



July 10, 2003

# Consumer Health Information for Better Nutrition Initiative

## Task Force Final Report

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**Memorandum**

Date: July 10, 2003

From: Chair and Vice Chair, FDA Task Force on Consumer Health Information for Better Nutrition Initiative

Subject: Task Force 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) Task Force on Consumer Health Information for Better Nutrition. The Task Force, which was announced on January 16, 2003, as part of the Consumer Health Information for Better Nutrition Initiative, includes representatives from FDA, the Federal Trade Commission and the National Institutes of Health. We have met eight times from February 5 to June 20, 2003. Four separate meetings were held with health professionals, industry, consumer groups, and academic and research organizations, respectively. A subgroup of the Task Force has met almost every week since the group was established to prepare for Task Force meetings and this report.

The Task Force was charged to:

- Report on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should apply the "weight of the evidence" standard established under the consumer health information initiative for qualified health claims in order to achieve these goals.
- Develop a framework for regulations that will give these principles the force and the effect of law.
- Identify procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of health claim petitions.
- Develop a consumer studies research agenda designed to identify the most effective ways to best present scientifically based, truthful and non-misleading information to consumers and to identify the kinds of information known to be misleading to consumers.

The report that follows provides details and timelines on the recommendations from the Task Force for your consideration. The major deliverables included in this report are as follows:

- Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
- Final Guidance: Interim Evidence-based Ranking System for Scientific Data
- Resources for Review of Scientific Data
- Consumer Studies Research Agenda -- Improving Consumer Understanding and Product Competition of Health Consequences of Dietary Choices
- Final Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
- "One-Year" Time Line for Qualified Health Claim Activities

The report also contains the list of the Task Force members, a summary of the four stakeholder meetings the Task Force held, and a summary of comments submitted to the docket.

We believe that the work of this Task Force provides a credible and effective framework for the agency and the food and dietary supplement industry to begin to use immediately, to provide more and better information to consumers about the health and nutritional benefits of their products. The Task Force believes that significant public health benefits will result when consumers have access to, and use, more and better information to aid them in their purchases, information that goes beyond just price, convenience, and taste, but extends to include science-based health factors. Armed with more scientifically based information about the likely health benefits of the foods and dietary supplements they purchase, consumers can make a tangible

difference in their own long-term health by lowering their risk of numerous chronic diseases. With millions of citizens making use of such information for their own health benefit, a great deal will be gained when this type of information is provided in food labeling.

The work of this Task Force is an important first step in realizing this broader potential of food and dietary supplement labeling. Yet, it is only a first step. We would expect that as soon as possible, there be serious steps taken to permit on food labeling, information in the form of health claims and dietary guidance that consumers can use now. For example, and as we point out in our report, we are aware that there is currently data available on the potential positive impact on health of consuming foods high in omega-3 fatty acids. Such a claim should be one of the first to be reviewed under the approach put forward by this Task Force. In addition, general dietary advice and guidance that addresses ways consumers can reduce the risk of cancer, for example, by consuming five-to-nine fruits or vegetables each day, should be an immediate focus of the agency to encourage and make available in the labeling of more food products. These are just two examples of opportunities available now.

Over the coming months, as we begin to receive qualified health claim petitions on September 1, 2003, under the guidance documents to be issued shortly above; as we conduct and analyze the planned consumer studies research; as we establish the working processes for the scientific review of petitions including review in collaboration with the Agency for Healthcare Quality and Research; as we refine our methodology for evaluating health claim evidence in petitions using our evidence-based ranking system; and as we consider whether to draft updated regulations to administer the qualified health claim petition process, we expect the process to become even more effective and useful.

We appreciate the opportunity to have served the FDA in this important initiative, and we stand ready to facilitate its implementation.

Lester M. Crawford, D.V.M., Ph.D. Chair Deputy Commissioner of Food and Drugs	Joseph A. Levitt Vice Chair Director Center for Food Safety and Applied Nutrition
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## OVERVIEW

### Background

On December 18, 2002, Commissioner of Food and Drugs, Mark B. McClellan, M.D., Ph.D., announced a major new initiative to make available more and better information about foods and dietary supplements, to help American consumers prevent diseases and improve their health by making sound dietary decisions. The Consumer Health Information for Better Nutrition Initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements: to encourage makers of conventional foods and dietary supplements to make accurate, up-to-date, science-based claims about the health benefits of their products, and to help eliminate bogus labeling claims by pursuing marketers of human dietary supplements

and others who make false or misleading claims about the health benefits or other effects of their products. Through these objectives, the agency seeks to help consumers improve their understanding of how their dietary choices may influence their health, to promote competition among product developers to find better ways to help improve health through better diets, and ultimately to prevent serious and life-threatening diseases through better dietary choices by Americans.

Health and Human Services Secretary Tommy G. Thompson said, "By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims. Such labeling can help empower consumers to make smart, healthy choices about the foods that they buy and consume."

The future of nutrition and diet/disease relationships is evolving very rapidly. Science is exploring opportunities for improving the health consequences of nutrition that range from a better understanding of the impact of general dietary patterns for the US population as a whole to the specific understanding of how an individual's genetic makeup interacts with food and the environment -- "nutritional metabolomics" -- increasing the ability to "design" foods and diets for individuals to maximize health. The Consumer Health Information for Better Nutrition Initiative is at the forefront of this evolution. It is designed to encourage the kind of marketplace where healthy foods can compete readily among all foods available; to foster research and better understanding about diet and health; and to protect consumers, and to help consumers protect themselves, from misleading claims by producers of foods and dietary supplements about health benefits that are not supported by science.

The agency is aware that there are many opportunities to greatly improve public health beyond those that have been traditionally associated with the product approval and enforcement activities of the FDA. These opportunities have much to do with assisting the public in making wise dietary choices that benefit long-term health. When FDA's mission is properly understood to include this role, a number of possible strategies become evident. For example, challenging the industry to channel competitive energies into disseminating health information in food labeling and promoting food products on the basis of nutritional value, as well as simply taste, price, and amount. The agency also sees the possibility to pursue a range of consumer information options in collaboration with other federal agencies, health researchers, and stakeholders as more information about substance/diet relationships becomes available. Thus, this report represents only the first concrete step in a larger and more far reaching program to improve public health.

Health messages on product labels that may influence consumer knowledge and hence dietary choices fall into three major categories. Agency policies on all three may have important consequences for consumer behavior. First, "health claims" have a different definition and regulatory provisions compared to other types of claim statements on conventional foods and dietary supplements. Health claims are specifically about the relationship between a substance and a disease, and they are reviewed and authorized by the FDA. An example of a health claim related to the disease osteoporosis is: *Calcium may reduce the risk of osteoporosis*. Second, "structure/function" claims are also allowed on foods, but make no reference to disease. Instead, they highlight how the food substance works within or otherwise supports the body. An example of a structure/function claim would be: *Calcium helps build strong bones*. These structure/function statements are not pre-reviewed by FDA but must be truthful and substantiated and not misleading. Though the statutory standards for structure/function claims

differ from health claims, they too may affect consumer behavior and thus assuring their accuracy is another important element for effective regulation of product claims for consumers. Finally, truthful and non-misleading general "dietary guidance" statements can also be made on food labels without FDA review. These statements, unlike health claims which target a specific substance and a certain disease, focus instead on general dietary patterns, practices, and recommendations that promote health. An example would be the "5-a-Day" program from the National Cancer Institute (NCI), which encourages the consumption of fruits and vegetables for better health. Such general guidance can help encourage better nutrition.

The Consumer Health Information for Better Nutrition Initiative has as its central focus improving the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. A better-informed public, supported by effective, science-based regulation of health information, would be expected to make better nutritional choices. Such regulation would also encourage food and dietary supplement producers to compete in ways that better protect the public from disease risks. As part of this Initiative, the FDA Task Force on Consumer Health Information for Better Nutrition (the Task Force) recommends that FDA use interim procedures and an interim evidence-based ranking system for qualified health claims on food labels (including conventional human food and dietary supplements).

Health claims are voluntary statements on food labels that were authorized by the 1990 Nutrition Labeling and Education Act (NLEA). They are intended to assist consumers in understanding the relationship between a substance in a conventional food or dietary supplement and its ability to reduce the risk of contracting the disease in healthy populations. They were put in place by Congress so that food manufacturers could voluntarily, by use of the food label and labeling, let consumers know about important beneficial food components that had the ability to reduce disease risk when integrated into the total daily diet. Health claims are not drug claims, which by law focus on diagnosing, treating, curing, or mitigating disease. Rather, health claims address the reduction of risk as part of a total diet. There is more evidence than ever that dietary choices have major impacts on population health. For example, researchers have indicated that changes in diet could lead to a significant reduction in chronic diseases such as heart disease.

As part of the 1990 NLEA, Congress gave FDA the option of establishing a different standard for health claims for dietary supplements labels as compared with that which Congress had provided for conventional foods. FDA determined that the best course of action was to use the same standard for both dietary supplements and conventional foods. This decision was motivated by public health considerations: All consumers eat conventional foods and most use dietary supplements; inconsistent standards would lead to consumer confusion and biased consumption choices. So, current regulations for health claims apply equally to dietary supplements and conventional foods.

In setting the rules for health claims, Congress provided for FDA to authorize health claims when the agency determined, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement (SSA), among experts qualified by scientific training and experience to evaluate such claims that the claim is supported by such evidence. Under existing regulations, health claims are put in place through a petition process by which FDA reviews the science in support of and against the claim, and determines whether to authorize the claim through notice-and-

comment rulemaking.

The NLEA required that FDA itself initially consider health claims for ten substance/disease relationships. FDA determined that there was significant scientific agreement concerning a number of these specified substance/disease relationships and in turn authorized eight claims. Not all relationships that Congress specified to be reviewed were found to meet the standard of significant scientific agreement. Accordingly, not all were authorized by FDA.

Dietary factors and sedentary lifestyles contribute substantially to the burden of preventable illnesses and premature deaths in the United States. Indeed, dietary factors are associated with 4 of the 10 leading causes of death: coronary heart disease, some types of cancer, stroke, and type 2 diabetes<sup>(1)</sup>. For example, high blood cholesterol is a major risk factor for coronary heart disease that can be modified by diet and other factors. Lifestyle changes that prevent or lower high blood cholesterol include eating a diet low in saturated fat and cholesterol, increasing physical activity, and reducing excess weight<sup>(2)</sup>. Fat intake in the United States as a proportion of total calories is lower than it was many years ago, but most people still eat too much saturated fat<sup>(3)</sup>.

There is growing evidence of a public health gap in knowledge and behavior with respect to substance/disease relationships. According to the recent Sloan State-of-the-Industry Report published in *Food Technology* (Top 10 Trends to Watch and Work On, April 2003), consumers have no problems holding dichotomous attitudes about the pleasures of food and its power to influence their health. As more shoppers acknowledge indulging their cravings, more of them also admit that what they eat can have a major effect on how healthy they feel.

The most recent Food Marketing Institute (FMI, 2002) Trends in the United States Survey indicated that the percentage of consumers who recognize the importance of eating healthfully and who are interested in trying foods that may improve their health is increasing. 86% *agree* or *strongly agree* that "in most cases, eating healthfully is a better way to manage illness than medications," up from 76% in 2001. 54% said they are *very interested* in trying health-promoting foods. 51% want products designed to help them with high blood pressure and diabetes; 50% with allergies; 49% with weight control; 41% with osteoporosis; 40% with arthritis, and 40% (women only) with problems with women's hormones.

Despite these encouraging findings, other results from the same survey indicate that the percentage of consumers who acknowledge unhealthy eating behaviors is also increasing. 72% of shoppers *agree* or *strongly agree* with the statement, "I eat foods I enjoy, even if they're not good for me," up from 64% in 2001. 34% *agree* or *strongly agree* with the statement, "I eat whatever I want and don't think much about how it affects my health," up from 25% in 2001.

In addition, there is growing concern about obesity and appropriate health messages to address this unmet public health need. Persons who are overweight or obese are at increased risk for several chronic diseases<sup>(4)</sup>. In recent decades, there have been a number of public and private sector efforts in the United States aimed at reducing obesity. However, we have achieved only modest success with many of these efforts, and no success to date in reversing the alarming trend in the increase in overweight and obesity in this country. For example, in 1999, an estimated 61% of U.S. adults were overweight or obese, with nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980<sup>(2)</sup>. The

tragic consequences of the current obesity epidemic have manifested themselves in premature death and disability, in increased health care costs, in lost productivity, and in social stigmatization. Approximately 300,000 deaths a year in this country are associated with overweight and obesity, with an estimated total cost of \$117 billion in 2000<sup>(2)</sup>. Thus, finding more effective ways to improve consumer understanding and behavior is an urgent public health priority.

Although the scientific evidence in a number of substance/disease relationships does not, or might not, meet the standard of SSA, there is considerable evidence of a relationship between dietary choices and health and, in turn, a need to more fully inform consumers. For example, the following relationship, which may not meet the SSA standard, may be said to be based on somewhat settled science and therefore be important information for consumers: *Foods high in omega-3 fatty acids and the decreased heart disease risk.*

For the general population, in neither of these cases is there any significant evidence that a balanced diet low in total fat, saturated fat and cholesterol that includes consumption of these foods presents safety or toxicity problems. Thus, even if only some of these apparently likely relationships are borne out in subsequent studies, greater consumer awareness of these relationships and changes in diet as a result would be expected to lead to significant public health benefits.

In addition, there is the opportunity to expand health messages beyond qualified health claims to dietary guidance. Public health priorities dictate a need for federal agencies and other stakeholders to partner to find useful and understandable health messages about general food choices and dietary patterns. For instance, FDA can partner with NCI in developing important messages about cancer. An example of such a dietary guidance statement from this Institute is: *"Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases."* This dietary guidance highlights a general category of foods and provides a valuable reminder to consumers about food choices.

Also, an increasingly important message for consumers is to substitute foods that decrease the risk of disease for those that do not, in order to build better diets. FDA can seek opportunities, using existing well-recognized government recommendations and partnerships, to identify the appropriate messages about food substitutions. For instance, the booklet "Dietary Guidelines for Americans" provides an important substitution health message about fats and heart disease: *"Substituting vegetable oils for solid fats may reduce your risk of heart disease."*

Developments in the law, as well as critical public health considerations, are motivating this Initiative. Several of the substance/disease relationships for which FDA failed to find significant scientific agreement became the subject of a lawsuit, *Pearson v. Shalala* (Pearson), brought by a dietary supplement manufacturer. The plaintiffs in *Pearson* challenged FDA's general health claim regulations for dietary supplements, as well as FDA's decision not to authorize the health claims. The District Court ruled for FDA, but the U.S. Court of Appeals for the D.C. Circuit reversed the decision in 1999. The Court of Appeals ruled that the First Amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. The Court did not rule out the possibility that, where evidence in support of the claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban the claim outright.

FDA's efforts to implement the Court ruling in *Pearson* have progressed through a series of steps. In order to provide for "qualified health claims," FDA issued a *Federal Register* notice in December of 1999 (64 FR 67289) outlining its plans to implement the ruling for dietary supplements. FDA updated its implementation plan in October 2000 (65 FR 59855), stating its intention to rely on enforcement discretion to provide for qualified health claims for dietary supplements.

In the December 20, 2002, *Federal Register*, the agency announced its intention to apply *Pearson* to conventional human food and provide for qualified health claims for such food. Recognizing the need for a regulatory framework to implement qualified health claims in light of the major scientific, public health, and legal developments of recent years, as well as the need both for scientific criteria to address the basis for qualified health claims and a better understanding of the nature of non-misleading claims on food labels, Commissioner McClellan formed the Task Force. The Task Force was given approximately six months to complete its work. The Task Force focused primarily on the issue of qualified health claims, but its discussions were enriched by considerations of promoting partnerships with sister public health agencies and others with the goal of improving the quality and impact of possible claims and labeling statements on conventional human foods and dietary supplements. Throughout the years, the federal government has worked to provide information to consumers about healthy eating patterns and wise food choices. Such advice originated with the Basic Four and has progressed through today's Dietary Guidelines for Americans and the Food Guide Pyramid. We expect that over time scientists will better understand these diet health relationships. As this happens, consumer actions based on this information should be encouraged and promoted by use of the food label.

An FDA determination concerning antioxidant vitamins and the reduced risk of certain cancers became the subject of a lawsuit known as *Whitaker v. Thompson*. In March 2000, the plaintiffs challenged FDA's refusal to permit the claim on dietary supplement products. FDA had determined that the evidence weighed more heavily against than in support of the relationship, and that the claim was therefore inherently misleading. On December 26, 2002, the U.S. District Court for the District of Columbia disagreed. It found that the claim was only "potentially misleading," and that FDA should permit the claim with a disclaimer. In interpreting the earlier *Pearson* decision, the District Court also used a "credible evidence" rather than "weight of the evidence" standard in evaluating the claim before it. Claims for which evidence is merely credible would generally not be expected to benefit the public health as much as claims for which the evidence is stronger. For this reason and given the agency's limited resources, in setting priorities, FDA intends to take into account, among other things, the strength of the evidence supporting a claim.

The FDA Task Force on Consumer Health Information for Better Nutrition was established on January 16, 2003, as part of the Agency's Consumer Health Information for Better Nutrition Initiative. The Task Force includes representatives from FDA, the Federal Trade Commission and the National Institutes of Health. Commissioner McClellan appointed FDA Deputy Commissioner, Dr. Lester M. Crawford as the Task Force's Chair, and Mr. Joseph A. Levitt, Director of the Center for Food Safety and Applied Nutrition (CFSAN), as Vice Chair.

The Task Force was charged to develop a framework to help consumers obtain accurate, up-to-date, and science-based information about conventional food and dietary supplements. Specifically, the charge to the Task Force included the following:

Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II).  
Circulation 89:1329-1445, 1994.

<sup>3</sup> U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (HHS). Dietary Guidelines for Americans. 5th ed. USDA Home and Garden Bulletin No. 232, 2000.

<sup>4</sup> U.S. Department of Health and Human Services. 2002. The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville, MD: Public Health Service, Office of the Surgeon General. Available from : U.S. GPO, Washington.

<sup>5</sup> The term, "unqualified health claim" is used in this report to refer to health claims that meet the Significant Scientific Agreement (SSA) standard and are or could be authorized under the Nutrition Labeling and Education Act (NLEA) and regulations promulgated under that Act including 21 CFR 101.70.

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