12 years) give little thought to good health, although they associate achieving "good health" with what they eat, rather than with physical activity. For many of the children involved in the research by Borra and colleagues, the term "healthy" had negative connotations; for example, it meant having to eat fruits and vegetables they did not like or not eating their favorite foods. In terms of weight, children between 8 and 10, regardless of their own weight, did not think about food choices. Equally disturbing, some 11-12 year olds who were overweight said they tried to lose weight by skipping meals, rather than by eating differently. Among a group of children perceived to be above normal weight for their age, Borra and colleagues found that although the children knew it was important to eat healthfully because their parents stressed it at home and they learned about nutrition in school, this teaching provided little useful information for the children.

These qualitative findings are supported by a recent unpublished survey conducted for the nonprofit Dole Nutrition Institute of more than 6,000 children between grades 1-8 in 194 classrooms (Dole, 2003). The responses to survey questions "What is obesity?" and "Which statement is true [about being overweight]?" indicate that many children seem to have either misperceptions or are misinformed about (1) the meaning of obesity and (2) the value of exercise in preventing or mitigating health problems due to overweight.

B. OWG Education Recommendations

The OWG recommends that FDA focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy choices for consumers. Any such efforts will require a long-term agency commitment. Education programs should help consumers make more informed food choices that result in better weight management; should direct messages to large audiences on a frequent basis; and should be crafted to reach a variety of audiences.

The OWG recommends that FDA implement education programs incrementally and design them to be flexible enough to take into account new research findings and policy decisions and possible changes in the food label (e.g., revisions to the content or format of the NFP). Education efforts, however, should not be delayed pending such changes. Education programs should be simple to understand and apply, and should focus on showing consumers how to achieve a specific goal.

Given the resources and time that FDA would need to develop and implement new education programs for multiple subpopulations, the OWG recommends that FDA, as part of a larger DHHS initiative, establish relationships with private and public sector partners for educational outreach. Such efforts will have the ability to reach larger and more diverse audiences on a more frequent basis, and will enable calorie-focused education campaigns to begin more quickly. Given the prevalence of obesity among children, establishing relationships with youth oriented organizations is especially important. For this reason, the following partnerships are being pursued as a part of a larger DHHS initiative:

- **Girl Scouts of the USA:** FDA and Girl Scouts of the USA seek to launch an initiative entitled "Healthy Living." Building on current Girl Scout resources and programs, the initiative will provide girls and their families with the skills, knowledge, and support needed to make healthier food choices, engage in physical activity, build self-esteem, and maintain a healthier lifestyle. This initiative includes developing a charm of the food label as a part of the Studio B teen collection.
- **National Association of State Universities and Land Grant Colleges (4-H program):** Youth health and obesity is one of three strategic priorities for 4-H Youth Development. FDA envisions a partnership that will use 4-H for targeted population evaluation of obesity/nutrition message(s), and use the 4-H network of over 3,500 professional Cooperative Extension programs across the United States for education and delivery of the message(s).

In addition, FDA, along with other components of DHHS, is participating in the "Shaping America's Youth" initiative to identify actions being taken to address childhood and adolescent inactivity and excess weight. Information collected for this initiative in an on-line survey will be used by "Shaping America's Youth" to prepare a report that provides an overview of current public and private programs that target physical activity and nutrition in our nation's children. As of the date of this report, Shaping America's Youth has registered over 1950 programs directed at the childhood obesity issue, collected surveys of funding and tactical information from over 1150 organizations and entities, and assembled nearly 800 fully completed in-depth surveys from programs representing all 50 states and the District of Columbia.

Public sector partnerships should have the goal of developing programs similar to the "Power of Choice" program FDA developed with the USDA, which teaches children who are 11-13 years of age how to make smart food and physical activity choices in real-life settings. Learning how to use the NFP to make healthy food decisions is a major skill throughout the "Power of Choice" program (see Appendix I for additional information about "Power of Choice"). One way to help better ensure collaboration and cooperation with our public health partners is for FDA to coordinate its messages and educational material with those of its partners.

- **Centers for Disease Control and Prevention:** FDA is pursuing a collaboration between the agency and the CDC to develop a holistic approach to healthy living for children that will enable the FDA to meld a caloric intake message with a CDC caloric output message on physical activity.

- **Department of Education**: FDA has made preliminary contact with the Department of Education to join in supporting programs that target school-age children.
- **Department of Agriculture:** FDA plans to work through DHHS with counterparts at USDA to ensure that the agency's focus on calories is considered as USDA revises its Food Stamp Program/WIC (Women, Infants, and Children) programs and its Food Guide Pyramid, and as DHHS and USDA collectively revise the *Dietary Guidelines for Americans*.

The OWG recommends that FDA work through a facilitator to establish a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on the needs of children. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

V. Supporting the Message

It is important to support any message(s) through appropriate actions and policies where the "calories count" focus is likely to have an impact on consumer knowledge, behavior, and/or treatment (i.e., food labels, restaurants, therapeutics, and research).

A. Food Labels

Food Labeling Recommendation Highlights:

- ***Calories:***
  - ***Issue an ANPRM to solicit public comment on how to give more prominence to calories on the food label...p. 19***
  - ***Consider authorizing a health claim on "reduced" or "low" calorie foods...p. 19***
  - ***Issue an ANPRM about serving sizes...p. 20***
- ***Serving Sizes:***
  - ***Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire contents can reasonably be consumed at a single-eating occasion...p. 19***
  - ***Highlight enforcement of serving sizes in FDA's food labeling compliance program and consider enforcement action against products that declare inaccurate serving sizes...p. 20***
- ***Carbohydrates:***
  - ***File petitions and publish a proposed rule to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods...p. 21***
- ***Comparative Labeling Statements:***
  - ***Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt – 29 percent fewer calories and 86 percent less fat")...p. 23***

The Commissioner directed the OWG to "develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity."

1. The Food Label

The Act, as amended by the NLEA, and FDA's implementing regulations require an NFP on the label of most packaged foods. The NFP lists the serving size, the number of servings per container, the number of calories per serving and the amount and %DV[13] per serving for specified nutrients.

[13] The %DV indicates the amount of a nutrient present in a serving in relation to reference levels for a daily diet. The reference levels for vitamins and minerals are based on Recommended Dietary Allowances established by the National Academies; the reference levels for macronutrients are based on recommendations in the *Dietary Guidelines for Americans* or as established by public health organizations. For macronutrients whose recommended intake levels are based on caloric intake (e.g., saturated fat intake should be less than 10% of calories), the %DV is calculated for a 2,000 calorie diet.

Before recommending any changes in the NFP relevant to obesity, it is important to understand how consumers currently use the NFP and to assess whether the NFP has been effective in facilitating positive dietary change. Research shows that most consumers are familiar with the nutrition information on food labels (Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001; FDA, 2003), which they use primarily for evaluating the nutrition quality of specific food products, but the percentage of consumers who use NFP information productively for weight management purposes is low (Barone *et al.*, 1996; FMI, 1996; Ford *et al.*, 1996; Levy *et al.*, 1996; Mitra *et al.*, 1999; Roe *et al.*, 1999; Garretson and Burton, 2000; Levy *et al.*, 2000; IOM, 2003; FDA, 2003) (e.g., see Table 1 below).

Table 1. Recent Trends in Reported Food Label Use: 1994-2002 HDS Surveys (Derby and Levy, 2000; Levy, 2004; Lin, 2004)

	1994	**1995**	**2002**
Sample size (N)	(1,945)	(1,001)	(2,743)
	% population (weighted)	**% population** (weighted)	**%population** (weighted)
(1) Percent who use food labels "often" or "sometimes" when buying a food product for the first time			
How often do you read the food label?	70	69	69
(2) Percent who use labels "often" for specific purposes[1]			
To figure out how much to eat	34	40	35
To see if food is high or low in calories, salt, vitamins, fat, etc.	77	83	67
To help in meal planning	34	36	32
(3) Percent who use specific label information "often"[2]			
Do you use the serving size information, when available?	29	26	Not Asked

[1] Based only on label users who "often" or "sometimes" use labels when they buy a food product for the first time.
[2] Based on all respondents.

Associations between dietary behavior and food label use have also been identified, although the body of literature is relatively small (IOM, 2003). A low-fat diet, for example, has been positively correlated with food label use, both in the general population and among family clinic patients. Clinic patients with health conditions (e.g., high blood pressure or high cholesterol) as well as consumers who are in action or maintenance stages of dietary change were also more likely to use the food label (Kreuter *et al.*, 1997; Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001). In addition, label claims (e.g., low sodium and low fat) may allow consumers to avoid specific ingredients or make food substitutions (Balasubramanian and Cole, 2002), resulting in changes to dietary patterns. Kim and coworkers (Kim *et al.*, 2001) analyzed data from the USDA's CSFII and the Diet and Health Knowledge Survey. Their findings

indicate that food label use is positively correlated with measurable increases in the Healthy Eating Index (Kim *et al.*, 2001).[14]

Despite reports of a positive correlation between label use and certain positive dietary characteristics, the trend toward obesity has accelerated over the past decade. It may be that consumers do not take advantage of the available information on the food label to control their weight, perhaps because they do not appreciate how the information could be used for weight management purposes or perhaps because they find it too hard to apply the available information to such purposes. In any case, it is clear that consumers would benefit if they were to pay more attention to and make better use of information, including calories, on food labels. Providing encouragement and making it as easy as possible for consumers to do so are worthy public health objectives.

2. FDA Focus Groups on Food Labels

As described in Box 2, FDA recently conducted focus group research in which it asked general nutrition questions as well as how consumers use the nutrition information on food labels.

The questions covered under general nutrition dealt with three topics: (1) attitudes towards nutrition; (2) macronutrients; and (3) %DV. Those covered under food label modification dealt with six topics: (1) large package sizes; (2) serving versus package; (3) calorie-related variations; (4) serving size variations; (5) calorie cues; and (6) "healthier" symbol. For additional information on FDA's focus group findings, see Appendix G.

Attitudes towards nutrition. In many of the groups, especially the women's groups, participants cared about nutrition and report using the NFP. At the same time, however, many also said that they do not always consider nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. Although participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium. Many participants reported not wanting to spend a lot of time reading labels.

Macronutrients. In general, individual participants tended to care more about some macronutrients than others, depending on their individual dietary practices. In most groups, at least one participant was familiar with the Atkins diet and many of these participants were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some participants checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.

%DV. Very few participants reported using the %DV column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to them since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a

[14] USDA's Healthy Eating Index is a summary measure of overall diet quality. It provides a picture of the type and quantity of foods people eat and the degree to which diets comply with specific recommendations in the *Dietary Guidelines for Americans* and USDA's Food Guide Pyramid. For further information go to http://www.usda.gov/cnpp/healthyeating.html

good way to estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Large package sizes. In all the groups, participants were presented with a mock-up label of a 20 ounce soda and a large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving listed.

Serving versus package. In general, participants thought it was misleading to list either product as having more than one serving. Many participants did realize that if the entire package is eaten, the number of servings should be multiplied by the amount of the nutrient of interest, though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

Calorie-related variations. The first test label added a %DV for calories, removed the *calories from fat* line, enlarged the calories line, and changed the way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most participants did not think it was an improvement over the existing language.

Serving size variations. The second test label had two %DV columns on the NFP, one for a specified serving size and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the specified serving size. After comments from these groups, the label was modified to have the absolute amount for both the specified serving size and the entire product. Participants reacted positively to this modification, but some thought it was not necessary to list the amount for a specified serving size.

Calorie cues. Both a "starburst" with the calories per serving and a white square with calories per whole product on the package's PDP were tested. Many participants thought that the starburst was misleading because they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product got mixed reactions, but many participants just said that they recognized these as high calorie products and would stay away from them.

"Healthier" symbol. Half of the groups tested a "healthy" meat lasagna with a purple keyhole symbol on the PDP. There was generally positive reaction to including a front-of-package symbol indicating that a product was "healthy," as long as participants understood the definition of the symbol and could trust that it was true. Participants believed that they would have to be educated as to the meaning of such a symbol. Some participants mentioned that they would look for the symbol when they were in a hurry in the store. They expressed some concern that these products would cost more or that they would lack in taste.

3. OWG Food Label Recommendations

The OWG recommends that FDA (1) develop options for revising or adding caloric and other nutritional information on food packaging (examples provided below); (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake; and (3) evaluate this information to make evidence-based decisions on which option(s) to pursue.

a. Calories and Serving Sizes

In light of the critical importance of caloric balance in relation to overweight and obesity, the OWG recommends that FDA: (1) solicit comment on how to give more prominence to calories on the food label; (2) consider authorizing a health claim on "reduced" or "low" calorie foods; and (3) reexamine the agency's regulations about serving size.

Solicit comments on how to give more prominence to calories on the food label. Many of the written and public comments submitted to the agency suggested that FDA develop ways to emphasize calories on the food label. To address this, the OWG recommends that FDA publish an ANPRM requesting comments on how best to give more prominence to calories. Possible changes to the NFP include: (1) increasing the font size for calories; (2) providing for a %DV for calories; (3) eliminating "calories from fat" listing as this takes the emphasis away from "total calories;" and (4) increasing the font size for serving size in order to give it more prominence.

Consider authorizing a health claim on "reduced" or "low" calorie foods. A number of comments submitted to the agency, including those from the FTC, suggested that FDA permit health claims on reduced calorie foods as a way to reduce the risk of certain chronic diseases associated with obesity, such as diabetes, coronary heart disease and cancer. To address this suggestion, the OWG recommends that FDA publish an ANPRM on whether to allow a health claim such as "Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease, and certain cancers" on certain foods that meet FDA's definition of "reduced" or "low" calorie. In addition, the OWG recommends that FDA encourage manufacturers to use dietary guidance statements (e.g., "to manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; and as a snack have an apple rather than a serving of potato chips").

Reexamine the agency's regulations on serving sizes. The comments that FDA has received at its public meetings and to the docket (including comments from the FTC) express concern about the serving sizes used in nutrition labeling, particularly on packaged products that can readily be consumed at one occasion but that indicate they represent more than one serving. To address this issue, the OWG recommends the following:

- In the short-term, that FDA encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes (21 CFR 101.9(b)(6)) that allows food packages to be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

- In the long-term, that FDA develop two separate ANPRMs. The first would solicit comment on whether to require additional columns within the nutrition label to list the quantitative amounts and %DV of the entire package on those products and package sizes that can reasonably be consumed at one eating occasion or, alternatively, declare the whole package as a single serving. This ANPRM would also solicit information on products and package sizes that can reasonably be consumed at one eating occasion. The second ANPRM would solicit comments on which, if any, RACCs of food categories appear to have changed the most over the past decade and therefore need to be updated.

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. By statute, the serving size is to be based on the "amount [of the food] customarily consumed" (section 403 of the Act). Accordingly, when implementing NLEA, FDA reviewed food consumption data obtained from USDA's 1977-78 and 1987-88 Nationwide Food Consumption Surveys and, based on the results of that review, established RACCs for 139 food categories (58 FR 2229, January 6, 1993). Inasmuch as there is evidence that Americans are eating larger portions than they did in the 1970s and 1980s, the OWG recommends that FDA determine whether and, if so, how to update RACCs.

The accuracy of the information in the NFP is crucial for consumers who use this information to monitor their intake of calories and nutrients. Current enforcement efforts targeted at the NFP as described in FDA's Food Labeling Compliance Program[15] are directed at ensuring that actual nutrient levels are within 20% of declared values. More limited resources have been directed at ensuring that serving sizes are calculated and declared accurately. Comments and other information submitted to FDA express concern about the inaccuracy of serving size declarations used in nutrition labeling and reiterate the importance of accurate serving size declarations because all of the information on nutrient levels is dependent upon the amount of the product represented. To address this issue, the OWG recommends that FDA highlight enforcement of serving sizes in the Food Labeling Compliance Program by April 2004, and consider enforcement activities against those products that declare inaccurate serving sizes.

b. Carbohydrate[16] Labeling

Today there is increasing interest in low carbohydrate diets (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value in Appendix B). FDA has recently received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. Claims for carbohydrate content of foods have become increasingly common in the marketplace while, at the same time, the level of carbohydrates in foods marketed under the various carbohydrate claims appears to vary widely. In order to ensure that terms are consistently defined and that carbohydrate claims are not false or misleading, the

[15] The Food Labeling Compliance Program gives instructions to FDA Field Offices that describes food labeling enforcement strategies and identifies/highlights specific areas where resources should be targeted with regard to the accuracy of the food label.(currently on the Internet at: http://www.cfsan.fda.gov/~comm/cp21008.html)

[16] For a further discussion on carbohydrates, see *Dietary Reference Intakes* – Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 1, Chapter 6 Dietary Carbohydrates: Sugars and Starches 6:1-57 (Institute of Medicine of the National Academies, 2002) and references cited therein.

OWG recommends that FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

c. Other Labeling Issues

The OWG considered comments from the FTC on the issues of (1) reduced/fewer calorie comparisons, (2) comparison to food of different portion size, (3) comparison to food of different product type, and (4) disclosure requirements for comparative claims.

Reduced/fewer calorie comparisons. The underlying principle for FDA's regulation is that reductions be **significant** compared to the reference food (21 CFR 101.60(b)(4). FDA determined that percentage reductions less than 25% were too small to be meaningful because of normal product variability. Such variability may be caused by factors such as: natural nutrient variability of the food due to season of the year, soil type, variety, and weather conditions; variability in processing; rounding rules (e.g., rounding to the nearest 5 calories up to 50 calories and to the nearest 10 calories above 50 calories); analytical variance (ranging from +/- 3-4% to +/- 30 % with an average variance of about +/- 15%); sampling procedures; and shelf life and stability of nutrients in the product.

As a result, 21 CFR 101.9(g) allows for a 20% excess in the actual (analytical) nutrient content of calories, sugars, total fat, saturated fat, cholesterol or sodium of a product compared to the declared nutrient values for that product (and consequently the qualifying values for nutrient content claims) before the food is considered to be misbranded. Therefore, nutrient reductions less than 25% are virtually within the allowable product variability and are not considered significant. The minimum absolute reduction (e.g., equivalent to the value of "low") was changed to permit claims compared to reference foods that were not already "low" in the nutrient because it was the agency's conclusion that benefits derived from several servings of nutritionally modified nutrient dense foods over a day could have a significant impact provided that the reduction was significant, i.e., 25 % or more. FDA further concluded foods already "low" in that nutrient were below the level at which the amount of nutrient in the food becomes significant relative to the total diet and therefore should not be used as reference foods.

For relative claims, the OWG notes that the Codex Alimentarius Commission[17] requires that there be a difference of at least 25% in energy value or nutrient content (except for micronutrients where a 10% difference in the nutrient reference value would be acceptable) with a minimum difference between the compared foods equivalent to a "low" value (FDA's proposed requirements for "less"). Moreover, Canada requires that comparative claims be based on differences which are both nutritionally and analytically significant.[18] Canadian regulations consider reductions of less than 25% from the reference value to be of questionable nutritional significance. Canada does not allow claims on reductions of less than 25%.

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[17] Guidelines for Use of Nutrition Claims (CAC/GL 23-1997).
[18] Guide to Food Labeling and Advertising. Section VI. Nutrient Content Claims 6.1.9(c).

The OWG recommends the agency be receptive to such a claim, if the proponent of such a claim is able to provide data and information to substantiate that:

1. The claim is not misleading due to the known variations in food composition and analytical methods, and
2. The claimed reductions are nutritionally significant.

Comparison to food of different portion size. FTC has suggested that FDA consider "allowing food marketers to make truthful non-misleading label claims comparing foods of different portion sizes." FTC provided the example of a 10 oz chicken and rice casserole labeled as having 33 percent fewer calories than 15 oz. of the same chicken and rice casserole.

Consuming a smaller portion size of the same food simply decreases caloric consumption proportionally. To enable consumers to make meaningful comparisons for calorie reduction, FDA requires such claims to be based on the amount per RACCs, or per 100 gram in the case of meal-type products. Thus, under FDA's current regulations (21 CFR 101.60(b)), a comparative calorie claim of the type that FTC proposes would not be allowed.

Nevertheless, using the food label to promote consumption of smaller portions may have merit. This is especially true if consumers understand that (a) the calorie reduction is solely a function of the reduction in portion size, and (b) that the smaller portion size is actually less than what they usually consume. Thus, the OWG recommends that FDA issue an ANPRM to solicit comments on truthful non-misleading and useful approaches for promoting consumption of smaller portion sizes, including FTC's suggestion.

Comparison to food of different product type (which the OWG refers to as comparative labeling statements). FTC suggests that FDA "consider allowing food companies to make label claims that compare the calories of foods [across] different product categories." FTC points out that switching from one category to another category often can be an effective means of reducing calories, such as substituting carrot sticks for potato chips or fruit for cookies. FTC notes that comparative caloric claims across categories could help consumers make these healthy substitutions. FTC offered as an example, "instead of cherry pie, try our delicious low fat cherry yogurt – 29 percent fewer calories and 86 percent less fat."[19]

Current FDA regulations do in fact permit certain comparative claims. In addition to the example that FTC provided, the OWG offers the following as examples of comparative claims that are permissible under current regulations:

- One medium apple (80 calories) contains 47% fewer calories than a one ounce serving of potato chips (150 calories).
- Carrots have 93% fewer calories than carrot cake. One 7-inch carrot (78 g) contains 35 calories while one slice of carrot cake with icing (125 g) contains 500 calories.

[19] This example also contains an express nutrient content claim ("try our delicious low fat yogurt"), and two relative claims ("29 percent fewer calories" and "86 percent less fat"). Hence, the statement, as written, would need to meet the regulatory requirements for these types of claims, and would also need to provide serving size information that would allow for appropriate comparison between the cherry pie and the cherry yogurt.

- Air-popped popcorn (without added toppings) contains one-half the calories of a plain granola bar (98 calories per 3-cup serving of popcorn, 200 calories per 1.5 ounce granola bar).

The OWG recommends that FDA encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories. Such comparisons provide valuable information that can be used in making food choices. Moreover, there is a flexible standard for product categories that is intended to facilitate useful comparisons for foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims (58 FR 2302 at 2363, January 6, 1993). Manufacturers have to use judgment in developing claims to ensure that the claims comply with the regulations and are not false or misleading under section 403(a) of the Act.

Disclosure requirements for comparative claims. FTC suggests that FDA "evaluate whether unnecessarily cumbersome disclosure requirements have deterred truthful, non-misleading comparative label claims for foods." As always, FDA is open to dialogue on such an issue, particularly when a proposal is supported by relevant data and information.

To make a comparative nutrient claim, a food marketer must provide information on the reference food, the percentage by which the nutrient in the reference food has been changed, and the absolute amount of the nutrient in the labeled and reference food (21 CFR 101.13(j)(2)). The agency, however, is not wholly prescriptive as to the actual words used or where all the information is placed on the label.

FTC offered as an example, a baked potato chip that is lower in both calories and fat than a regular potato chip, and indicated that label claims explaining the benefits would be awkward to place (and read) on the front panel. According to FTC, under FDA regulations, the claim would read as follows (italicized phrases may be placed on the back nutrition label):

> "Reduced fat and fewer calories than our Classic Potato Chips. Fat reduced by 85 percent, *from 10 grams per ounce to 1.5 grams per ounce*. Calories reduced by 27 percent, *from 150 calories per ounce to 110 calories per ounce*."

The OWG notes that the FTC example could be more succinct. As FTC suggests, more than 50% of the text may be placed on the back nutrition label. Beyond that, under FDA's current regulations (21 CFR 101.13(j)), the PDP could simply read:

> 85% less fat and 27% fewer calories than our Classic Potato Chips.

B. Restaurants/Industry

Restaurants/Industry Recommendation Highlights:

- ***Short-term***
  - ***Urge restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers...p. 26***
  - ***Encourage consumers routinely to request nutrition information in restaurants...p.26***
- ***Long-term***
  - ***Development of a series of options for providing voluntary, standardized, simple, and understandable nutrition information, including calorie information, at the point-of-sale to consumers in restaurants...p. 27***
    - ***FDA to seek participating restaurants for a pilot program to study these options in well controlled studies...p. 27***
    - ***FDA to provide incentives, if necessary, for voluntary industry participation in the pilot program...p. 27***
    - ***FDA to evaluate results of the pilot program to determine whether further research is warranted before such a program is implemented on a large scale...p. 27***
  - ***Exploration of the concept of third-party certification of weight-loss diet plans and related products...p. 28***
- ***Enforcement***
  - ***Together with the FTC, increase enforcement against weight loss products having false or misleading claims...p. 29***

The Commissioner directed the OWG to "develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers."

In light of the growing proportion of American meals consumed outside of the home, it is important to enlist the assistance and support of restaurants in addressing population obesity. Since the late 1990s and projecting through 2004, American households are spending approximately 46 percent of their total food budget on food consumed outside the home (ERS, 2003; NRA 2004). During 1994-1996, food consumed outside the home, especially from restaurants and quickservice food establishments, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS, 2000). Thus, food consumed away-from-home is an important part of American diets and more informed dietary choices away-from-home could help reduce calorie over-consumption and the risk of obesity and its associated health problems.

The distribution of meal sources has also shifted over the past few decades, and this shift may be another significant factor in weight gain. Food consumed outside the home has increased from approximately 33 percent of U.S. consumers' food budget in 1970 to approximately 47 percent as of 2002 (ERS, 2003; Young and Nestle, 2002). Over a similar period, total calories from food consumed outside the home, especially from quickservice restaurants, increased from 18 percent to 32 percent. In addition, food consumed outside the home was higher per meal in calories, total fat and saturated fat, as well as was lower in fiber, calcium and iron on a per-calorie basis (Guthrie *et al.*, 2002).

As noted above, under the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet; rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale.

1. FDA Focus Groups on Restaurants

As described in Box 2, FDA recently conducted focus group research in which it asked questions about what type of nutrition information participants would like to see in quickservice restaurants. Participants discussed and reacted to various presentations of nutrition information at restaurants. The questions dealt with four topics: (1) nutrition information; (2) menu board information; (3) menu board section; and (4) "healthier" symbol. For additional information on FDA's focus groups, see Appendix G.

Nutrition information. Most participants seemed interested in having nutrition information available to them when they eat at fast food and/or quickservice restaurants, though they might not use it every time they eat out. Participants suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.

Menu board information. Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, participants liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. Although participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many of them. Participants thought that calories could be a signal for the level of other macronutrients.

Menu board section. Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.

"Healthier" symbol. Many participants also reacted favorably to a purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well.

Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

2. OWG Restaurant Recommendations

The OWG recommends that FDA encourage restaurants to provide more, and more readily available, nutrient content information at the point-of-sale. The restaurant industry has voiced concern that requiring nutrition labeling for all menu items is infeasible because recipes change frequently, and patrons often request customization of their meals and the number of options available for customization is large. For example, recent National Restaurant Association research indicates that 70% of consumers customize their meals when eating in restaurants.[20] Nevertheless, the OWG believes that the restaurant industry could provide some level of nutrition information to its patrons to enhance their ability to make wise food choices. Calculating nutrition information may have been a difficult task for most members of this industry in the past, when such information had to be determined by direct chemical analysis. This task, however, is easier today because nutrient composition databases and software for labeling are readily available. Possibilities for providing nutrition information to consumers include: segregating "healthier" menu items with simple nutrition information in a separate section of the menu; providing icons for individual "healthier" menu items; and presenting nutrition information in locations in the restaurant where patrons can readily use it (i.e., at the point-of-sale).

The OWG also recommends that FDA encourage consumers routinely to request nutrition information in restaurants. Because restaurants respond to consumer demand (as evidenced by comments made by members of the restaurant panel at the November 20, 2003, workshop), such demand may help create an impetus for more restaurants to provide such information.

The OWG believes that there is a need for research to determine the best way(s) to present nutrient content information to consumers so that they will make healthier choices when eating food away from home. The OWG recognizes, however, that such research will take a substantial period to plan and complete. In the interim, the pervasiveness of the obesity epidemic means that more nutrition information must be presented to consumers in restaurant settings. Accordingly, the OWG has developed both short-term and long-term recommendations

The OWG recommends that in the short-term, FDA urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for customers.

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[20] From remarks by Hudson Riehle of the National Restaurant Association at the November 20, 2003, workshop "Exploring the Connections Between Weight Management and Food Labels and Packaging" (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

Over the long-term, the OWG recommends that:

> *(1) Options be developed for providing voluntary standardized, simple, and understandable nutritional information, including calorie information, at the point-of-sale in a restaurant setting.*

Ideally these options should focus on the caloric content and nutritional composition of complete meals rather than individual menu items. Although a focus on total calories is the most useful single piece of information in relation to managing weight, additional information on nutrient content of the meal is also important. This is true, for example, for people with diabetes or coronary heart disease who need to more carefully control their consumption of certain nutrients (e.g., carbohydrates, sodium, fat). An alternative to listing detailed numeric information is to use a graphical representation that conveys the same information using a picture or symbol.

> *(2) FDA seek participating restaurants for a pilot program to study these options in well controlled studies.*

The number of restaurants participating in the pilot program should be large enough to include a variety of locations, cuisines, and average price of menu items. The pilot program needs to be long enough to account for any time required to understand the new menu formats and nutrition information. Participating restaurants would need to provide item-by-item sales data before, during, and after the pilot. Experimental economics methods could substitute partly but not wholly for actual market data to assess the impact of various labeling options on consumer behavior.

FDA could also use this pilot program to explore engaging the restaurant industry as a powerful distribution system for the agency's messages on obesity and its education programs.

> *(3) FDA provide incentives, if necessary, for voluntary industry participation in the pilot program.*

Such incentives could include allowing restaurants to use FDA's name to promote the pilot in advertising, on stickers, and on their menus; and/or coupling the pilot program with an overall FDA education campaign, which may include space on restaurant menus or on separate handouts for FDA messages on healthy lifestyles.

> *(4) FDA evaluate results of the pilot program.*

FDA would need to analyze the results of any pilot program to determine whether further research is warranted before such a program is implemented on a large scale.

In order to pursue these more long-term recommendations, the OWG recommends that FDA work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on food consumed away from home. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

3. OWG Weight-Loss Diet Plan Recommendations

Just as consumers spend a significant amount of money for foods consumed outside the home, they spend substantial sums on weight-loss diet plans and diet-related products. Such plans and products have the potential to affect all food choices by at least some consumers. The long-term weight or health effects of these and other weight control measures remains unclear (Connors and Melcher, 1993; Ayyad and Andersen, 2000; Saris, 2001; Anderson, *et al.*, 2001; and Phelan, *et al.*, 2003). This raises the question of whether consumers who follow these plans and buy these products understand the health implications, particularly the systematic difficulties of long-term weight management. For these reasons, the OWG also considered the health consequences of using weight-loss diet plans and related products. The OWG concluded that, in the long-term, research needs to be done outside of FDA to determine whether claims for such diet plans and related products have been or can be substantiated. Thus, the OWG recommends that there be an exploration of the concept of third party certification of weight-loss diet plans and related products. The goal is to improve consumer information about the health consequences of their overall dietary choices.

With respect to diet-related products, on December 18, 2002, FDA announced a significant enforcement initiative targeted at misleading claims about dietary supplement-associated health benefits. Dietary supplements are used by an estimated 158 million Americans, and so misleading claims about their health benefits may have significant consequences – not only for wasting consumers' money but also for luring consumers interested in improving their health in wrong directions. Although FDA's enforcement goals related to truthful and non-misleading statements about health benefits apply to all of the products the agency regulates, this initiative was especially focused on products that in recent years have been the subject of important misrepresentation.

As part of the December 18 announcement, FDA released the "Dietary Supplement Enforcement Report" that pledged to closely scrutinize and bring enforcement actions against products identified as "clearly problematic." Dietary supplements that falsely claim effectiveness as treatments for overweight were included among those identified as "clearly problematic."

CFSAN and the Office of Regulatory Affairs have focused their dietary supplement enforcement budgets principally on targeted inspections and, where appropriate, recommending enforcement action against parties who violate the Dietary Supplement Health and Education Act (DSHEA). In terms of the strategies used to enforce DSHEA, FDA has proceeded on several fronts: (1) traditional enforcement activities (e.g., inspections, warning letters, seizures and injunctions, criminal enforcement); (2) inter-agency and international enforcement; and (3) consumer and industry education.

More recently, in December 2003, FTC staff released a report, *Deception in Weight-loss Advertising Workshop: Seizing Opportunities and Building partnerships to Stop Weight-Loss Fraud* (FTC, 2003). This FTC staff report lays out a number of opportunities for industry and media to assume a leadership role in addressing deceptive weight loss advertising. To

complement these efforts, the OWG recommends that FDA continue its enforcement initiative targeted at misleading claims about dietary supplement weight loss products.

C. Therapeutics

Therapeutics Recommendation Highlights:

- ***Convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity...p. 30***
- ***Continue discussions with pharmaceutical and medical device sponsors about development of new obesity therapies...p. 31***
- ***Revise 1996 draft guidance on developing obesity drugs and re-issue for comment...p. 31***

The Commissioner directed the OWG to "develop an approach for facilitating the development of therapeutics for the treatment of obesity."

The role of obesity in many acute and chronic diseases is well documented. The contribution of obesity to premature mortality through increased risks of diabetes, heart disease, stroke, and cancer, among others, mandates an aggressive, proactive stance by the entire medical community.

1. Background

Modern medicine's experience with weight loss drugs dates to the late nineteenth century when initial enthusiasm for the weight loss properties of thyroid extract were eventually tempered by the negative effects that iatrogenic hyperthyroidism had on lean muscle mass, bone, the central nervous system (CNS), and cardiac function (Schwartz, 1986; Bray, 1976). The next century of obesity drug development saw the introduction of a number of drugs that proved to have significant side effects: Dinitrophenol (cataracts, neuropathy) in 1934; Amphetamine (addiction, CNS and cardiac toxicity) in 1937; Rainbow pills, or digitalis and diuretics (cardiac arrest) in 1967; Aminorex (pulmonary hypertension) in 1971; and Redux (cardiac valvulopathy) in 1996 (Bray and Greenway, 1999).

Prior to 1996, all approved obesity drugs were labeled for short-term treatment of obesity based on pre-approval clinical trials of up to 12 weeks' duration and of limited size by today's standards. Over the past 10-15 years, increasing recognition of several facts have led to changes in the approach to the treatment of obesity and thus to the study of new drugs for this condition: (1) obesity is a chronic condition with long-term morbid and mortal sequelae; (2) maintenance of weight loss, even while on continued drug therapy (and certainly after discontinuation of drugs) is the rare exception rather than the rule; and (3) maintenance of a "healthy" weight (rather than weight "cycling") is the key to reduced risk for obesity-associated adverse sequelae.

2. FDA's Draft Guidance

In 1996, FDA issued draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs." The draft guidance gives recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the effectiveness and safety of weight-loss medications.[21] This guidance proposed two alternative criteria for effectiveness for drug therapies:

- Mean weight loss in the drug-treated group is 5% greater than the mean weight loss in the placebo group following one year of treatment.
- The proportion of patients that lose at least 5% of their baseline weight is greater in the drug vs. the placebo group.

3. Existing Therapies

Under the criteria in the 1996 draft guidance, three drugs have been approved for the long-term treatment of obesity: dexfenfluramine (Redux) in 1996 (withdrawn in 1997 for safety reasons), sibutramine (Meridia) in 1997, and orlistat (Xenical) in 1999. In addition, a number of drugs were approved prior to 1996 for the short-term (e.g., a few weeks) treatment of obesity (e.g., phentermine (Adipex) and diethylpropion (Tenuate)).

FDA-approved drugs for the long and short-term treatment of obesity are indicated for use by those patients with: (1) a body mass index of > 27 kg/m^2 when accompanied by obesity-related comorbidities such as hypertension, diabetes, and dyslipidmeia; or (2) a body mass index > 30 kg/m^2.

For patients with extreme obesity (those with BMIs at or over 40), for whom no other measures have been effective in promoting weight loss, surgical or device-mediated gastroplasty is increasingly employed. Worldwide, over 100,000 of these devices have been implanted over the past 8 years. In the United States alone, tens of thousands of devices are implanted each year to restrict the size of the stomach and thus severely limit food intake. Despite serious complications, gastroplasty procedures as well as device implantations are effective for some individuals, with average durable loss of 35-40% of excess (over ideal) weight.

4. OWG Therapeutics Recommendations

Ideally, individual consumers will avoid becoming overweight or obese through diet and exercise. Yet the OWG recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. The OWG concurs with agency plans to (1) convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing therapies (i.e., head-

[21] On January 26, 2004 (69 FR 3588), FDA issued a *Federal Register* notice specifically to solicit comments on this previously published draft guidance. FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. Once the agency revises the draft, FDA will issue the guidance again for comment before finalizing the guidance.

to-head comparisons of marketed drugs, cardiovascular endpoint studies); (2) continue discussion with pharmaceutical and medical device sponsors about new obesity medical products; and (3) revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

D. Research

Research Recommendation Highlights:

- ***Pursue research on obesity prevention with USDA/ARS...p. 31***
- *Support and collaborate, as appropriate, on obesity-related research with others, including NIH...p.32*
- ***Pursue obesity related research in the following five areas:***
  - ***Information used to facilitate consumers' weight management decisions...p. 32***
  - ***Relationship between overweight/obesity and food patterns...p. 32***
  - ***Incentives to product reformulation...p. 32***
  - ***Potential for FDA regulated products unintentionally to contribute to or result in obesity...p. 33***
  - ***Translational research....p. 33***

The Commissioner directed the OWG to "identify applied and basic research needs relative to obesity that include the development of healthier foods as well as a better understanding of consumer behavior and motivation."

1. Joint Research with USDA/ARS

As part of its research efforts, the OWG recommends that FDA collaborate with USDA/ARS on a national obesity prevention conference to be held in October 2004. The conference will draw on the expertise of both the public and private sector scientific communities to provide guidance for research agendas in the short- and long-term to address obesity prevention from a variety of scientific and other disciplines. Such disciplines will include diet and nutrition, behavioral and economic science, and research involving exercise, education, integrated programs, and outreach.

2. Survey of Research

The OWG focused on three areas of research related to its charge: (1) "labeling information"[22] and consumer perceptions and dietary behaviors with regard to weight management; and (2) support for safety evaluation with respect to the potential for FDA regulated products unintentionally to contribute to or result in obesity; and (3) translational research conducted by FDA's National Center for Toxicological Research and CFSAN's Office of Applied Research and Safety Assessment. to enable the agency to use the basic scientific research conducted by

[22] For the purposes of V.D.2., "labeling information" includes possible changes to the NFP, possible changes to the PDP, graphic devices, caloric/nutrient density indicators, and nutrient content claims.

such agencies as the NIH in FDA's regulatory activities. Of these three, the OWG considers the first two to be more directly and immediately relevant to its charge. Translational research, because of its link to basic nature, takes a long time to yield practical results. Nevertheless, the OWG believes FDA should continue to conduct translational research in order to gain a better understanding of obesity.

Based on a review of the relevant research as well as comments provided during a variety of public meetings, the OWG has identified several knowledge gaps related to the two research areas above. The OWG recommends that further obesity-related research be conducted in the following areas: (1) information used to facilitate consumers' weight management decisions, (2) the relationship between overweight/obesity and food consumption patterns, (3) incentives to product reformulation, and (4) the potential for FDA-regulated products unintentionally to contribute to or result in obesity, and (5) the extension of basic research findings to the regulatory environment through translational research. In addition, the OWG recommends that FDA pursue collaborations with other groups who are undertaking obesity research such as NIH, which has recently issued an obesity research agenda, and CDC.

Information used to facilitate consumers' weight management decisions. The OWG recommends conducting additional qualitative and quantitative research with an emphasis on (1) consumer reaction to and effectiveness of current packaged food labeling and possible changes to the food label (e.g., highlighting calories, listing the quantitative amounts for all nutrients in multi-size packages, and using "healthy" symbols, graphic devices, or caloric/nutrient density indicators), (2) consumer reaction to and effectiveness of current restaurant nutrition information and possible changes (e.g., listing nutritional information such as calories, fat and sodium for both *a la carte* items and meals and using "healthy" symbols), and (3) consumer dietary behavior and attitudes toward weight management.

Relationship between obesity and food consumption patterns. The OWG recommends conducting research to evaluate the relationship between obesity in adults and children and the frequency of foods obtained from and/or consumed in different locations (e.g., home cooked meals, packaged foods, and quickservice establishments/restaurants) and with respect to socioeconomic status and vulnerable populations (e.g., Hispanic Americans, African Americans, American Indians, and the elderly). This research would be conducted in collaboration with the Economic Research Service of the USDA using CDC and National Health and Nutrition Education Survey data to evaluate these relationships.

Incentives to product reformulation. The OWG recommends conducting further research with the packaged food and restaurant industries in addition to that currently being conducted by OASPE in collaboration with FDA (FDA, 2003). This research would (1) examine whether the incentives (e.g., label prominence and other label characteristics of calorie and weight management information) and barriers (e.g., food additive and claims approval processes and the regulatory policy related to standards of identity and fortification) to reformulation identified by the packaged food industry during previous discussions are real or perceived, and (2) expand the scope of the research conducted by OASPE to include additional discussions with key restaurant industry, including quickservice, personnel regarding the barriers and incentives to the development/reformulation of healthier restaurant foods.

Potential for FDA-regulated products to unintentionally contribute to or result in obesity. Although most FDA-regulated products are intended to be used or consumed for purposes other than weight management, weight gain may be an unintentional adverse side effect associated with use of some of these products. In general, for both foods and drugs, weight gain or obesity has not consistently been measured, evaluated, or considered as an adverse effect when designing study protocols or evaluating submitted research results. Strategies to systematically evaluate this endpoint are needed as part of the safety assessment for FDA-regulated foods and drugs. Thus, the OWG recommends conducting research to investigate (1) the promotion of weight gain as an adverse side effect of FDA-regulated drugs and whether this is a factor that should be taken into account regarding drug safety and (2) the development of animal model assessment strategies that encompass the evaluation of long-term effects on weight gain as a safety assessment parameter.

Translational research. Translational research is essential for FDA to use basic research from other agencies and academic institutions in developing regulatory policies and actions. Thus, the OWG recommends extending basic research on (1) developmental imprinting[23] to differentiate among food components and eating behaviors of neonates, or nutrient/food component exposures of fetuses via maternal diets, with regard to weight management challenges in adolescence and adulthood, (2) biomarker and effects-evaluation techniques through emerging genomics, proteomics and metabolomics technologies to identify how FDA-regulated products modify risk factors and susceptibilities for weight gain, obesity, and co-morbidities, and (3) development of animal models to evaluate the effects of diets and dietary components, drug therapies, and medical device uses on long-term weight maintenance, health and longevity. The OWG further recommends that FDA take into account translational as well as other obesity-related research being done by NIH, as it considers future research in these areas.

VI. Stakeholder Investment to Help Ensure Results

Stakeholder Investment Recommendation Highlight:

- ***Continue to promote and engage in active dialogue with invested stakeholders…p. 36***

The Commissioner charged the OWG to set out specific means for developing and implementing "an active dialogue with outside invested stakeholders including consumers groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition."

[23] The developmental imprinting hypothesis suggests that the increase in childhood obesity is, in part, a result of an epigenetic effect of poor nutrition or exposure to some toxic agent during the perinatal period when metabolic pathways are being established in the fetus and neonate, creating a dysfunctional metabolic pathway. As the child ages, these dysfunctional metabolic pathways, in conjunction with other factors, such as inadequate exercise, may become sufficient to cause or contribute to overweight or obesity. This developmental programming hypothesis, developed from epidemiological data, has also been recently extended to animal models.

A. Background

Recognizing the high level of interest in obesity among FDA's many stakeholders, the OWG initiated a process for establishing ongoing relationships with individuals and organizations from all sectors. A key aspect of this process included providing the public with multiple opportunities to become involved in a dialogue with the OWG on its activities and the issues associated with helping consumers address the problem of obesity.

As one of its first major outreach initiatives, the OWG sponsored a public meeting on October 23, 2003,[24] to accomplish several objectives:

- To initiate a discussion of FDA's role and responsibilities in addressing the major public health problem of obesity;
- To focus on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans; and
- To obtain stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition.

Approximately 320 attendees representing diverse stakeholder viewpoints registered to participate in this discussion, with nineteen organizations making formal presentations on issues associated with the six focus questions. These nineteen organizations represented science/research, academia, consumers, health and medical associations, industry, and advocacy groups. In addition to the formal presentations given at the October 23 public meeting, interested and concerned stakeholders submitted written comments to Docket No. 2003N-0338 on various aspects of the six focus questions.

The scope of the discussion at this meeting, and at two subsequent roundtable meetings (held with health professionals/academicians and with consumer groups, on December 15-16, 2003, respectively) centered on the following six focus questions:

1. *What is the available evidence on the effectiveness of various education campaigns to reduce obesity?*

Stakeholders regarded education as an essential component of FDA's contribution to public health efforts to confront the problem of obesity. Stakeholders consistently reinforced FDA's leadership role in educating the public about the food label, good nutrition, and healthy diets.

Stakeholder comments focused on four key areas: (a) effectiveness of existing education campaigns; (b) type of education campaigns needed; (c) what campaigns should address; and (d) what messages are likely to affect weight gain, weight management, or weight loss.

2. *What are the top priorities for nutrition research to reduce obesity in children?*

[24] In the *Federal Register* of October 8, 2003 (68 FR 58117), FDA announced this public meeting. Transcript of the meeting is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm).

Stakeholders were particularly concerned about childhood obesity. Stakeholders emphasized the importance of parental involvement in efforts to address childhood obesity. The views focused on the scope of the problem, as well as on the research on activities that are needed to address the issue of childhood obesity.

3. *What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations or both?*

Stakeholders expressed a range of views and perspectives about what would inform FDA decisions in preventing and treating obesity.

4. *Are there changes needed to food labeling that could result in the development of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?*

Stakeholders were highly interested in participating in the area of food labeling. The views focused on (a) general advice; (b) calories; (c) energy balance; (d) serving sizes; (e) current health-related information on the label; (f) consumer education on the food label; (g) messages on the food label; and (h) expanding nutrition information availability in restaurants.

5. *What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?*

Stakeholders provided a diverse array of research needs, creative incentives for the development of healthier foods/diets, and general advice.

6. *Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?*

Stakeholder views related to three major categories: (a) food labels; (b) research; and (c) education.

On November 20, 2003, FDA, in conjunction with OASPE, sponsored a workshop on "Exploring the Connections Between Weight Management and Food Labels and Packaging."[25] The two major issues explored at this workshop were:

1. Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity and
2. Data supporting options for change

This daylong workshop involved presentations by researchers, academicians, and public health officials, who discussed issues such as the effect of portion/package size, shape and structure on consumption (e.g., comments by Brian Wansink in transcript of November 20 workshop); and presentations by representatives of the restaurant industry, who addressed issues surrounding provision of nutrition information in restaurants.

The OWG organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

FDA also met with representatives of the packaged food and restaurant industries to learn about their obesity-related activities.

B. OWG Stakeholder Investment Recommendations

The OWG believes it is worthwhile to maintain contacts with stakeholders concerned about the obesity issue both to benefit from their continued involvement and to ensure that, to the extent possible, collective obesity efforts are mutually supportive.

VII. Overall Conclusions

In response to the charge to the OWG, this report provides a range of recommendations for addressing the obesity epidemic. These recommendations address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; formulating educational strategies in the form of partnerships, to support the dissemination and understanding of these messages; specific new initiatives to improve the labeling of packaged foods with respect to caloric and other nutritional information; initiatives enlisting and involving restaurants in the effort to combat obesity; the development of new therapeutics; the design and conduct of effective research in the fight against obesity; and the continuing involvement of stakeholders in the process.

As noted previously in this report, achieving ultimate success against obesity will occur only as a result of the complementary efforts over time by many concerned sectors of our society. It is the

[25] In the *Federal Register* of October 17, 2003 (68 FR 59795), FDA announced this public workshop. On November 19, 2003 (68 FR 65303), FDA amended its original announcement to reflect that the agency was requesting comments regarding the workshop. Transcript of the workshop is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

belief and the hope of the OWG that the recommendations contained in this report, when carried out by FDA in concert with the complementary ongoing and planned efforts of other sister DHHS agencies and other agencies of government, will make a significant impact in reversing current trends.

VIII. References[26]

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APPENDIX A - List of Acronyms and Abbreviations

ANPRM	Advance notice of proposed rulemaking
BMI	Body mass index
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
CNS	Central nervous system
CSFII	USDA 1994-1996 Continuing Survey of Food Intakes by Individuals
CSPI	Center for Science in the Public Interest
DSHEA	Dietary Supplement and Health Education Act of 1994
DHHS	U.S. Department of Health and Human Services
FDA	Food and Drug Administration
FTC	Federal Trade Commission
FR	*Federal Register*
IFIC	International Food Information Council
IOM	Institute of Medicine
NFP	Nutrition Facts panel
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act of 1990
OASPE	DHHS Office of the Assistant Secretary for Planning and Evaluation
OWG	FDA's Obesity Working Group
PDP	Principal display panel
RACCs	Reference amounts customarily consumed
the Act	Federal Food, Drug, and Cosmetic Act
USDA	U.S. Department of Agriculture
USDA/ARS	U.S. Department of Agriculture/Agricultural Research Service
%DV	Percent Daily Value
21 CFR	Title 21, Code of Federal Regulations

APPENDIX B - Text Boxes on Body Mass Index (BMI), Energy (Calorie) Balance, Carbohydrates and Other Macronutrient Contributions to Caloric Value

Body Mass Index (BMI)

Body mass index (BMI) is a way of characterizing weight status. For example, an adult's weight status is classified as underweight (BMI < 18.5), normal (BMI = 18.5 - 24.9), overweight (BMI = 25.0 – 29.9), or obese (BMI ≥ 30.0). For children and adolescents, somewhat different BMI ranges are used to classify their weight status. The BMI has gained increasing use by health professionals because it is highly correlated with body fat.

The BMI values used to classify adults as underweight, normal, overweight, or obese are based on their ability to predict the effect of body weight on the risk for some diseases. For example, common conditions associated with increased risk in adults classified as being overweight or obese include premature death, cardiovascular disease, high blood pressure, osteoarthritis, some cancers, and diabetes. Although BMI is only one of many factors used to predict the risk of these diseases, it is an important factor and one that can be modified by individual changes in eating and physical activity behaviors.

For adults, BMIs are calculated from mathematical formulas that take into account an individual's height and weight. BMI can be calculated using pounds and inches with this equation:

BMI = (weight in pounds/(height in inches x height in inches) x 703

A calculator that automatically estimates the BMI for an individual is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm).

BMI values for children and teens are used to assess their body fatness changes over the years as they grow. Unlike adults, where the same BMI ranges are used for both men and women and across all ages, gender- and age-specific BMI values are used to classify the weight status of children and teens. This is necessary because children's body fat levels change over the years as they grow. Also, girls and boys differ in their body fat levels as they mature. BMI decreases during the preschool years and subsequently increases into adulthood. BMI-for-age tools are useful for children and teens because they compare well to laboratory measures of body fat levels and can be used to track body size throughout life. More information on BMI values for children is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-for-age.htm).

For some individuals such as athletes who have a muscular body with relatively small amounts of body fat, the use of BMI values may inappropriately classify them as overweight. For these individuals, the additional use of other estimates of body fat such as waist circumference may help to more accurately estimate their weight status. For example, a waist measurement greater than 40 inches in men and 35 inches in women is usually indicative of excessive abdominal fat, which is an independent predictor of risk factors and ailments associated with obesity.

Calorie (Energy) Balance[1]

Overweight and obesity result from an imbalance that occurs when the calories consumed exceeds the calories expended. Even small imbalances over time can result in weight changes. For example, a difference of one 12-oz soda (approximately 150 calories) or 30 minutes of brisk walking most days can add or subtract approximately 10 pounds of body weight per year.

There are many physiological factors (e.g., gut hormones) that operate to maintain body weight at a constant level even though calorie intake often varies considerably from day to day and week to week.[2] The physiological factors regulating food intake tend to be more effective in defending against weight loss than against weight gain. This is thought to be an adaptive mechanism that protected humans from the adverse effects of famine and starvation. However, the physiological factors that tend to maintain calorie balance can be overwhelmed by environmental and behavioral factors that favor high calorie consumption or low physical activity. When weight gain occurs, a person's energy balance thermostat is reset to achieve calorie balance at the new, higher level of body weight. Thus once weight gain occurs, a new calorie balance level is established. The body then tends to defend against weight loss from this new, larger weight status.

Although the tendency for overweight and obesity is a product of complex interactions between physiological, genetic, environmental, and behavioral factors, the rapid increase in rates of overweight and obesity in the United States over the last several decades has occurred too rapidly for changes in genetic or physiological mechanisms to be solely the cause. Therefore, the emerging obesity epidemic is almost certainly due to changes in consumer food choices and physical activity levels resulting in an overall positive calorie balance and weight gain.

Total calorie intake refers to all energy consumed as food and drink. Proteins, carbohydrates, fat, and alcohol provide 4, 4, 9, and 7 calories per gram, respectively. Some calories (e.g., approximately 1.5 calories per gram) are obtained from dietary fiber that undergoes bacterial degradation in the large intestine to produce volatile fatty acids which are then absorbed and used as energy in the body. Physical activity such as walking 2 miles in 30 minutes burns approximately 150 calories. The body stores excess calories as body fat, regardless of whether the excess calories are caused by inadequate physical activity or excessive intakes of calories from any of the nutrient sources of calories. Reductions in large body fat reserves, which have often accumulated gradually over long periods of time, and subsequent maintenance of healthy body weight, will likely require long-term commitments to changes in eating and physical activity.

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[1] The term "energy balance" is commonly used to describe the relationship between the number of calories consumed from foods and the calories used by the body. For purposes of this document, however, the term "calorie balance" is used in place of "energy balance" since calories are the unit of energy measurement used for nutrition labeling and best understood by consumers. Therefore, in this document, the terms "energy balance" and "caloric balance" are used interchangeably.

[2] Among the factors affecting body weight are body size and fat-free mass (i.e., the weight of the body less the weight of its fat mass) and also to a lesser degree age, gender, body composition, nutritional status, inherited variations, and/or differences in the hormonal status. Physical activity is the most variable of the calorie expenditures among individuals. For some individuals, physical activity is only a small proportion of the total calorie requirements; for very active individuals, it can be a significant proportion of daily calorie needs. Body weight is a major determinant of the calorie expenditure from physical activity. For example, the calorie cost of walking a mile at a moderate pace is 69 calories for a 140 pound individual and 58 calories for a person weighing 114 pounds. The intensity of physical activity can also affect calorie expenditure. For example, more calories are expended when jogging than when walking for the same amount of time.

Carbohydrates and Other Macronutrient Contributions to Caloric Value

Macronutrients are the components of food that provide energy (i.e., calories). There are three categories of macronutrients: carbohydrates, proteins and fats. Carbohydrates represent over half, and fats about a third, of the energy intake of typical Western diets. Understanding the caloric contribution of macronutrients to the diet requires knowledge of their chemical composition.

Carbohydrates - Carbohydrates (sugars, e.g., glucose, sucrose; and starches) provide energy to cells in the body and glucose is a primary source of energy for the brain. Sugars and starches are broken down to glucose and the energy provided is 4 calories per gram. Other types of carbohydrates such as sugar alcohols (e.g., sorbitol, maltitol) and dietary fiber are not well absorbed by the small intestine and are fermented by bacteria in the large intestine. Carbohydrates that are fermented in this manner provide a lower energy value per gram.

The rapidity and extent of carbohydrate absorption by the body directly influence the speed and extent of the rise in blood glucose (i.e., glycemic response), which, in turn, triggers an insulin response. The glycemic index of carbohydrate-containing foods has been proposed as a way to quantify the blood glucose response following their consumption (Jenkins *et al.*, 1981). Many factors can affect the glycemic index of a single food, especially when the food is consumed in a meal.

Foods or meals that have a high glycemic index trigger the release of insulin into the blood. Elevated blood insulin levels stimulate the uptake of fat from the blood into fat cells, and inhibit the breakdown and release of stored fat from fat cells. Some scientists believe that consuming a high glycemic index food (e.g., a food that contains sugar or starch) can result in an increase in stored body fat.

Weight loss plans based on greatly restricting carbohydrate intakes have been promoted for more than a decade. "Low" carbohydrate products are being promoted as a way to reduce weight and to assist diabetics in their control of carbohydrate intake; however, not all carbohydrates raise blood glucose levels, nor deliver the same energy value per gram. In addition, when one macronutrient is restricted in a food product, it is often replaced with another macronutrient. For example, when "low" fat products were introduced several years ago, carbohydrates often were the replacement macronutrient. In many of the current "low" carbohydrate products marketed today, fat is often the replacement macronutrient. Also today many of the low carbohydrate products replace the high glycemic index carbohydrates (e.g., sugars and starches) with other carbohydrates such as sugar alcohols, which have no measurable glycemic index and may provide fewer calories per gram. Thus, it is important to look at the NFP to determine the calorie content of and the type of carbohydrate in a product.[1]

Fats (lipids) - A major source of energy for the body is derived from fats (lipids). Fats aid in the absorption of fat-soluble vitamins and carotenoids. There are two essential fatty acids, α-linolenic and linoleic. Fats contribute 9 calories per gram. There are three major components: saturated fatty acids, *trans* fatty acids and unsaturated fatty acids (monounsaturated fatty acids and polyunsaturated fatty acids). All yield the same caloric value, but may affect metabolism differently. Saturated fatty acids and *trans* fatty acids raise blood lipid levels, especially cholesterol and low density lipoprotein cholesterol, which have known adverse health effects. There is no known requirement for *trans* fatty acid for specific body functions.

Acceptable Macronutrient Distribution Range (AMDR) has been estimated for individuals. The AMDR is the range of intake for a particular energy source that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients. The AMDR for carbohydrates and fats is estimated to be 45 to 65 and 20 to 35 percent of energy, respectively, for all adults. Consumption of carbohydrates and fats within these ranges reduces the risk for obesity, as well as certain chronic diseases such as coronary heart disease and diabetes.

Proteins - Proteins make up the major structural components of cells and are composed of amino acids. There are 20 essential amino acids. Proteins function as enzymes, hormones, and have other important functions in the body. Proteins provide 4 calories per gram. Animal protein sources (e.g., meat, milk, eggs) generally contain balanced amounts of the essential amino acids whereas vegetable protein sources frequently have a limited amount of one of the essential amino acids. Foods that are low in fat tend also to be low in protein; foods that are low in carbohydrate tend to be high in protein and fat.

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[1] FDA has received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. As discussed in section V.A.3.b., the OWG recommends that FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

APPENDIX C - Notice Concerning July 30, 2003, Secretary's Roundtable on Obesity/Nutrition

Department of Health and Human Services
Secretary's Roundtable on Obesity/Nutrition
Wednesday, July 30, 2003
10:00 a.m. – 12:00 noon
Washington, D.C.

Public Docket 2003N-0338

The Department of Health and Human Services (HHS) has established a public docket 2003N-0338 to receive additional information, perspectives, and suggestions from participants who attended the Secretary's Roundtable on Obesity/Nutrition on July 30, 2003.

Obesity is a growing and urgent public health problem in the United States. To address this problem, HHS Secretary Tommy G. Thompson has led the Department in its efforts to encourage healthy habits such as healthy diets, more exercise, and making healthy choices. Secretary Thompson continues to challenge HHS agencies and the leadership of the public health community to intensify their efforts to realize these improvements. The Secretary's Roundtable on Obesity/Nutrition is intended to enhance an HHS discussion with leading thinkers and experts in the public health community on the role that HHS can play in reducing or reversing the weight gain that leads to obesity. The Roundtable agenda included the following five focus questions:

1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?

2. What are the top priorities for nutrition research to reduce obesity in children?

3. What is the available evidence supporting whether public efforts should prioritize behavioral interventions to prevent obesity versus medical interventions to treat obesity?

4. What changes to food labeling could result in the development of healthier, lower calorie foods and the selection of healthier, lower calorie foods by consumers? What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

5. Based on the scientific foundation available today, what is the one thing that HHS could do that would make a significant difference in efforts to address the problem of obesity?

The Department has opened public docket 2003N-0338 to receive additional information, references, or thoughts from Roundtable participants in follow up to the July 30 discussion. We would appreciate receiving all follow up information and views by *Tuesday, September 30, 2003*. You should submit written comments to the Dockets Management Branch (FDA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You may also submit comments electronically to http://www.fda.gov/dockets/ecomments or by email to FDADOCKETS@oc.fda.gov We request that you submit two copies of any written comments; individuals may submit one copy. Please ensure that you include the docket number 2003N-0338 in your submission. All comments submitted to the public docket are public information and may be posted to the FDA website (http://www.fda.gov) for public viewing.

APPENDIX D – August 11, 2003, Charge Memorandum

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

FROM: Commissioner of Food and Drugs

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

DATE: August 11, 2003

SUBJECT: FDA Obesity Working Group

I am requesting the formation of a Working Group to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition. This issue is a top priority of the Office of the Commissioner as well as of the public health community both within and outside of government, because of the importance of consumer choices in preventing the serious health consequences associated with obesity, and in improving the health of the population. I am requesting that you serve as the Chair of this Working Group. Because the leadership role on nutrition issues in FDA resides within the Center for Food Safety and Applied Nutrition (CFSAN), I am requesting that Joseph Levitt, Director of CFSAN, assist you as the Vice Chair of this Working Group.

The goal of the FDA Obesity Working Group is to issue, within six months, a report that includes an action plan setting out specific means for developing and implementing the following goals:

1. Message.

    - The Working Group will develop a clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic.

2. Education Program to Deliver the Message.

    - Outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent the disease.

3. Supporting the Message.

    - *Food Labels*: Develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity;
    - *Restaurants*: Develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers;

- *Therapeutic Treatment*: Develop an approach for facilitating the development of therapeutics for the treatment of obesity;
- *Research*: Identify applied and basic research needs relative to obesity that include the development of healthier foods as well as a better understanding of consumer behavior and motivation.

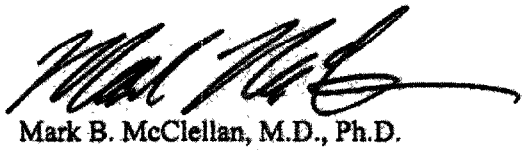
4. Stakeholder Investment to Ensure Results.

    - Provide for an active dialogue with outside invested stakeholders including consumer groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition.

Please consult with Joe Levitt as soon as possible regarding those who should be called upon to serve on the Working Group either as members or as supporting staff. While I encourage you to include experts from across FDA's Centers, as well as the Office of the Commissioner, I expect the Working Group's activities to be focused in and led by CFSAN. I also encourage you to seek the advice and input of other HHS agencies as needed.

Please report back to me by September 12, 2003, regarding the membership of the Working Group and an overall timetable for the group's work.

Thank you in advance for assuming a leadership role in confronting this extremely important and challenging public health crisis.



Mark B. McClellan, M.D., Ph.D.

APPENDIX E – FDA Obesity Working Group Membership

NAME	TITLE / AFFILIATION
MEMBERS	
Lester Crawford (Chair)	Deputy Commissioner/Food and Drug Administration (FDA)
Robert Brackett (Vice Chair)[27]	Director/Center for Food Safety and Applied Nutrition (CFSAN)
Patricia Kuntze (Executive Assistant)	Sr. Advisor for Consumer Affairs/FDA
Peter Salsbury (Executive Secretariat)	Acting Director, Executive Operations Staff/CFSAN
Alan Rulis	Senior Advisor for Applied Nutrition/ CFSAN
Susan Bond	Special Assistant to the Deputy Commissioner/FDA
Donna Howard	Special Assistant to the Senior Advisor for Applied Nutrition/CFSAN
Anne Crawford	Assistant to the Senior Advisor for Applied Nutrition/CFSAN
Christine Taylor	Director, Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS)/CFSAN
Elizabeth Yetley	Lead Scientist for Nutrition/CFSAN
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[27] When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.

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APPENDIX F - FDA Obesity Working Group - Subgroup Members

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MESSAGE

Lead (Message): Peter Pitts
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EDUCATION

Lead (Education): Susan Bond
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FOOD LABELS

Lead: Kathy Ellwood
Members: Virginia Wilkening, Felicia Satchell, Amy Lando, Alan Levy, Mary Brandt, Lori LeGault, Ritu Nalubola

RESTAURANTS/INDUSTRY

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Members: Mike Landa, Faye Feldstein, Glenda Lewis, Rich Williams, Clark Nardinelli, Carolyn Young, Andrew Estrin, Mark Schwartz

THERAPEUTICS

Lead: David Orloff
Members: Eric Colman, Patricia Beaston

RESEARCH

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REPORT WRITING

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APPENDIX G - Report from the Division of Market Studies Office of Scientific Analysis and Support, FDA CFSAN

Office of Scientific Analysis and Support
Center for Food Safety and Applied Nutrition, FDA

In support of the Obesity Working Group, FDA

December 28, 2003

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*** This report was prepared for Ms. Laina Bush of the Office of the Assistant Secretary for Planning and Evaluation, DHHS. Ms. Bush funded the studies and is a Project Officer on all of the individual studies except the survey of restaurant Web sites.**

Helping Consumers Lead Healthier Lives through Better Nutrition: A Social Sciences Approach to Consumer Information, Food Choices and Weight Management

A Report from the Division of Market Studies
Office of Scientific Analysis and Support, FDA CFSAN

January, 2004

Executive Summary

This summarizes an interim report on the social science research on weight management done for both the Obesity Working Groups in FDA and the Office of the Assistant Secretary for Planning and Evaluation, DHHS. In these studies, we examined how consumers use existing food labels for weight management; how changes to food labels might improve those practices; how restaurants are currently labeling; how consumers would react to different kinds of labels; and what policies could induce manufacturers to produce healthier foods. Our research has included both review of the current social sciences literature and some new studies. First, in qualitative studies, consumers claim they do not wish to spend a significant amount of time reading and comprehending labels. This is borne out by the fact that many use health or nutrient content claims as signals as to the quality of the entire product and do not check the nutrition facts panel on the back. Also, consumers appear to be confused by serving sizes, particularly by multiple servings listed on small packages, as well as by percentage daily values listed in the nutrition facts panel. Consumers use food labels for multiple reasons, including diet plans and pre-existing health conditions such as diabetes and heart disease, and look for macronutrients of concern. Although we found some labeling in restaurants (by examining their websites), consumers clearly want more nutrition information in restaurants although most claim they will use it only part of the time. In fact, the limited number of studies we examined showed mixed results as to whether restaurant labels would be used but studies also show a correlation of overweight with a higher percentage of food consumed away from home. Consumers state qualitatively that they would like all nutrition information in restaurants but would even find calorie labeling helpful. Finally, consumers appear to be interested in signals of healthy foods, both in supermarkets and restaurants. In interviews, manufacturers state that to encourage production of healthier foods FDA should examine not just labeling policies, but other areas that affect product formulations such as food standards.

Two projects underway are not far enough along to give interim reports. The first is the creation of an economic model of food choice that will answer such questions as, "do food labels help consumers maintain their desired weight"? In addition, we are in the process of getting a restaurant chain to investigate actual market consumer reactions to nutrition labeling on menu boards. The source of our suggested menu board changes will be the results of our focus group studies. Beyond these initial studies, additional research could be done for food labels to investigate both whole package labeling (instead of serving sizes) and nutrient density labeling (e.g., calories per cup). To give consumers better signals, we could also investigate the use of a logo on the front of the package to both signal consumers to the presence of a healthy (or

healthier) food and to serve as a motivator for production of such foods. Alternatively, we could evaluate the effectiveness of educating consumers on both the use of daily values and how servings sizes should be evaluated in light of portion sizes. The relationship between eating out and weight management could be investigated both for various kinds of restaurants and for different socioeconomic groups. Finally, there are a number of existing FDA policies such as food standards and nutrient content claims that could be examined to see how changes could encourage more reformulation toward lower calorie or healthy foods.

I. Purpose

In August, 2003, FDA Commissioner Mark B. McClellan declared FDA's intention to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition. FDA's Center for Food Safety and Applied Nutrition (CFSAN) plays a leadership role in nutrition issues at FDA. Within CFSAN, the Division of Market Studies (DMS) in the Office of Scientific Analysis and Support (OSAS) provides expertise in Social and Population Science issues related to CFSAN's mission, including expertise in Economics and Consumer Sciences. Our first charge was to undertake a group of short-term studies on: a) how consumers use current food labels to maintain weight; b) how consumers would use potential changes in food labels, including new labeling in restaurants; and, c) how manufacturers react to labeling requirements with new products and product reformulation. Our second charge was to develop a longer term research agenda on labeling and weight management.

The research goal is to develop knowledge on how to lower the cost (time and effort in choosing foods) to consumers of managing their weight, using labeling and education. In choosing foods for healthy eating, consumers must solve a series of information problems including: 1) determining what constitutes a healthy diet; 2) finding products that meet their nutritional needs; and, 3) evaluating nutritional characteristics of particular products. This information comes from a variety of sources such as media, friends, school, physicians and, of course, food labels and restaurant menus. From the standpoint of consumer behavior, or the "demand side" of the market, we will examine the psychology of people's perceptions, eating habits and desires relative to healthy eating and weight management. From the standpoint of producer behavior, or the "supply side" of the market, we examine how producers make decisions to make and market healthy foods (including decisions about serving and package sizes) and provide information about those foods. Our research follows the natural division of packaged food products in grocery stores and food consumed in restaurants, although issues in these two areas often overlap. Our results are cross-cutting, with relevance to several areas, including food labels, restaurants and research.

II. General Concepts of Weight Management

Public health importance. The scope of the growing and urgent public health problem of obesity was outlined in the Surgeon General's Report (US DHHS 2001). In 1999-2000, 65% of U.S. adults were overweight, increased from 56% when surveyed in 1988-1994; 30% of adults were obese, increased from 23% in the earlier survey (Flegal 2002). Among children age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (Ogden

2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 300,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Allison 1999, US DHHS 2001). The total economic cost of obesity in the United States is about $100 billion per year, including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures **(US DHHS 2001, Finkelstein 2003).**

Energy balance. Weight gain occurs when there is an energy imbalance, with "energy in" (calories from food) exceeding "energy out" (resting metabolism plus physical activity). This report addresses issues related to the "energy in" side of the energy balance equation: food choices and the food environment. A general consideration of increasing "energy out" through physical activity, while important, is beyond the scope of this report. However, we do consider how information about the physical activity equivalent of food calories might affect consumer food choices.

Genes and the environment. Genetic influences on obesity are complex and are just beginning to be elucidated (Shuldiner 2003). Based on twin, adoption and family studies, it is estimated that 40 to 70% of the current population variation in body mass index (BMI) can be explained by genetic factors (Shuldiner 2003, Allison 2003). However, even relatively modest decreases in the remaining, non-genetic, "environmental liability" for obesity can nevertheless be predicted to result in meaningful decreases in BMI and corresponding health risks (Allison 2003).

Weight management and the food environment. Evidence from research on taste preferences, eating regulation and weight-loss interventions suggests that overweight individuals and those prone to overweight may be particularly vulnerable to the modern food environment (Lowe 2003). This "obesigenic" environment features unlimited quantities of a variety of foods high in caloric density (which tend to be foods high in fat, sugar, or both), together with minimal need for energy expenditure (Lowe 2003), perhaps making it more difficult for obesity prone individuals to regulate energy intake. A promising approach to improving weight control is therefore to focus on changes in the food environment: the availability, structure, composition and portion size of foods. There is potential for changes in the food environment both at the general (or population) level and at the level of the individual (personal food environment). For example, a change in the food environment at the population level might be the availability of more food choices that facilitate weight control. A change in the personal food environment might be to stock one's home with ingredients and foods that facilitate weight control (Lowe, 2003). A current challenge is to provide information and assistance to enhance the ability to determine one's personal food environment.

The role of food labeling. Since passage of the Nutrition Labeling and Education Act 10 years ago, consumers have had nutrition labeling on most packaged foods (small product lines were excluded as were foods packaged on premises in supermarkets and delis). As discussed later, it is clear that consumers both like and use the nutrition information on the back of food packages and the health and nutrient content claims on the front of packages. However, it is not clear how successful consumers have been at using labels to eat healthy diets. Research is necessary to establish whether the food label is as useful as it could be in assisting consumers by making weight management as easy as possible.

The role of restaurants. Unless restaurants make nutrient content or health claims, they are not required to provide consumers with any information on the nutrient content of their foods, an obvious gap in information. This exclusion applies to all eating places away from

home, including school cafeterias, nursing homes, military establishments and hospitals. Research is needed on how to address the current information gap by tailoring labeling to the special circumstances of eating places away from home. Unlike packaged food, restaurant food is characterized by frequent recipe changes, both for routine use and at the request of consumers for special preparation. This may have been an insurmountable hurdle for most restaurants in the past, when nutrition information had to be determined by direct chemical analysis. However, this hurdle may be decreased at present with the ubiquitous availability of nutrient composition databases and software for labeling, coupled with the explosive growth in personal computers and personal digital assistants, even if the restaurant labeling lacks the precision of that now required of packaged foods.

A changing environment. In the quantum uncertainty principle in physics, observation of a system perturbs the system, resulting in measurement uncertainty. Similarly with the restaurant industry, recent attention by public health officials, litigators and the media on restaurants and weight management issues has resulted in changes in the marketplace. Restaurants have begun offering more nutrition information and featuring healthier menu selections. Research is needed to describe current restaurant practices, and to evaluate their effectiveness in assisting consumers with weight management. Additionally, although the introduction of healthier food selections by packaged food manufacturers dates to before the passage of NLEA, the current interest in weight management is likely to speed the introduction of products for healthier eating.

III. Overview of Current Issues and Related Literature

A. Current Issues.

In response to current concern about problems of obesity and weight management, some specific issues have emerged in articles, statements, presentations, and dialogue among consumers, industry, scientists and public health officials.

Consumers and packaged food labels. Even though food labels are widely used and accepted in the population, there are potential problems that may be limiting food label use or its effectiveness as a tool in weight management.

- **Numerical calories.** Is the numerical calorie designation prominent enough on the food label? Do consumers understand and use the numerical calorie designation? Do consumers do the math needed to calculate their daily caloric intake using food labels? Should they do so? Can or should consumers know how their own recommended calorie intake compares with the 2000 calorie per day reference on the food label?
- **Daily Values.** Do consumers understand or use the percent Daily Value (%DV) figures on food labels? If they neither use nor understand them, can consumer education develop an appreciation and understanding of these figures? How can the food label best help consumers place the calorie content of foods in the context of a daily diet: for example, add a %DV for calories, add a qualifier such as "high", "medium", "low", use symbols to indicate "high", "medium", "low", etc?
- **Serving sizes.** Larger package sizes that are commonly consumed in one sitting may contain two or more standard servings for nutrition labeling. If consumers are not aware of the number of serving sizes, they may believe they are consuming fewer calories than they are if they consume the entire package.

- **Nutrition goals.** Because consumers are interested in different types of nutrition information from food labels depending on their particular health concern or diet, do they want to know, in a global sense, whether or not a food is "healthy"? Would consumers benefit from qualitative symbols or cues on labels of "healthy" foods?
- **Trade-offs.** Rather than numerically calculate a "daily diet", consumers may rather try to choose foods that are healthy when they are inclined. They may balance a healthy choice if they have made an unhealthy choice in the previous eating occasion, but not quantitatively. How can the food label use qualitative symbols or cues to build on consumers' inclinations for qualitative "trade-offs"?
- **"Halo" effects of claims.** A "halo" effect occurs when a consumer reacts to a particular positive claim about a product and assumes that the entire product has positive attributes. For example, a low fat claim may signal to some consumers that the product is also low calorie. How can the food label use claims effectively to assist consumers in weight management, while avoiding halo effects or other unintended consequences of claims?

Restaurants. As noted above, the absence of calorie and nutrition labeling of restaurant food represents an information gap.

- **Portion size and calories.** In part because of large portion sizes in many restaurant offerings, the calorie content of restaurant meals may be much higher than consumers realize. Additionally, restaurant offerings may have higher calorie and saturated fat density (per weight or volume) than similar foods eaten at home. Would better availability of calorie information in restaurants help consumers with weight management?
- **Restaurant information format.** Some restaurants voluntarily offer nutrition information, but it is often not in an accessible format. The information is often available only after purchase, and may have confusing charts or formats and very small type size. What is the current status of voluntary restaurant nutrition information and what guidelines for format and availability would best help the consumer with weight management?
- **Menu item variability.** Are there creative approaches that would make restaurant nutrition labeling feasible in spite of the variations in menu item preparation?

Food Formulation. Changes in food labels and shifts in consumer perceptions and public health concerns can change the incentives and constraints food manufacturers face in producing and marketing foods. Producers may decide to change the formulation of foods if their expected private benefits exceed their expected private costs. Reformulation of existing products or introduction of new products occurred as a result of the appearance of health claims on food packages in the 1980's, the mandatory listing of fat content on food labels in the 1990's and awareness and proposed labeling of trans fat in the late 1990's.

- **Weight management and food reformulation.** Have producers formulated products to be low in calories or to respond to the weight management issue? What are the barriers or incentives to food formulation for weight management? How could these barriers be removed or incentives provided?

B. Related Literature.

[Contributors to literature review: Steve Bradbard, Andrew Estrin, Amber Jessup, Kathleen Koehler, Amy Lando, Jordan Lin, Clark Nardinelli, Linda Verrill, David Zorn]

The importance of social science principles in formulating and implementing nutrition policy was recognized years ago with the work of the National Research Council's Committee on Food Habits during World War Two (Gifford 2002). More recently, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the Facts panel format. Since NLEA, FDA and other researchers have studied how consumers use the Nutrition Facts panel, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

Food label use and diet. Research clearly shows that most Americans are familiar with and use the Nutrition Facts panel. In a 2002 FDA survey, 69 percent of the U.S. population reported using food labels often or sometimes when they buy a product for the first time (FDA, 2003). Our more detailed review of the literature on food label use is in Appendix A. The literature on food label use was also recently reviewed by the Institute of Medicine (IOM 2003).

In FDA's survey, people reported using the food label for many reasons, most commonly to see how high or low the food is in calories and in nutrients such as fat, sodium, or certain vitamins (FDA 2003). However, although consumers report using the food label to make dietary choices, they may not fully understand all of the information on the Nutrition Facts panel, particularly the %DV (Appendix A, IOM 2003). Evidence from experimental studies suggests that %DV information can help consumers judge the healthfulness of a food better than absolute amounts of nutrients alone (Levy, Fein, and Schucker, 1996 and Barone et al, 1996). However, in some surveys the majority of respondents could not accurately define or use the %DV for fat (FMI 1996, Levy et al 2000).

In experimental studies, consumers could correctly use the Nutrition Facts panel on the back of food packages to verify and evaluate the health and nutrient content claims on the front of packages (Garretson and Burton, Mitra et al, Ford et al., Roe et al.). However, when there was no Nutrition Facts panel, consumers were misled by claims into thinking a product was - healthier than it really was (Ford et al., Roe et al.) and when consumers were not specifically directed to consult the Nutrition Facts panel some cut short their information search and drew conclusions based on health or nutrient content claims (on the front of the package) alone (Roe, Levy and Derby).

As noted by the Institute of Medicine, the body of literature on the association of food label use and diet is relatively small (IOM 2003) Several studies have reported correlations between food label use and diet (Appendix A). For example, survey respondents who used the Nutrition Facts panel were more likely to consume a lower fat diet, both in the general population and among family clinic patients (Neuhouser et al, Kreuter et al). Clinic patients with health conditions such as high blood pressure and high cholesterol were more likely to look on the label for sodium and cholesterol information, respectively (Kreuter et al).

The calorie content of food is a common use of the food label, and was among the top three pieces of information sought by 80 percent of label readers in one survey (IOM 2003). However, there has been little research on the relationship between label use and weight management/weight loss or gain.

The use of "healthy" food logos on food packages was recently reviewed (Smith et al 2002). Such programs feature a package logo or symbol on food meeting certain nutrition criteria set by the program's administering body. Examples include the U.S. American Heart Association "Heart Check", the Canadian Heart and Stroke Foundation "Health Check", the Australian "Pick the Tick" and the Swedish "Green Keyhole". In general, consumers report support for the programs and are able to interpret meaning accurately (Smith et al 2002). Some evidence also indicates the programs have a positive effect on food formulation. Additional research is needed on the effect of such programs on food purchase and consumption (Smith et al 2002).

Restaurants. A number of experimental studies have examined consumer behavior in cafeteria, restaurant and vending machine settings in response to nutrition information or health messages. The results of these studies are mixed; differences in results among studies may be due to differences in experimental designs, including size of sample, demographic characteristics of participants, experimental setting, length of study, type of nutrition information or health message and type of behavioral outcome studied (Appendix A).

In general, consumers have mixed reactions to nutrition information in cafeterias and restaurants. Both health claims and listing of nutrition information have been found to be capable of producing positive influences on consumer evaluations of menu items and the influences appear to be strongest when nutrition information about alternative menu items is absent. Although nutrition information may influence choices and attitudes, other factors may be more salient: whether the respondent is on a diet, attitudes toward nutrition, price of food, health claim vs. nutrition information, taste/perceived taste.

An analysis of studies received from the USDA Economic Research Service (their own and others) shows that eating away from home, particularly increasing consumption in fast food restaurants, is correlated with increases in BMI. Further, the per capita number of restaurants in a state was positively related to individual's BMI and the probability of being overweight. See Appendix A for charts summarizing these studies, used courtesy of USDA ERS.

Motivation. The process of consumers' motivation and readiness for lifestyle changes such as weight management are described by a behavioral sciences model, the Transtheoretical Model of Change (Prochaska). The model identifies five stages-of-change – Pre-contemplation, Contemplation, Preparation, Action, and Maintenance; and emphasizes that a message must be matched to a respective stage in order to be most effective (e.g., messages targeting consumers in the action stage will likely be ineffective for consumers in the pre-contemplation stage). Thus, the effectiveness of food and restaurant labeling or messages for weight management would depend in part on consumer readiness and stage of change.

Portion sizes and energy density. Although consumer motivation is important for weight management, there is also interest in other factors that facilitate weight management in the current "obesigenic" environment. Two aspects of the food environment have been recently highlighted as having implications for weight control: increased portion size and the energy-density of foods. Portion size of restaurant foods increased from the 1970's through the 1990's (Rolls 2003). National survey data show that portion sizes of food eaten both in the home and away from home increased from 1977 to 1998 (Rolls 2003). Energy density refers to the number

of calories per given weight or volume of food. The fat content of food increases the energy density and the water content lowers the energy density. Although energy density can be decreased by decreasing the fat content of the food, this approach can be self-limiting because decreasing the fat content also decreases satiety, the extent to which the food satisfies the urge to eat. Research has shown that increasing the proportion of water-rich vegetables in mixed dishes such as casseroles decreases the energy density without decreasing satiety (Rolls 2003).

Eating cues. Other research has examined consumer behavior in the context of the eating environment. Results indicated that people's eating responses are often automatic and respond to cues such as package size, shape and structure (Wansink 2003). For example, research participants ate more food when they were given larger containers, even when the food was unpalatable stale popcorn. People also reduced consumption automatically in response to cues such as package structure or dividers, for example, red potato chips at intervals in a tube of regular chips (Wansink). This research suggests that changes in food packaging and presentation can be complementary to labeling and nutrition information in assisting consumers with weight management.

Weight management and economic theory

One economic rationale for government action is a situation called market failure, in which there is a consumer demand not being met by the market. One possible market failure is the absence of nutrition labeling in restaurants, where restaurateurs know more about the nutritional content of their meals than their clients. Further, information remedies provided by the government work best if information is structured in a way that best assists consumer understanding and use. It is not clear after ten years of experience whether the label on packaged food, including both claims and the nutrition facts panel, is presented in the optimal way for consumers.

However, although many consumers clearly wish to lose weight, survey's show that they believe this is primarily the responsibility of each individual. It is not clear exactly which market can help consumers to control their own eating habits although weight loss and diet information and programs and clubs are widely available at reasonable prices. Although there is no obvious market failure, there is a sense that FDA could do more to assist consumers with the important public health issue of weight management. The theory of constitutional economics holds that people often turn to government to constrain their choices to assist them in their long-term goals (Brennan and Buchanan, 1985, especially pp. 67-81), and this theory can provide a rationale for government action on weight management. Consumers may prefer to have food choices externally constrained rather than to bear the cost of restraining their own food consumption. If FDA can take actions that alter the set of food choices offered to consumers, consumers may be better off even if those changes eliminate foods that are currently consumed. An example is stimulating reformulation of current foods through changes in labeling. If labeling causes changes in the food offered to consumers, then the set of available foods has been altered. Consumers may prefer this form of external restraint to voluntarily restraining their daily food consumption.

Changes in product formulation. ***Evidence suggests that not only do consumers respond to labeling, but producers also respond to consumers' concerns about diet by producing healthier products. Decisions to change the composition of foods will depend on whether producers anticipate that the expected private benefits of changing the formulation***

will exceed the expected private costs of doing so. Analyses conducted for FDA have examined the effect of hypothetical labeling policy changes on manufacturers' expected decisions to reformulate foods (Honeycutt et al 1998, White et al 2002, Muth et al 2003). Further research is needed with respect to weight management and food formulation; to evaluate how labeling changes might motivate product reformulation, provide opportunities for marketing healthful products, and stimulate competition based on nutrient and health claims that assist consumers with weight management.

III. Current Research Projects.

The Division of market Studies is currently engaged in four short-term projects to address current issues in weight management. The projects are: 1) focus groups on consumer response to nutrition information on packaged food and in restaurants; 2) a survey of nutrition information available on restaurant web sites; 3) discussions with manufacturers regarding incentives and barriers to food formulation; 4) a quantitative social sciences model of dietary and weight management behavior. Preliminary results, currently available for the first three projects, make possible some suggestions for further research and indicate issues for further consideration. We plan to conduct further analysis of the complete results and consideration of the relationships among the four projects.

1. Focus Groups on Food and Restaurant Labeling and Weight Management [Amy Lando, Steve Bradbard]

In response to FDA's concern over the rise in obesity and overweight in the United States, we conducted a series of eight focus groups, funded by HHS/ASPE, to explore: (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quick service restaurants; and, (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the Nutrition Facts Panel and the principal display panel on food packages and to various presentations of nutrition information at restaurants.

The focus groups were held in November and December 2003, in Calverton, Maryland, Philadelphia, San Antonio, Texas, and Chicago. The groups, which each had between 7 to 10 participants, were segregated by gender and education. All focus group participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quick service restaurant in the past month.

TOPLINE RESULTS:

The following findings are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers. These topline results are not based on a complete analysis of the focus group tapes and/or transcripts, which will be used to compile the Final Report. Also, since these findings are based on qualitative research with small sample sizes, they should not be viewed as nationally representative or projectable.

General Nutrition:

1. **Attitudes towards nutrition.** In many of the groups, especially the women's groups, people cared about nutrition and report using the Nutrition Facts Panel (NFP). Many were quite savvy about nutrition. At the same time, however, many also said that they don't always consider nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. While participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium.
2. **Macronutrients.** In general, individual people tended to care more about some macronutrients than others depending on the diet that person was following. In most groups, at least one person was familiar with the Atkins diet and many of these people were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some people checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.
3. **% Daily Value.** Very few participants reported using the % Daily Value (%DV) column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to then since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a good way estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Food Label Modification:

4. **Large package sizes.** In all the groups participants were presented with a mock-up of a 20oz soda and large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving size listed. Most participants said that neither the muffin nor the soda was a healthy food. They pointed out that the soda had a lot of sugar and calories and that the muffin was high in fat, calories, and carbohydrates.
5. **Serving versus package.** In general, participants thought it was misleading to list either product as having more than one serving. Many did realize that if you eat the entire package you would need to multiply the serving size by the nutrient of interest, though some were confused and made mistakes when trying to calculate in their heads. They were not surprised to see these products labeled as multiserving packages.
6. **Calorie-related variations.** The first test label added a %DV for calories, removed the *calories from fat* line, enlarged the calories line, and changed that way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most did not think it was an improvement over the existing language.
7. **Serving size variations.** The second test label had two %DV columns on the NFP, one for a single serving and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the single serving size. After comments from these groups, the label was modified to have the absolute amount for both a serving and the entire product. Participant reaction to this modification was positive, but some thought it was not necessary to list the amount for a single serving, and others preferred to have the absolute amount replace the %DV in the columns.
8. **Calorie cues.** We tested both a starburst with the calories per serving (first four groups) and a white square with calories per whole product (last four groups). The starburst was misleading to many since they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product

got mixed reactions, but many just said that they recognized these as high calorie products and would stay away from them.

9. **"Healthy" (keyhole) symbol.** In half of the groups we tested a "healthy" meat lasagna with a purple keyhole symbol on the front of the package. There was generally positive reaction to including a front of package symbol indicating that a product was healthy, as long as they understood the definition of the symbol and could trust that it was true. They believed that they would have to be educated as to the meaning of such a signal. Some mentioned that they would look for the keyhole when they were in a hurry in the store. They expressed some concern that these products would cost more or that they would lack in taste.

Restaurant Labeling:

10. **Nutrition information.** Most people seemed interested in having nutrition information available to them when they eat at fast food and/or quick service restaurants, though they might not use it every time they eat out. They suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.
11. **Menu board information.** Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, people liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. While participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many people. They thought that calories could be a signal for the level of other macronutrients.
12. **Menu board section.** Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.
13. **"Healthier" (keyhole) symbol.** Many also reacted favorably to the purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well. Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

Messages:

14. There was no one message that participants universally thought was meaningful or liked. Different groups had different preferences, but many thought some message would be good reminders for them to look at the NFP, and also good for prompting children to examine the label.

In summary, many consumers said they are very interested in nutrition information and they report using the NFP to help them determine what to buy and eat. They are interested in many different nutrients in addition to calories. In all the groups, participants felt that multiserving products that are commonly consumed at one sitting should be labeled as such. Many consumers said they are looking for labels that have uniform and realistic serving sizes and are interested in having nutrition information available to them at fast food restaurants.

Based on this preliminary analysis, these focus groups suggest some questions for future research:

- How many consumers use the %DV and how do they use it? Are there other ways to signal to consumers that a product is high or low in a certain nutrient? Is a healthy symbol on the front panel useful for consumers?
- Are there better ways to communicate serving sizes on the Nutrition Facts Panel?
- How do consumers react to nutrient content claims and health claims about calories on the front panel of packaged foods?
- Will nutrition information on restaurant menu boards or other locations change purchasing behavior?

2. Nutrition Information in Restaurant Menus: An Online Survey
[Cristina McLaughlin]

The restaurant industry, especially the chain restaurant industry, has used a variety of methods to inform the public about the nutritional characteristics of menu items, in response to current interest in the contribution of restaurant meals to the American diet. One information source is restaurant company web pages on the Internet. The National Restaurant Association website includes a bulletin highlighting chain restaurant menu offerings or information marketed towards healthy lifestyles (NRA 2003). Each of the 19 restaurant entries includes a short description of the health or nutrition-oriented menu feature, and a link to the specific restaurant web site. A systematic survey of restaurant web sites could provide an overview of available information, and could answer the following questions. What nutritional information is currently available to consumers on the Internet regarding menu items at major chain restaurants? Do restaurant web sites indicate the availability and format of nutrition information found at the restaurant locations? How are chain restaurants responding to current concerns about nutrition and obesity, as indicated by menu features and nutrient profiles on their web sites?

The purpose of this project is to survey restaurant web sites and compile a data base of nutrition information in restaurant menus available in the Internet. The list of restaurants was based on the top 100 United States restaurant firms by sales, obtained by searching Dunn & Bradstreet 2003). The top 100 firms identified in the search own a total of 125 restaurants and chains, including 71 casual dining, 28 fast food and 26 other (upscale, pizza delivery, buffets, etc). We reviewed the websites for each of the 125 restaurants or chains, and summarized the information in an Excel spreadsheet. The next step of the project will be to convert the tabulated information to an Access database.

Sample spreadsheet pages for the first 30 restaurants, ranked by total sales, are included in Appendix C. The spreadsheet provides the restaurant name and description followed by the site page (URL) address that includes the nutrition information or that brings us closest to it. The next columns summarize whether nutrition information is available on the site, and whether the information is interactive or in printable (pdf or html) format; reference to "Light" but no additional nutrition information; indication that nutrition information is available on premises and in what format (menu board, menu, tray liner, napkin, brochure, other); whether the nutrition information covers all menu items or partial or targeted items (such as dietary recommendations); and other information, including features marketed for healthy lifestyles.

Of the 125 restaurant web sites surveyed, 36 included nutrition information as either an interactive tool, such as a meal builder, a printable version or both. Of these, about 22 included printable versions only, 3 were interactive only and 12 provided both. Only 4 restaurant websites made reference to "light" items in their menu without additional nutrition information.

The nutrition information, when available online, generally included calories and nutrients covered by nutrition labeling of packaged foods: calories, calories from fat, total fat, saturated fat, sodium, etc. A few websites, such as Wendy's and Au Bon Pain, even included information on trans fat. Although nutrition information was often available online, it was not clear whether similar information would be readily available at the point of purchase. Only a few websites indicated whether the nutrition information available online would be available on premises as well. Further exploration of this question would require actual physical visits to the restaurants.

Of the 36 restaurants with nutrition information on their websites, 11 provided both complete nutrition information on all menu items and recommendations for special dietary requirements. Overall, 17 offered nutritional information on their whole menu, and 28 restaurants offered nutrition information on some items such as "Most Popular" or recommended items. Although a number of restaurant web sites provide fairly complete nutrition information online, often the nutrition information was not closely tied to the online menus themselves. Many online menu pages displayed little or no overall emphasis on caloric intake or weight-management-related information. The nutrition information, when provided, was generally in a separate file from the online menu. A few online menus were available in a format that probably resembles the actual, on premises restaurant menu but none of these menus showed information on calories or fat.

In summary, many restaurants, but not a majority, provide some nutrition information on their websites. The nutrition information is often displayed separately from the menu web pages, and of course is also separate from the actual point of purchase of a restaurant meal. Restaurant web sites also provide anecdotal, qualitative information about featured menu items related to nutrition, calories or weight management. Some examples of healthy eating menu features are indicated in the Notes section of our spreadsheets (Appendix C) and summarized in the NRA web page overview (NRA 2003). For future research, we plan to expand our survey to include the top 100 fast food firms, convert the information to a relational (Access) database, and undertake a content analysis or other qualitative review of the restaurant web sites. This qualitative review will more fully describe the current status of restaurant initiatives to assist consumers with weight management.

3. Qualitative Investigation of Motivation for Food Product Reformulation [David Zorn]

Restructuring Consumers' Choices: Changing the Foods Offered to Consumers

Since implementing the NLEA labeling regulations in 1993, FDA has learned the enormous importance to health and nutrition that comes by changing the supply of food. When labeling gave consumers information on certain nutrients that they should consume less of, their net reduction was on average about 1% (Levy et al 1985). Consumers who chose different products reduced consumption by more than 1%, but consumers who did not use the labeled information did not benefit from the labeling of a static product set. But if an existing product is reformulated to reduce its calorie content, then all consumers of that product benefit, even if they are not actively seeking to reduce calories. And new products with fewer calories may attract consumers other than those actively engaged in weight management.

Currently DHHS ASPE and FDA have paid a contractor to conduct confidential discussions with food manufacturers and restaurants to provide input on what FDA could do to encourage them to provide consumers with different food offerings to assist in weight management. Because this research is not yet complete, we are reporting initial findings here (Muth and Kosa, 2003). This preliminary summary provides information on discussions with seven food manufacturers and seven restaurant chains regarding the characteristics of food products and servings. Additional discussions are scheduled in the near future. Once all of the discussions are complete, the contractor will provide a formal report containing a full summary of the discussions and a description of the project background and the methods of the study, including the process for conducting the discussions (Muth and Kosa, 2003)

- **Label Prominence**

Manufacturers respond to required information depending on how prominent it is required to be on the label. For an earlier project, some manufacturers had indicated that they would only reformulate to reduce trans fat in margarine if information on trans fat was going to be prominently mentioned on the label, either by placing it on a separate line in the Nutrition Facts panel or by allowing nutrition content claims. (Honeycutt, et al., 1998). Currently, the signal on calories is weak relative to other signals on the label. Some manufacturers told us that:

  - the Nutrition Facts panel should focus more on calories and perhaps be simplified.
  - FDA should establish a seal related to weight management goals to give prominence to the issue. Other third party seals are very expensive to use.

- **Visual Cues**

We are learning that consumers use visual cues to judge their food consumption. Changing the packaging of products even with their existing formulations, would likely affect the amount of calories consumed.

  - Some manufacturers suggest allowing single serving packages to contain only one serving rather than 2.5 servings; others suggested readjusting labeling serving size to represent the entire package or what people generally eat.

- **Dietary and Health Context**

It is important that consumers have a context for the information given to them. Currently, the Nutrition Facts panel gives calories only as a scalar number, with no context at all for a complete diet. Some manufacturers suggest

  - giving a daily value for calories, just as there is a daily value for almost every other macronutrient based on a 2000 calorie diet.
  - development of one message on weight management common to all federal agencies.
  - that consumers be educated about calorie balance, possibly illustrated by pictorials on packages to correspond to energy expenditure activity equivalent to the calorie content of the food.

- **Reformulation Factors**

Four key factors affect how favorable a food category is to being reformulated: cost of reformulation, consumer sensitivity to sensory changes in the product, consumer sensitivity to what is on the product label, and the competitiveness of firms within the food category. A labeling change required by FDA is most likely to result in reformulation when the combination of these factors favors the reformulation, such as for beverages, breakfast foods, dairy products, egg products, infant foods, seafood, soups, and weight control foods (Muth, et al., 2003). It may

not be possible to influence reformulation of all foods. However, modest changes in food consumption can result in enormous improvements in public health.

- **Regulatory Policy**

Manufacturers suggested several areas where current regulatory policy is a barrier to reformulation

  - The food additive approval process. One firm even supported user fees to fund a simplified and expedited review process. Improvements in the GRAS notification process have been helpful, but additional steps would encourage innovation. They especially mentioned faster review of artificial sweeteners, including cyclamate. Some manufacturers also recommended that FDA provide stronger advocacy and support for the use of fat and sugar substitutes.
  - The claims approval process. Some firms want to be able to make factual nutrient content claims without disqualifying limitations relating to other nutrients, want less wordy claims, and they want the claim approval process expedited. Some manufacturers want to be able to label foods with 80-90 calories as low calorie because below this level it is difficult to provide enough nutrition; some want to be able to use "low carbohydrate" claims.
  - The standards of identity and fortification policy. Allow fortification of reduced calorie products so that they can meet the standards of identity. For example, allow fortification of reduced calorie orange juice with folic acid.
  - Standard calorie values for macronutrients. One manufacturer wanted calories from soluble fiber like oligofructose not to be included in the calorie count at the full 4 calories per gram.

- **Restaurants and Food Service Establishments**

Restaurateurs had the following suggestions.

  - Educate consumers about appropriate portion size, caloric balance, eating wisely, and asking for customized orders to reduce calories.
  - Educate consumers that small changes in diet can make significant differences for weight management. Restaurants would disseminate on bags, cups and tray liners.
  - Educate consumers on using restaurant nutrition information that is increasingly available and be flexible on the format and placement of such information.
  - Assist restaurants with analytical methods for foods.
  - FDA and FTC need to be more flexible about comparative claims. Currently 20% calorie reductions can't be claimed but they are significant for weight management improvements.

In summary, discussions with manufacturers indicated some areas in which labeling policy and other regulatory policy could provide incentives or remove barriers to manufacturer initiatives to assist consumers with weight management. As noted above, these are preliminary results from the initial manufacturer discussions, which are still in progress. Note that these findings are based on qualitative research with small sample sizes, therefore, they should viewed as suggestive, and not as representative or projectable to all manufacturers. In the near future, we will have information available on a complete analysis of the full set of discussions.

4. Quantitative Social Sciences Model of Dietary and Weight Management Behaviors [Amber Jessup]

Current social sciences literature and data sets contain a wealth of information about consumer decisions affecting weight, including attitudinal and behavioral factors related to exercise, food choice, food quantity, and frequency of eating. Realization of the full potential of this information to address public health questions about obesity will require intensive, systematic review and model-building. FDA, in collaboration with OASPE, is working with a contractor, ERG, to review the literature and build a model focused on food label use and weight management. The main components of the project include: an annotated bibliography and written literature review, theoretical and empirical (data-based) models of label use for weight management and a summary of future research needs.

The model will address important individual and environmental factors that can influence consumer dietary and weight management behaviors. In our review of literature in economics, psychology, nutrition, health behavior, and other social science disciplines we are identifying critical factors affecting motivation and execution, such as habit, risk perception, efficacy of behavior, availability of and access to nutrition and health information, and education. We are organizing information from selected articles in a structured, annotated bibliography with brief summaries of the article focus, economic/econometric model used, data source, statistical methodology, results, including a critical review of strengths and weaknesses, and relation to the modeling project. Examples of the annotated bibliography format are in Appendix B. We will next write a literature review synthesizing the conclusions about label use and weight management that can be drawn from the literature.

The theoretical model will be based on Grossman's theory of a household health production function (Grossman 1972). In this framework, health is produced from a combination of time, purchased goods, and human capital. This approach is appealing because health is typically not a commodity that can be directly purchased, but results from a combination of lifestyle choices and purchases. Under the theory, the consumer maximizes his or her utility from health, leisure, and consumption of other goods, such as food. This model acknowledges that food may enter into consumers' utility function in multiple ways: directly, say, due to the pleasure of eating chocolate cake and indirectly, say, through the detrimental effects of chocolate cake consumption on health. Additionally, the consumer is constrained by both time and income. Information, in the form of labeling, may enter into his or her health production function by affecting the choice of foods and into his or her time constraint by reducing the time required to choose foods.

For building the empirical model, nationally-representative data on food choices, nutrient intakes, and diet and health-related attitudes and knowledge (including nutrition label use) are available from USDA's Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS), 1989-1991 and 1994–96. To understand how consumers use labels to aid in managing their weight, we will model caloric intake as predicted by label reading. The independent or predictor variables will include other aspects of health, preferences and attitudes towards food and nutrition and demographic characteristics.

Because of the complex relationships among dietary knowledge and attitudes, label reading, and calorie consumption, there are limitations in the use of cross-sectional data, such as CSFII, to infer causal relationships between label reading and dietary choices. For example, consumers with high levels of knowledge and concern about nutrition are likely to eat a healthier

diet than consumers that are unconcerned about nutrition. Consumers who are well informed about nutrition are also more likely to read labels and will be better able to use labels to guide their diet. Conversely, label reading may inform consumers about nutrition. For example, health claims may inform consumers about the relationship between diet and disease, or the presence of a macronutrient on the Nutrition Facts panel may signal to consumers that the macronutrient plays an important role in the diet. Thus, although some studies have using simple, single equation methods such as OLS or probit regressions to describe the relationship between label use and nutrient consumption (Neuhauser et al 1999, Kreuter et al 1997), this approach can establish a correlation between label use and diet, but does not establish a causal relationship.

Studies using more complex techniques, such as a two-stage Heckman selection model or an endogenous switching regression model, have attempted to control for the consumers' self-selection to use labels (Guthrie et al 1995, Kim et al 2000) However, neither of these studies focused on calories, a key dietary variable in weight control, and both studies controlled for self-selection of label reading by using data on nutrition knowledge and attitudes to predict label use. But these characteristics may also be the result of self-selection and therefore may not be suitable controls.

In order to overcome these problems, we will test the robustness of the independent association of label use and caloric intake using several modeling approaches, including a single equation multivariate model, a two-stage model, an endogenous switching regression model, and a model using the difference in label availability between waves of data. The latter approach exploits the implementation of the Nutrition Labeling Education Act (NLEA) in 1994, between waves of the CSFII and DHKS, to conduct a natural experiment of the effect of label changes on consumers. Differences in the effectiveness of label use between waves of the CSFII and DHKS, while controlling for other observable factors, can be reasonably attributed to increased availability and standardization of labels.

This model will enhance understanding of the relationship of dietary behavior and consumer label use and of consumer characteristics that influence the effectiveness of label use. By considering relevant and important individual and environmental factors, this model can go beyond the existing literature to help identify the role that food labels play in health decisions. The model will provide information on the marginal benefits of label use on health and can be used in cost-benefit analysis of current labeling, of possible changes in labeling regulations, and of obesity-related policy issues at FDA and HHS.

We expect to use the model to test the effectiveness of policy interventions such as label changes, product reformulation, and educational messages. The data should also enable us to profile different groups of consumers who have different knowledge, attitude, and behavior; this information can also be useful in identifying and prioritizing intervention and education efforts. For example, the model will attempt to answer questions such as:

- Do food labels help consumers maintain their desired weight?
- Are less educated consumers less able to use food labels to maintain a healthy weight than more educated consumers?
- How does ethnicity and other cultural factors affect consumers ability to use the food label?
- How does mother's use of the food label affect the health of their children?

The model developed in this project will use existing data, such as the CSFII/DHKS, BLS price data, and supermarket scanner data. The project will also identify data gaps and recommend additional data collection and improvement of this social sciences model.

IV. Future/Potential research projects for addressing weight management problems

Although not finished, some preliminary observations can be made from our research so far. First, although consumers clearly use food labels, including health claims and the nutrition facts panel, the information may not yet be structured in a way to optimize understanding and use. Second, although our research has uncovered some information being offered in restaurants, consumers appear to want more information and in a more structured format. We have uncovered several promising formats including segregation of meals or logo indicators for low calorie or healthy alternatives. Finally, our research shows that manufacturers will respond to changes in labeling policies to reposition their foods to take advantage of information that is prominently required. These preliminary findings suggest some avenues of future research.

1. Food Labels

Research is needed to find out if there are ways to reformat the nutrition facts panel (NFP) to make it easier to use and to provide incentives for manufacturers to offer more lower calorie foods that are also healthier than the current selection. From the existing literature and from the preliminary reports from the current projects, some possible areas include:

a. Daily values – either evaluate the effectiveness of an education campaign to see if people will start using these or possibly look for replacements to indicate whether nutrients are high or low. These replacements could be graphical devices or wording changes such as high or low.
b. Serving sizes – Because consumers are having difficulty, either because of time or ability, with the multiplication necessary to calculate nutrient values consumed, consider replacing some or all nutrient information with total container information or nutrient density information.

Research is also needed to see how we can provide better signals on the front of the label, the principal display panel (PDP). Because consumers often do not look at the back of the label when there is a claim, and often take the claim to apply to the entire product, research is needed to see if FDA can provide an alternative signal that addresses the entire product. This may be an indicator of the healthiness of the product, such as the Swedish keyhole, or an indicator of calories in the product.

2. Restaurants

Research is needed to evaluate the effectiveness of various kinds of nutrition labeling, including labeling calories and indicators of healthiness for both a la carte items and meals. Different kinds of labeling may work differently depending on the type of restaurants, e.g., quick serve versus family style restaurants. The desirability of some type of labeling was conclusive in qualitative research but more quantitative research may be necessary. Also, nutrition labeling in restaurants may not be able to be as precise as labeling for packaged products. It is not clear whether people would use nutrition information in restaurants in a different manner than they would for packaged food. Although there is some information provided to us by the Economic Research Service, it might be useful to more completely establish the link between overweight and the prevalence of eating out, both with respect to the types of restaurants and the socioeconomic characteristics of overweight consumers who

eat out frequently It may also be useful to know whether people who perceive themselves to be overweight in fact eat fewer meals in restaurants because of that fact and whether or not, if so, labeling would increase the number of meals eaten out.

Finally, we have a potential volunteer chain of restaurants that will use some of the information obtained from the focus groups to test in an actual market situation how consumers will react to this type of labeling. The final details are expected to be worked out in the next month or two.

3. Food Reformulation

Some of FDA's existing policies for nutrition labeling, food standards and food additives may need to be examined to see if there are barriers to reformulating existing foods. In addition, changes that might be suggested to food labels or restaurant menu's should be evaluated to see how it would change the supply side of the market and increase the number of low calorie/healthy foods or meals offered.

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VII. Appendices

A. Review of Literature

B. Sample Annotated Bibliography Entries

C. Sample Pages from Spreadsheet of Restaurant Web Sites

Appendix A.
Review of Literature

Review of literature on nutrition labeling and restaurant point-of-purchase labeling
[Contributors to literature review: Amy Lando, Jordan Lin, Andrew Estrin, Amber Jessup, David Zorn, Clark Nardinelli]

Nutrition labeling

The Nutrition Labeling and Education Act (NLEA) (1990) gave FDA authority to require a Nutrition Facts panel on the label of most packaged foods. The Facts panel states the standardized serving size, the number of calories per serving and the amount and percent of the Daily Value (DV) per serving for specified nutrients. (The Daily Value is a reference amount for daily intake of a nutrient in a 2000 calorie diet.) Before NLEA, nutrition labeling was required only in certain instances, such as when claims were made about nutrient content.
In addition to the Nutrition Facts panel, FDA also permits specified nutrient content claims and health claims on food labels. FDA defines criteria for nutrient content claims, such as "low in fat" or "a good source of calcium". Health claims highlight a relationship between a food or nutrient and a disease or health-related condition, such as calcium intake and reduced risk of osteoporosis.

Social science research methods

Before NLEA, FDA conducted consumer research about the usefulness of potential choices for the Facts panel format. Since NLEA, a number of researchers have studied how consumers use the Facts panel, nutrient content claims, and health claims (separately and in combination) to make dietary choices. Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Depending on the the goals of the project, research methods may include qualitative data collection, quantitative surveys or experimental studies.

- In qualitative research, open-ended questions are used to elicit unstructured consumer reactions and thoughts to different topics or stimuli. Qualitative research, including the focus group format, is useful for obtaining the range of consumer opinions about a given topic and is often conducted as a preliminary step, before quantitative surveys or experimental studies. Unlike experimental studies or quantitative surveys, results from focus groups and other qualitative studies are not generalizable to any population.
- In quantitative surveys, information is collected by structured questionnaires and the resulting data categorized by demographic and other characteristics. When the survey sample is nationally representative, the results provide population estimates and the conclusions can be generalized nationally. Nationally representative surveys can help inform policy makers, risk assessors, and health educators of the knowledge, attitudes and self-reported behavior of the U.S. public about a certain topic.
- Experimental studies test consumer response to manipulated stimuli, such as real or hypothetical food labels that vary in format or content. Each respondent is randomly assigned to an experimental group that responds to a particular type of food label. The response of each group is recorded, and differences in response across groups are attributed to the corresponding experimental conditions or labels. Experimental studies

can statistically test differences in consumers' understanding of and ability to use different label information and formats.

- Intervention studies are another type of experimental study. Intervention studies measure differences in peoples' behavior when specific conditions are varied according to an experimental design. For example, intervention studies may examine purchasing behavior in grocery stores or eating behavior in restaurants in which different types or amounts of nutrition information are presented.

Food label use

Research clearly shows that most Americans are familiar with and use the Nutrition Facts panel. In a 2002 FDA survey, 69 percent of the U.S. population reported using food labels often or sometimes when they buy a product for the first time (FDA, 2003). People reported using the food label for many reasons, most commonly to see how high or low the food is in calories and in nutrients such as fat, sodium, or certain vitamins.

Many consumers do not fully understand the information on the Facts panel, even as they use it to make dietary choices. One study suggest that percent DV information helps consumers judge the healthfulness of a food better than absolute amounts of nutrients alone (Levy, Fein, and Schucker, 1996). However, in a national survey (FMI, 1996) less than half of respondents could accurately identify the meaning of the percent DV for fat and another study found that DVs are not helpful for consumers to make correct judgments about the healthiness of a product (Barone et al, 1996)..

Some experimental food label studies have found that, when presented with nutrient content claims or health claims in the absence of the Nutrition Facts panel, consumers can be misled into thinking a product is healthier than it really is (Ford et al., Roe et al.). These misperceptions may be remedied if consumers also look at the Facts panel. For example, regardless of the fat and fiber claims on the front of packages with varying fat and fiber content, consumers who were asked to read the Facts panel could correctly identify a product as being low or high fat (Garretson and Burton). Varying the level of fiber made no difference in the consumers' perceptions of the healthfulness of the food. This suggests that fat is a more salient nutrient to consumers than is fiber. Similarly, regardless of their education level, consumers presented with the Facts panel could judge product healthfulness corrrectly even in the presence of an implied claim about heart health ("It Does Your Heart ♥ Good!"). However, without the Facts panel, consumers were significantly more likely to be influenced and potentially misled by health claims (Mitra et al).

In the above studies, the research subjects were specifically directed to consult the Facts panel. However, in a study that gave respondents the option to look at any part of a food package, consumers did not look at the Facts panel to verify claim information, but truncated their examination to just the claim on the front of the package (Roe, Levy and Derby). This resulted in incorrect inferences about the product healthfulness, particularly about nutrients not mentioned on the front. Although more research in this area is needed, this study provides some evidence that consumers do not customarily verify front panel information by consulting the Nutrition Facts panel.

Food label and diet

Correlations between food label use and diet have been reported in a number of studies. For example, survey respondents who used the Facts panel were more likely to consume a lower fat diet, both in the general population and among family clinic patients (Neuhouser et al, Kreuter et al). Clinic patients with health conditions such as high blood pressure and high cholesterol were more likely to look on the label for sodium and cholesterol information, respectively (Kreuter et al).

A limitation in interpreting cross-sectional surveys about label use and diet is that consumers who are concerned about their diet may be more likely to read the nutrition label. Thus, although label reading may be correlated with healthy diet practices, the cause of the healthier diet may be the concern about nutrition, not the label reading. For example, in one study that found lower total fat intake among label users than non-users, consumers with higher fat intakes were less likely to search for fat information on the label and food label use was strongly correlated with attitudes toward food labels (Lin and Lee). In another study using statistical analysis to control for different characteristics of label users and non-users, food label users had lower average percent of calories from total and saturated fat, cholesterol, and sodium than non-label users (Kim, Nayga, and Capps).

In an intervention study using grocery store shelf labels with nutrition information, the nutrition shelf labels increased the purchase of healthier alternatives in some product categories, but decreased the purchase of healthier alternatives in other product categories (Teisl and Levy). The authors suggested that consumers might use an implicit health risk "budget" to compensate for eating healthier foods in some categories where taste differences among choices were small, by eating less healthy foods in categories that had greater taste differences among choices. The ability to make such choices could be beneficial to consumers, although not leading to overall improvements in diet. The results support the idea that providing nutrient information may allow consumers to more easily switch consumption away from "unhealthy" products in those food categories where differences in other quality characteristics are relatively small.

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Restaurant labeling

In 1999, American households spent an average of $2,116 or 42 percent of their total food expenditure on food away-from-home (BLS 1999). According to the latest data, during 1994-6, away-from-home food, especially from restaurants and fast food locations, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS 2000). Thus, food away-from-home is an important part of American diets and more informed dietary choices away-from-home can potentially help reduce the risk of health problems such as obesity. Nutrition labeling on menus, including the use of claims and symbols, is one way to help consumers make more informed dietary choices. The effectiveness of labeling, however, depends largely on how consumers respond to the measure. Although the

NLEA does not mandate restaurant nutrition labeling, there is a body of research that has investigated consumer responses to nutrition labeling on food away-from-home.

A number of experimental studies have examined consumer behavior in cafeteria, restaurant and vending machine settings in response to nutrition information or health messages. The results of these studies are mixed; differences in results among studies may be due to differences in experimental designs, including size of sample, demographic characteristics of participants, experimental setting, length of study, type of nutrition information or health message and type of behavioral outcome studied.

In a British college cafeteria, display of calorie and nutrient content of food items on the menu board had a negative effect, resulting in higher calorie and fat intake at lunch (Aaron et al 1995). The differences were greater for males and for less restrained eaters. The authors stated that the results indicate the importance of assessing the motivational choices of potential recipients of nutrition education programs. A second study in a British sit-down restaurant with a limited menu found fewer participants selected an entrée marked as a lower fat option, although the difference was not statistically significant (Stubenitsky et al). However, those selecting the lower fat entrée had lower calorie and fat intake both from the entrée and from the complete lunch. Sensory expectations and post-meal acceptance measures were similar for the entrée in its regular or lower fat version, both when the lower fat version was labeled and when it was unlabeled.

In a cafeteria for the general public, prominent labeling of certain items as "lower caloric selections" had no effect on calories eaten or perceived calories eaten, either among restrained eaters (dieters) or unrestrained patrons (Johnson et al 1990). Restrained eaters did choose lower calorie meals, but their choices were not related to the presence of the "lower caloric selection" label. In a college cafeteria, changes in the proportion of patrons choosing items from various food groups resulted from labeling the caloric content of food items, highlighting healthier choices with a symbol, or providing tokens for monetary incentive for healthier choices (Cinciripini). Changes in food group selection with labels or tokens were different for males and females and for lean, normal or obese participants. Overall, calorie labeling decreased the selection of starchy foods and red meat items; healthier selection labeling with incentive tokens increased the selection of vegetables/soup/fruit/lowfat dairy, chicken/fish/turkey and salads and decreased the selection of high fat/dessert/sauces. In a family-style, table-service restaurant, special healthful entrees were highlighted by rotating messages: a nonspecific message, a healthfulness message and a taste plus healthfulness message (Colby et al). Sales of the healthful chicken or tuna entrees were higher when the taste plus health message was used than with the health alone message.

One recent study compared the effect of health messages and lowered prices, separately and together, on the purchase of healthy food items in a counter-service, delicatessan-style restaurant (Horgen and Brownell 2002). Price decreases alone, rather than a combination of price decreases and health messages, were associated with increased purchases of some healthy food items over a 4-month period. The authors suggested that health messages may have paradoxical effects if foods labeled as healthy are assumed to taste bad.

Restaurant patrons at a table-service restaurant for university students and staff indicated their labeling preferences among menus using an apple symbol to highlight healthy selections, menus using colored dots to highlight specific nutrition guidelines, or a leaflet listing numeric values for nutrient content (Almanza and Hsieh). Both the apple symbol and the leaflet were preferred over the colored dots, and were considered more attractive, less time-consuming and

easier to use. The apple symbol was preferred over the leaflet by women patrons and those younger or less educated. However, this study did not examine whether patron labeling preferences were related to consumption behavior. Previous FDA research has suggested that label format preference does not necessarily equate to format effectiveness (Levy, Fein, and Schucker 1992).

An experimental study, conducted by mail using a consumer household research panel of primary food shoppers, found interactions between the effects of a heart disease claim and a Nutrition Facts panel on either a package for a frozen lasagna entrée or a menu listing a lasagna entree (Kozup, Creyer, and Burton 2003). When no nutrition information was present and there was a heart disease claim on the package or menu, subjects thought that regular consumption would reduce the risks of heart disease and stroke, and the claim had a positive effect on their attitudes toward the food, its healthiness, and intention to purchase the food. Regardless of presence or absence of the heart disease claim, better nutrient content had a positive effect on perception of the food's relationship to heart disease risk as well as a positive effect on attitude toward the food, the healtfulness of the food and intention to purchase. Poorer nutrient content had corresponing negative effects. Addition of the claim to positive nutrition information further increased the perception of reduced heart disease risk, but did not increase other positive attitutes compared with nutrition information alone. Addition of the claim to negative nutrition information (inconsistent with the claim) had no effect on product evaluations and led to a negative impression of the credibility of the manufacturer or restaurant marketing the food. In a further experiment, evaluations of a menu item were affected by alternative items presented. If the nutrition information of alternative items was more favorable, then the evaluations of the item were less positive, and vice versa. This suggests that the alternative or nontarget menu items served as a reference for the target items. If the nutrition information of alternative items was present, then the positive effect of the heart disease claim was limited to perception of the food's reduction of heart disease risk.

Practical problems in restaurant labeling and obstacles to labeling as reported by large restaurant chains have been reviewed (Boger 1995, Almanza 1997). Problems include the fact that NLEA guidelines were developed for packaged foods, not restaurant food, with respect to serving sizes and criteria for health and nutrient content claims; different sized portions for lunch and dinner; variability of menu item from day to day. A suggestion for further research was whether consumers use nutrition information on packaged foods differently than in restaurants (Almanza 1997).

In summary, consumers have mixed reactions to nutrition information in cafeterias and restaurants. Both health claims and listing of nutrition information have been found to be capable of producing positive influences on consumer evaluations of menu items and the influences appear to be strongest when nutrition information about alternative menu items is absent. Although nutrition information may influence choices and attitudes, other factors may be more salient: whether the respondent is on a diet, attitudes toward nutrition, price of food, health claim vs. nutrition information, taste/perceived taste.

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Restaurant studies from the Economic Research Service

An analysis of studies received from the USDA Economic Research Service (their own and others) show that eating away from home, particularly increasing consumption in fast food restaurants, is correlated with increases in BMI. Further, the per capita number of restaurants in a state was positively related to individual's BMI and the probability of being overweight. These studies are summarized in the following charts, used courtesy of USDA ERS.

Question 1 (and 4): Correlations between BMI and Consumption of Foods Away From Home (FAFH)

Author(s)	Source	Title	Data Source	Dependent Variable	Estimated Effect of FAFH-Specific	Estimated Effect of FAFH-General
Binkley, Eales, and Jekanowski	International Journal of Obesity (2000) 24, 1032-1039	"The relation between dietary change and rising US obesity"	CSFII 1994-1996	BMI	The average man who was 1.77m tall and consumed restaurant food was .9 kg heavier than those who did not eat at a restaurant. If he consumed food at FF places, he was .8 kg heavier. The average women who was 1.63m and consumed restaurant food weighed .2 kg more than a woman who did not consume FF.	For men, both fast food and restaurant consumption positively and significanlty impacted BMI. For women, only FF consumption positively and significantly impacted BMI.
Lin, Huang, and French	Submitted to the International Journal of Obesity	"Women's and Children's Body Mass Indices	1994-1996 and 1998 CSFII	BMI	All Women: a 1% increase in FAFH was associated with an 1.28 point increase in BMI. For high income women, this was associated with a 1.63 point increase in BMI	For all women, increasing the percent of meals consumed away from home significantly increased BMI. When seperating by income, effect was still significant for higher income women (>185% of poverty level). No such correlation for lower income women. No significant correlation for children either.
Chou, Grossman, and Saffer	"An Economic Analysis of Adult Obesity: Results from the behavioral risk factor surveillance system."	NBER: Working Paper 9247 http://www.nber.org/papers /w9247	1984-1999 BRFSS	Reported and Adjusted BMI	Increasing the number of restaurants was estimated to increase BMI by 1.7% and increase the probablity of being obese (PO) by 9%. Increasing the price of fast, restaurant and home food was estimated to increase BMI by .5, .2 and .35% respectively. These prices were estimated to increase the	The per capita number of restaurants in a state was positvely related to an individual's BMI and probability of being overweight. FF, Restaurant and Home Food prices were all negatively related to BMI
Kuchler and Lin	"The Influence of Individual choices and attitudes on adiposity"	International Journal of Obesity (2000) 26	CSFII 1994-1996	BMI	All respondents: a 1% increase in FAFH was associated with an .93 point increase in BMI. For women, this was associated with a 1.24 point increase. No significant increase for men	Overall, and for women, increasing the percent of meals consumed away from home significantly increased BMI.
Variyam	No title	ERS Presentation	NHANES I Follow-up study	BMI	Among the individuals who consumed <=10% of cals away-from-home, 34.2% of healthy weight became overweight over a 20-year period and 28% went from overweight t healthy weight.	Among those who consumed >10% of cals away-from-home 39.3% became overweight, and 18% went from overweight to healthy weight. (Note this was only a simple bivariate anaysis, so keep the usual caveats in mind.)

Question 2: Are Calories From Foods Purchased Away From Home More Dense?

Author(s)	Source	Title	Data Source	Note	Dependent Variable	Calories	Fat
Lin, Guthrie, and Frazao	FoodReview, Volume 24, Issue 2	"American Children's Diets Not Making the Grade"	NCFS 1987-1988 CSFII 1994-96	See Attached Chart			
Lin, Guthrie, and Frazao	ERS Service Report	"Away From Home Foods Increasingly Important to Quality of American Diet"	NCFS 1987-1988 CSFII 1994-96	See Attached Chart			
Mancino	PhD Thesis	"American's Food Choices: The Interaction of Information, Intentions, and Convenience	CSFII 1994-1996		Per Meal Caloric Intake and Per Meal Percent of Calories From Fat	Evaluated at the sample means and using the RDI, a man who ate a meal from home, a restaurant, or a fast food restaurant consumed and average of 807, 1097 and 1041 calories at that meal. A woman consumed 503, 702, and 664 calories, respectively	Evaluated at the sample means an individual who at a meal from home, a restaurant, or a fast food restaurant consumed an estimated 24, 30, and 32 percent of his or her calories from fat
Variyam	In the works	Are Nutrition Labels Effective	CSFII 1994-1996			After adjusting for other factors, at-home food is between 360 to 540 calories/kg less dense than FAFH	

Comparison of Total Calories and Caloric Density of Foods Prepared At Home and Food Prepared Away From Home

	1987-1988						1995					
	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast-Food	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast-Food
Calories	1876	*	1369.48	506.52	93.8	93.8	2043	*	1348.38	694.62	163.44	245.16
Percent of Calories From Fat	37	30	36.3	38.7	41.3	39.7	33.6	37	30	37.6	40.1	39.3
Percent of Calories from Saturated Fat	13.8	10	13.5	14.7	15.5	15.4	11.5	10	10.9	12.8	12.5	13.8
Milligrams of Cholesterol per 1000 calories	286	166	161	151	215	138	268	147	129	134	176	124
Milligrams of Sodium per 1000 calories	1672	1328	1678	1656	1824	1575	1637	1175	1630	1651	1873	1674
Grams of Fiber per 1,000 calories	7	10.7	7.5	5.8	5.8	5	7.4	10.4	8.1	6.1	6.2	5.6

Sample: Non pregnant, non-lactating individuals over the age of 2

Source: Lin, Guthrie, and Frazao 1999

	1987-1988						1994-1996					
	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast-Food	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast-Food
Percent of Total Calories			80	20	11	2	*	*	68	32	4	10
Percent of Calories From Fat	35.93	30	35.2	38	40.5	38.8	32.99	30	31.6	36.1	38.1	36.3
Percent of Calories from Saturated Fat	13.39	10	13	14.5	15.2	15.2	12.01	10	11.5	13.2	12.5	13.6
Milligrams of Cholesterol per 1000 calories	143	170	149	129	176	125	115	153	118	106	142	101
Milligrams of Sodium per 1000 calories	1616	1363	1637	1561	1674	1484	1575	1222	1570	1588	1721	1621
Grams of Fiber per 1,000 calories	6.4	8.2	6.6	6.2	5.2	4.9	6.7	7.3	6.9	6.2	6.2	5.6

Sample:Children aged 2-17

Source: Lin, Guthrie, and Frazao 2001

Appendix B.
Sample Annotated Bibliography Entries

Authors:	Kim, Sung-Yong, Rodolfo M. Nayga, Jr., and Oral Capps, Jr.
Date:	July 2000
Title:	The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis
Citation:	*Journal of Agricultural and Resource Economics* 25(1): 215-231.
Relevance:	HIGH

Focus

Kim et al. (2000) look at the impact that use of nutrition labeling has on five nutrient intakes (calories from total fat, calories from saturated fat, cholesterol, dietary fiber, and sodium). They use data from the 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS). They control for self-selection to use labels with an endogenous switching regression model. Use of the endogenous switching regression model allows them to also look at factors that influence label usage.

Data

As noted, the data comes from the 1994- 1996 CSFII and DHKS. They use observations on 5,203 individuals that completed both the day-1 and day-2 surveys and that had complete data otherwise. No indication is given of the sample size relative to the total sample.

In forming the variable that measures label use, they convert a four-point scale to a binary yes/no variable. Respondents were asked about their frequency of label use for each of the five nutrients studied in the analysis. They were given four response options: "often," "sometimes," "rarely," and "never." Kim et al. convert "often," "sometimes," and "rarely" responses into "yes" answers and "never" responses into "no" answers. This differs from the mapping used by Guthrie et al. (1995).

Statistical Methodology

The switching regression framework employed by Kim et al. is a standard application of this method. Maddala (1983, Section 8.3) provides a treatment of this method. In brief, the model involves estimating separate regressions for label users and non-users for each of the five nutrients. A third equation that uses the label use decision as a dependent variable is also estimated. The three equations (nutrient intake for label users, nutrient intake for label non-users, and the decision to use labels) are not independent and have non-zero correlations across the error terms. The system is estimated using full information maximum likelihood.

To estimate the impact that food labels have on nutrient intakes, Kim et al. follow a standard method employed in switching regression models. First, they calculate the predicted values for nutrient intakes for label users. This is done for each nutrient using the label user equation. Next,

they calculate the predicted values of nutrient intakes for label users using the label non-users' equation. That is, they take the label users and generate predicted values for nutrient intakes using the label non-users equation. The difference in the mean values of these predicted values represents the impact of label use on nutrient intake.

Results

The results of their statistical analyses indicate that label use has beneficial impacts for each nutrient. The use of labels is associated with:[28]

- A 16.1 percent decrease in the intake of calories from fat;
- A 15.1 percent decrease in the intake of calories from saturated fat;
- A 21.0 percent decrease in the intake of cholesterol;
- An 87.1 percent increase in the intake of dietary fiber; and
- A 0.9 percent decrease in the intake of sodium.

None of the estimated impacts were judged for their statistical significance, even though this is possible in a switching regression model.

Kim et al.'s analysis also look at the factors that influence label use. They find that income, education, a good knowledge of diet-health issues, being on a special diet, exercising regularly, and being the family meal planner are all positively associated with label use. Factors that are negatively associated with label use include: household size, age, being male, living in a non-metropolitan area, using food stamps, and being a smoker.

Relation to CFSAN Study

This study is **highly relevant** for the CFSAN study.

- The study focuses on the same issues that the CFSAN study will look at: how does use of labels affect nutrient intakes and what factors influence use of labels.
- The study uses the same data that will be used in the CFSAN analysis.
- We anticipate use of a similar method as is used in this analysis.

Comments

- The study looks at five nutrient intakes, which are likely to be related to one another. The method, however, does not attempt to account for any cross-equation relationships. We suggest that a seemingly unrelated regression (SUR) framework be investigated for use in combination with this method to capture cross-equation relationships.
- The use of a binary variable for label use may be too simplistic. We expect that more than three categories can be specified: "always uses labels," "sometimes or rarely uses labels,"

[28] Estimated percentages reflect our conversion of results reported in Table 5 of the paper to percentage numbers. In calculating these, we divided the "Before Using Nutrition Label" column by the "Net Change" column for the "Average Nutrient Intakes."

and "never uses labels." This would complicate the switching regression framework, but not to an unmanageable degree. This would also allow CFSAN to look at how influencing consumers that are "never" users to become "sometimes" users would affect nutrient intakes. Additionally, CFSAN could look at how influencing "sometimes" users to become "always" users would affect nutrient intakes.

- The statistical method does not appear to account for sampling weights.
- Restricting to respondents that are in both the day-1 and day-2 survey may result in sample selection that is uncontrolled by the switching regression framework.

Closely Related

Guthrie et al., 1995

Authors:	Guthrie, Joanne F., Jonathan J. Fox, Linda E. Cleveland, and Susan Welsh
Date:	July-August 1995
Title:	Who Uses Nutrition Labeling, and What Effects Does Label Use Have on Diet Quality?
Citation:	*Journal of Nutrition Education* 27(4): 163-172.
Relevance:	HIGH

Focus

Guthrie et al. (1995) look at the impact of the use of food labels on the intake of 26 food components (e.g., protein, total dietary fat, etc.). They use data from the 1989 Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS). They control for self-selection to use labels with Heckman's self-selection model. As part of their analysis, they also examine factors that influence the use of food labels.

Data

The study uses data from the 1989 CSFII and DHKS. Their sample consists of 1,901 individuals that responded to the DHKS portion of the survey. The 1989 CSFII was designed to collect three days of food consumption data from respondents. The first day was (day-1) was collected using the 24-hour recall method (i.e., "What did you eat in the last 24 hours?"). The second and third day data were collected through a 2-day food record. Guthrie et al. only use the day-1 data in this study. They note that 1,548 respondents (of the 1,901 that completed the DHKS) submitted a full three days of food consumption data. Their reason for using the day-1 data only is to maintain sample size.

The study uses sampling weights in the statistical analysis, when appropriate. The sample design for the CSFII/DHKS calls for over-sampling of low-income households. Thus, the use of sampling weights in the analysis controls for the survey design.

In forming the variable that measures label use, Guthrie et al. convert a four-point scale into a binary yes/no variable. Respondents were asked about their frequency of label use for each of the five nutrients studied in the analysis. They were given four response options: "often," "sometimes," "rarely," and "never." Guthrie et al. convert "often" and "sometimes" responses into "yes" answers and "rarely" and "never" responses into "no" answers. This differs from the mapping used by Kim et al. (2000).

Statistical Methodology

The authors follow Heckman's standard model of self-selection to generate the coefficient estimates. In their analysis, individuals self-select to use nutrition labels. They first estimate a probit model for label use and then calculate the inverse mills ratio for each individual in the data. The inverse mills ratio is then added to the regression models that use the 26 food components as dependent variables. They estimate only one label-use equation rather than one for each food component. This differs from the Kim et al. (2000) study, where a separate label use equation was estimated for each of the five nutrient intakes investigated.

The basic regression equation for the food components regresses the amount of the food component on a set of explanatory variables that includes a zero-one binary variable for label use. The addition of the inverse mills ratio to the equation controls for self-selection to use labels.

One interesting aspect of this study is its use of principal components analysis (PCA) to pare down the number of variables that reflect individuals' "attitudes and values" that guide them in making food choices. The DHKS asks a number of questions regarding the individuals' preferences for either avoiding or ensuring the consumption of various food components. Inclusion of all of these variables in a regression framework would lead to significant multicollinearity. Using PCA, the authors are able to reduce the number of variables that reflect food choice values to two factors, thereby overcoming the multicollinearity problem.

Results

In the article, the authors only present the estimated coefficient for the zero-one binary variable for label use and the coefficient for the inverse mills ratio rather than the full regression model results (26 equations). For the 26 equations, only two show a significant impact of label use: higher intake of Vitamin C and lower intake of cholesterol. Additionally, self-selection only appears to be an issue for Vitamin C and cholesterol intakes.

Relation to CFSAN Study

This study is **highly relevant** for the CFSAN study.

- The study focuses on the same issues that the CFSAN study will look at: how does use of labels affect nutrient intakes and what factors influence use of labels.
- The study uses the same, but earlier, data that will be used in the CFSAN analysis.
- We anticipate use of a similar method as is used in this analysis.

Comments

- The study looks at 26 nutrient intakes, which are likely to be related to one another. The method does not attempt to account for any cross-equation relationships. We suggest that a seemingly unrelated regression (SUR) framework be investigated for use in combination with this method to capture cross-equation relationships.
- The use of 26 nutrient intakes is very broad. It appears that this restricts what they can say on any one nutrient intake.
- The study's use of a binary variable for label use may be too simplistic. We expect that three categories can be specified: "always uses labels," "sometimes or rarely uses labels," and "never uses labels."
- Restricting the sample to the day-1 data only may influence the results to an unknown degree. The use of day-1 data only was based on maintaining sample size. Restricting the sample to individuals with three days of data may also result in bias, however. Nevertheless, it may be possible to develop a panel analysis (individuals over days) that accounts for sample attrition (i.e., individuals that do not provide day-2 or day-3 data). This would expand the nutrient intake data.
- The results are not convincing that labels influence diet. Only two of the 26 food components, or eight percent of the regressions, have a significant coefficient for label use. At a five percent level of significance we can expect to be "wrong" about a statistical inference five percent of the time. This set of results comes close to that critical cut-off. More convincing results would involve a significant coefficient in one-third or more of the regressions.
- Not providing the full regression results limits our ability to fully assess this study. It would be interesting to see the signs and significance of all other variables included in the analysis.

Closely Related

Kim et al. (2000)

C. Sample Pages from Spreadsheet of Restaurant Web Sites

Restaurant number	Name	description	Website	Nutrition info available online		
				interactive	pdf or html	"light" but no nutritional info
1	McDonald's	Fast Food	http://www.mcdonalds.com/countries	yes	yes	no
2	KFC	Fast Food	http://www.yum.com/nutrition/menu.a	yes	yes	no
3	Pizza Hut	Casual Dining	http://www.yum.com/nutrition/docum	yes	yes	no
4	Taco Bell	Fast Food	http://www.yum.com/nutrition/menu.a	yes	yes	no
5	A&W	Fast Food	http://www.yum.com/nutrition/menu.a	yes	yes	no
6	Long John Silver	Fast Food	http://www.yum.com/nutrition/menu.a	yes	yes	no
7	Au Bon Pain	Fast Food	http://www.aubonpain.com/	yes	yes	no
8	RED LOBSTER	Casual Dining	http://www.redlobster.com/homeflash	no	no	no
9	Olive Garden	Casual Dining	http://www.olivegarden.com/ourmenu	no	yes	no
10	Bahama Breeze	Casual Dining	http://www.bahamabreeze.com/food.	no	no	no
11	Smokey Bones Bar-b-q	Casual Dining	http://www.smokeybones.com/menu/	no	no	no
12	Starbucks	Coffee shop	http://www.starbucks.com/retail/nutrit	yes	no	no
13	Chili's Grill & Bar	Casual Dining	http://www.chilis.com/menu/default.a	no	yes	no
14	Romano's Macaroni Grill	Casual Dining	http://www.macaronigrill.com/menu/d	no	no	no
15	On The Border Mexican	Casual Dining	http://www.ontheborder.com/menu/de	no	no	no
16	Maggiano's Little Italy	Casual Dining	http://www.maggianos.com/menu/de	no	no	no
17	Corner Bakery Cafe,	Fast Food	http://www.cornerbakery.com/default	no	no	no
18	Cozymels Coastal Mexic	Casual Dining	http://www.cozymels.com/menu/defa	no	no	no
19	Big Bowl Asian Kitchen	Casual Dining	http://www.bigbowl.com/menu/BIGBO	no	no	no
20	Rockfish Seafood Grill.	Casual Dining	http://www.rockfishseafood.com/	no	no	no
21	Wendy's	Fast Food	http://www.wendys.com/food/index.js	yes	yes	no
22	Sbarro	Fast Food	http://www.sbarro.com/	no	no	no
23	Krispy Kreme	Coffee and Doughn	http://www.krispykreme.com/nutri.pdf	no	yes	no
24	Outback Steakhouse	Casual Dining	http://www.outback.com/menu/menu	no	no	no
25	Flemings Steak House	Casual Dining	http://www.flemingssteakhouse.com/	no	no	no
26	Roy's	Upscale	http://www.roysrestaurant.com/docs/	no	no	no

Restaurant number	Name	Nutrition info available in restaurant *						nutrition info coverage		Notes
		menu board	menu	tray	napkin	brochure	other	all items	info on partial or targeted items	
1	McDonald's					yes			yes	nutritional info for most popular items, food exchanges and recommendations
2	KFC							yes	yes	Additional healthier options menu
3	Pizza Hut							yes	yes	Info on healthier choices
4	Taco Bell							yes	yes	Additional info on Fresco or lower cal foods
5	A&W							yes	yes	Info on healthier choices
6	Long John Silver							yes	yes	Lower calorie suggestions--leave out the sour cream or tartar sauce, etc.
7	Au Bon Pain							yes	yes	Interactive Menu, lots of info and special nutrition info.
8	RED LOBSTER									Online menu with no nutrition info
9	Olive Garden		yes						yes	nutrition info on "Garden Fare" foods only.
10	Bahama Breeze									Online menu with no nutrition info
11	Smokey Bones Bar-b-q									Online menu with no nutrition info
12	Starbucks					maybe				
13	Chili's Grill & Bar		yes						yes	Guiltless Grill menu (in restaurant has fat but no calorie info)
14	Romano's Macaroni Grill									Online menu with no nutrition info
15	On The Border Mexican (									Online menu with no nutrition info
16	Maggiano's Little Italy									Online menu with no nutrition info
17	Corner Bakery Cafe,									Online menu with no nutrition info
18	Cozymels Coastal Mexic									Online menu with no nutrition info
19	Big Bowl Asian Kitchen									Online menu with no nutrition info
20	Rockfish Seafood Grill.									Online menu with no nutrition info
21	Wendy's					maybe		yes	yes	Interactive Menu, lots of info and special nutrition info.
22	Sbarro									Under construction -menu not available
23	Krispy Kreme									Hard to find nutrition page. Uses packaged food format for nutritition info
24	Outback Steakhouse									
25	Flemings Steak House									Online menu with no nutrition info
26	Roy's									Online menu with no nutrition info

APPENDIX H – Developing Effective Consumer Messages

Effective consumer health messages about weight management and obesity prevention should be research-based and take into account the values, beliefs, motivations, needs and behaviors that comprise the "consumer reality" of the target audience. It is important that these messages be clear, simple, and understandable and do not undermine the credibility and impact of public health agencies.

There are six key questions to consider when developing research-based messages that encourage knowledge utilization:

1. What is the purpose?
2. Who is the target?
3. What is the promise (i.e., motivators)?
4. What is the support?
5. What is the image?
6. Where are the best opportunities for delivering the messages?

In determining the target audience(s) for research-based messages, it is important to consider that communication theory holds that more direct, population subgroup-focused messages typically have greater impact than messages that address a wider audience (e.g., the general public). At the same time, overweight and obesity have been identified as a national health problem, so it seems important to develop focused messages that affect large population subgroups.

Among private sector organizations, IFIC has been prominent in recent efforts to develop effective nutritional messages. IFIC uses a five-part system (Borra *et al.*, 2003):

1. Defining the relevant issues
2. Developing the initial message(s)
3. Examining candidate messages in focus groups
4. Refining the messages
5. Validating the messages in quantitative surveys

IFIC has drawn a number of conclusions from its efforts, many of which are supported by other researchers (Marietta *et al.*, 1999; Kennedy and Davis, 2000; Borra *et al.*, 2001; Patterson *et al.*, 2001; Balasubramanian and Cole, 2002; Ikeda *et al.*, 2002; Gans *et al.*, 2002; Borra *et al.*, 2003; Gans *et al.*, 2003; IFIC 2003):

1. Consumers will not react positively to messages unless the messages set forth concrete goals that consumers view as achievable.
2. Consumers perceive general nutrition guidelines as too abstract and requiring too much planning and calculation to translate into action.

3. Consumers are receptive to messages that make direct, concrete suggestions and therefore provide tools with which consumers may exercise choice. Consumers resist being told what they must do.
4. Goals should be incremental rather than monolithic so that consumers can receive continuous positive feedback. Concrete and incremental goals sustain and reinforce consumers' desire for autonomy. Equally important is that setting and achieving incremental goals provides more opportunities for reinforcement (both self and external), which is important for sustaining positive behaviors. Consumers view monolithic goals as unrealistic because they would have to make substantial changes in diet and habits.
5. Overemphasis on one or a few nutritional components of a diet may impede the overall goal of achieving a healthy, varied diet.
6. Health and nutrition messages should be developed with an awareness of the varied cultural backgrounds found among the American public; different ethnic and cultural groups exhibit different dietary patterns and practices.

In qualitative studies, consumers claim they do not wish to spend a significant amount of time reading and comprehending labels. This is borne out by the fact that many use health or nutrient content claims as indicators as to the overall quality of the product and do not check the nutrition facts panel on the back (Roe, *et al.*, 1999). Also, consumers appear to be confused by serving sizes, particularly by multiple servings listed on small packages, as well as by the %DV listed in the nutrition facts panel. Consumers use food labels for multiple reasons, including diet plans and pre-existing health conditions such as diabetes and heart disease, and look for macronutrients of concern. On the other hand, taste, convenience, price, mood and family preferences influence purchases and are often at odds with healthy eating. Such factors present challenges for developing effective messages.

Other findings indicate that adults do not like "diets" and do not believe they work over the long term (Borra *et al.*, 2003). They also question whether there is any new nutrition information that they will find useful. Also, the qualitative studies found that encouraging parents and children to work together resonated, as did messages promoting better appearance[29] and self-esteem. Consumers need to hear new kinds of information, or a re-packaging of old information in new and relevant ways, that will serve as "motivation to jumpstart new thinking and behaviors."

[29] At this time, FDA does not intend to use "better appearance" as a motivator for any of its obesity messages, given the larger concern about the effect such a focus may have on those with eating disorders (e.g., anorexia and bulimia).

APPENDIX I – Power of Choice

Power of Choice

The Power of Choice is an after-school program developed jointly by FDA and USDA's Food and Nutrition Service. The materials guide pre-teens toward a healthier lifestyle by motivating and empowering them to make smarter food and physical activity choices in real-life settings. A Leader's Guide, containing ten sequenced interactive sessions engage adolescents in fun activities that develop skills and encourage personal development related to choosing foods wisely, preparing foods safely, and reducing sedentary behaviors. Most activities require little or no pre-planning and are simple to do. The Leader's Guide also includes easy snack recipes, 170 Nutrition Facts cards, and posters on four key topics, and a computer disk provides supplemental activities to each of the 10 sessions, a self-training video for the leader, community support suggestions, and much more.

Current status: Currently, the Power of Choice is being distributed either in hard copy or it can be downloaded on the Team Nutrition Web site, USDA' Food and Nutrition service (http://www.fns.usda.gov/tn/Resources/power_of_choice.html). Of the original 15,000 copies published, less than 4,000 copies remain for free distribution to those belonging to USDA's Child Nutrition Programs (includes schools). Response from users has been virtually unanimously positive: "One of the best government products I've seen in a long time"; "I love this material. Please send me more"; "I think it's great! Exciting!! I've been needing something like this—thank you for doing such a great job".