

THE KEYSTONE NATIONAL
POLICY DIALOGUE
ON
FOOD, NUTRITION, AND HEALTH

FINAL REPORT

The Keystone Center
Keystone, CO and Washington, DC
March 1996
Printed on recycled paper

EXECUTIVE SUMMARY

Passage of the Nutrition Labeling and Education Act of 1990 (NLEA)¹ marked the culmination of considerable debate, particularly regarding the information on nutrient composition and health impact that should appear on food labels. Even after the enactment of NLEA, however, disagreements about this aspect of the law and the rationale behind it remained, as did concerns about its implementation. The controversy stemmed from three general sources:

- 1) Fundamental differences in philosophy about the appropriate role that government should play in regulating dissemination of information about the nutritional benefits of food products by the food industry. Different views exist regarding the best public policy on food and nutrition issues, including a difference of views regarding the primary purpose and accomplishments of NLEA. NLEA, which amended the federal Food, Drug, and Cosmetic Act of 1938 (FDCA), created opportunities to communicate health information to consumers about relationships between food substances and disease or other health-related conditions. NLEA also clarified Food and Drug Administration (FDA) authority to prevent misleading claims about the healthful attributes or benefits of foods, some of which were being made before enactment of the legislation. Different perspectives concerning the predominant emphasis of these aspects of NLEA continue to exist.
- 2) Lack of understanding about how FDA was and would be implementing NLEA, such as the application of the significant scientific agreement standard in determining the validity of a diet-disease relationship proposed for authorization as a health claim. Some people believe that the significant scientific agreement standard is essential for establishing a high level of confidence in the diet-disease relationships stated by health claims. Others believe that the standard is too strict to allow authorization of a sufficient number of health claims.
- 3) Lack of knowledge and understanding of the regulatory process used to implement NLEA, as demonstrated by the various perspectives concerning FDA's review of the relationships between food substances and disease or health-related conditions mandated for evaluation in the law. Because of the statutorily imposed deadlines, FDA had an inadequate amount of time to communicate with all interested parties about the process and methodology that it was using to review the 10 diet-disease relationships proposed for authorization as health claims or to provide details on the implementation of new regulations. As a result, the information void was filled with speculation and conjecture and resulted in distrust of the agency's decisions.

¹ Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343 (1994)).

In the midst of this uncertainty, the Keystone National Policy Dialogue on Food, Nutrition, and Health was convened to initiate a discussion of these issues. The Dialogue began in the fall of 1993 and concluded in late 1995. It brought together decision makers from federal and state governments, industry, consumer groups, health promotion organizations, and academia. The Dialogue Group members focused their discussions on how NLEA had been implemented and how it might be improved. This focus served as a starting point to explore and formulate public policy recommendations that would encourage the development and promotion of healthful dietary choices through research, regulation, and promotion of foods that convey particular health benefits. This Keystone initiative was characterized by collaborative discussions intended to help resolve many of these issues, bringing to bear the diverse resources, views, and opinions at the heart of the controversies surrounding NLEA.

All participants agreed that dietary intake is critical to health. Research findings strongly suggest that the prevalence of certain diseases could be reduced and the quality of life improved with some changes in diet, as well as in other lifestyle habits such as physical activity. Research also suggests that the incidence of certain diet-related chronic diseases is increasing. In addition, the health care costs associated with diet-related conditions are staggering. These facts alone are compelling enough to justify devoting time and energy to the public policy issues associated with the communication of information regarding the relationships between diet and health. In addition, the opportunities for communicating the health benefits of food, as well as the potential for misrepresentation or overstatement concerning these benefits, were major motivating

factors. The numerous challenges involved in formulating effective public policy in an area fraught with scientific, communication, legal, and political complexities also were of interest to the Dialogue Group. Interest in addressing and exchanging information on these issues led to the Keystone National Policy Dialogue on Food, Nutrition, and Health.

The Dialogue Group established goals for the Keystone National Policy Dialogue on Food, Nutrition, and Health that, if achieved, would benefit public health. The goals were to identify and propose recommendations for public policy that, in the context of a healthful diet,

- promote the consumption of currently available foods that advance health,
- promote the development of foods that advance health, and
- better enable consumers to make informed food choices.

Participants recognized and agreed that many approaches to providing food, nutrition, and health information to consumers should be pursued. This Dialogue primarily focused attention on understanding how FDA reviewed the first 10 proposed relationships between food substances and diseases or health-related conditions, which it was asked by the U.S. Congress to assess, and improving future implementation of the health claim provisions of NLEA. Health claims authorized under NLEA are statements that describe a relationship between a food substance and a disease or other health-related condition,² hereinafter referred to as a “diet-disease relationship” or “food substance-disease relationship.” After NLEA enactment, misunderstanding persisted about the basic mechanics of the law’s implementation regarding the use of health claims in food labeling.³

² 21 U.S.C. § 343(r)(1)(B) (1994).

³ “Labeling” includes “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m) (1994).

Authorized health claims were the focus of a substantial amount of discussion because of their potential to help improve public health and sell healthful food products, as well as their potential for misuse.

In addition to authorized health claims, other means of communicating the health benefits of foods were discussed. Dialogue Group members tried to consider the role of health claims in the context of the full range of opportunities to communicate information. The Dialogue Group discussed issues concerning advertising and the differences between the authorities and policies of the Federal Trade Commission (FTC) and FDA. Additional issues of interest included the communication of emerging scientific information about diet-disease relationships, consumers' understanding and perception of health messages, and changing dietary behavior. Therefore, the Dialogue and this Final Report focus on both NLEA-authorized health claims and other nutrition messages in the broad context of communicating diet and health information to consumers.

Information that relates foods and diet to health can be communicated via a range of vehicles. The Dialogue Group categorized these vehicles into three groups: labels and labeling, advertising, and the media. In addition, the Group discussed the types of information communicated and focused on health claims, nutrient content claims,⁴ structure-function claims,⁵ and dietary guidance.⁶

The nature of the Dialogue process is to use facilitated, intensive, problem-solving sessions to highlight key issues of concern; develop a collective understanding of different view-

points; and collaboratively create a Final Report that captures the various perspectives, provides an overview of the discussions, and focuses on the areas of agreement concerning the direction of public policy surrounding the key issues. The participants attended as individuals, not as formal representatives of their respective agencies, organizations, or companies. The power of the observations and recommendations in this Report is generated not only from their substantive strength but also from the diversity of viewpoints that converged to create them.

In addition to a greatly enhanced understanding of NLEA, the Dialogue Group developed consensus-based recommendations through the exchange of ideas. When a view is stated to reflect a consensus, all members of the Group found the statement of the view to be acceptable, if not ideal. These recommendations range in level of detail and breadth of focus, reflecting the many different types of issues that the Dialogue Group discussed. Other issues were not resolved by the Dialogue Group, but differences of opinion are characterized, and some options for facilitating resolution of the debate are provided. Consensus solutions or an outline of the different views when consensus was not reached are identified and highlighted below.

AUTHORIZED HEALTH CLAIMS ON LABELS AND IN LABELING

The Dialogue Group began its discussions by reviewing NLEA and the authorization process for health claims on food labels. This exercise was essential for understanding the implementation of NLEA. The primary

⁴ A nutrient content claim (also referred to as a nutrition claim or a nutrient descriptor) is a claim that, either expressly or by implication, characterizes the level of any nutrient required to be listed on the nutrition label. 21 U.S.C. § 343(r)(1)(A) (1994).

⁵ Structure-function claims describe the effect of a food or food substance on a structure or function of the body. These types of messages fall outside the scope of NLEA because they do not directly relate food substances to disease or health conditions. U.S. Department of Health and Human Services (DHHS). Food and Drug Administration (FDA). Food Labeling: General Requirements for Health Claims for Food, Final Rule. Fed. Reg., v. 58, Jan. 6, 1993. pp. 2478-2536.

⁶ Dietary guidance includes messages about general food choices or achievement of a healthy lifestyle that typically are not regulated as health claims under NLEA. *Id.*

issues associated with health claims authorized under NLEA are divided into two categories: 1) establishing the scientific basis for determining the validity of health claims and 2) determining the best way to communicate scientifically valid, nonmisleading health claims that are understandable to consumers.

The major issues regarding the establishment of a scientifically valid relationship include 1) understanding the application of the significant scientific agreement standard to current and future health claims, 2) understanding the authorization process, 3) the appropriateness of the qualification and disqualification rules, and 4) the appropriateness of the rule, sometimes referred to as the “jelly bean” rule, that requires a food to contain a minimum amount of a certain nutrient before a health claim may appear on the label.

The Dialogue Group agreed that authorized health claim messages should be scientifically valid, nonmisleading, and compelling. The key issues involved in determining the best way to communicate such a health claim message include the following: 1) the most compelling way of providing NLEA health claim information concerning foods to consumers and 2) the informational elements considered critical to a health claim in order for it to be scientifically valid and nonmisleading.

The Dialogue Group’s recommendations address multiple facets of the authorization process, the technical challenges of scientific research and development, the disqualification of certain food substances from bearing a health claim, the construction of effective health messages, and incentives to encourage research and investment regarding 1) the science and communication of health claims and 2) the development of foods that advance health.

Science Supporting Proposed Diet-Disease Relationships

The Dialogue Group first established a collective understanding of the review process for determining a scientifically valid diet-disease relationship. The first 10 proposed relationships Congress required FDA to review were risk reduction relationships, but future health claims may also characterize other kinds of relationships, such as those between certain foods and the enhancement of health.

The Dialogue Group examined the scientific evidence required by FDA and how the agency reviewed the data in the authorization of the statutorily proposed health claims. In particular, the Group wanted to understand the meaning and application of the “significant scientific agreement” standard to the evaluation of the diet-disease relationships that NLEA mandated to be assessed. Initially, a substantial amount of confusion existed about the significant scientific agreement standard in terms of whether it required a prohibitive level of scientific data.

At the conclusion of its review, the Dialogue Group observed that, given the constraints placed on FDA in fulfilling the statutorily mandated review of the 10 food substance and health-related condition relationships, the agency did a commendable job, using appropriate scientific data and applying the significant scientific agreement standard in an objective, flexible, and responsive manner. The Dialogue Group believes that in the future the application of the significant scientific agreement standard should continue to be objective, flexible, and responsive.

RECOMMENDATION: The Dialogue Group recommends that the significant scientific agreement standard be used in a manner that is objective, flexible, and responsive, consistent with FDA’s review and authorization of the statutorily proposed health

claims, and incorporating the changes as set forth in this Report. Data may not always be consistent, some studies may not be optimally designed, and, taken individually, not all studies may be of sufficient strength to be persuasive. Application of the standard should continue to take into account these and other possibilities, as long as the accumulated data are sufficiently consistent and powerful and enough studies are appropriately designed to convince qualified scientists that the asserted relationship exists.

The Dialogue Group also supported one of the central tenets of the application of the significant scientific agreement standard: consideration of the total body of evidence relevant to the relationship between the food substance and a disease or other health-related condition that is the subject of the proposed health claim.

RECOMMENDATION: *The Dialogue Group recommends that FDA's decisions on the authorization of health claims continue to be based on the totality of evidence relating to the proposed relationship. If studies are conducted to support a particular health claim, it is recommended that all data from those studies be submitted.*

By stating that the “totality” of the evidence should continue to be considered, the decision to authorize a health claim must be derived from accumulated information from all studies. FDA recognized that in some cases, large, lengthy intervention trials may not be feasible or necessary; thus, they may not be required. However, if clinical intervention trials are feasible, they should be conducted.

Depending on the strength of the accumulated observational data, there may need to be more or fewer clinical intervention trials to establish a diet-disease relationship. That is, when observational data are strong and are

derived from several studies, the number and extent of intervention trials needed are less than those required in a situation in which observational data are limited.

The Dialogue Group also discussed several factors that make further research in this area particularly challenging, including the limited number of established surrogate markers for the purpose of authorizing health claims. A surrogate marker is a biological observation, result, or index that predicts the development of a chronic disease. It is an “intermediate” or “substitute” indicator for the chronic disease. Surrogate markers are established when they are recognized by the scientific community as valid predictors of chronic disease risk, such as serum cholesterol levels serving as predictors of coronary heart disease.

To stimulate research in this area that potentially could lead to authorization of additional health claims, the Dialogue Group believes that it is important to encourage the confirmation of additional surrogate markers.

RECOMMENDATION: *For the purpose of stimulating research on or providing support for the authorization of health claims, the Dialogue Group recommends that FDA and other prestigious scientific bodies actively work toward confirming surrogate markers of disease risk. FDA should create and oversee a mechanism to review potential surrogate markers for use in the authorization of health claims.*

Foods and Food Substances Must Qualify for Health Claims

The Dialogue Group next discussed the foods that should bear health claims. FDA evaluates foods for both their risk-increasing and risk-reducing impacts on health to determine which foods can bear a health claim.

FDA's regulations adopted pursuant to NLEA establish several standards that limit the types of foods that can bear health claims. These standards include 1) the levels of four nutrients determined to increase the risk of disease, 2) a qualifying level (expressed as a minimum or a maximum) of the substance that is the subject of a health claim (e.g., the level of sodium in a food that still enables that food to bear a sodium-hypertension health claim), and 3) a minimum level of one or more of six nutrients to ensure that the food bearing the claim has a minimum nutritive value.

The Dialogue Group supported this general approach to the qualification of foods that can bear health claims. The Dialogue Group agreed that some foods, consumed regularly, may not contribute to a healthful diet and would be inappropriate candidates for bearing a health claim. The Group agreed that this inappropriateness is true even if a food substance that has an established relationship with a disease or health-related condition is added to or contained in a food. However, given this support, the Dialogue Group remains concerned that these qualifications may result in missed opportunities for providing important information to consumers simply because some foods do not meet all of the necessary criteria.

The Dialogue Group recognizes two options within the current statute for resolving this issue under the appropriate circumstances: 1) using a nutrient content claim rather than a health claim to highlight favorable nutritional content and 2) using the current petition process for waiving disqualification criteria for health claims when an overall public health benefit would result. Nutrient content claims already are an available alternative. The petition process for waiving disqualification criteria for health claims is also in place, and the Dialogue Group encourages the industry to fully use the petition process for waiving disqualification requirements (i.e., levels of particular nutrients that prohibit a food

from bearing a health claim). The Dialogue Group also strongly suggests that FDA be given sufficient resources to act on these petitions in a timely manner and to develop specific criteria for responding to these petitions for waiving disqualification requirements.

RECOMMENDATION: The Dialogue Group recommends that FDA develop criteria for determining whether to waive health claim disqualification requirements in response to a petition and recommends that the following areas, identified by the Group, be considered in developing those criteria:

- 1) the scientific rigor of the underlying data related to the health claim;*
- 2) the public health significance of the disease addressed by the health claim and the contribution of the food or nutrient to reducing the risk of that disease;*
- 3) the public health significance of the disease associated with the disqualifying substance and the probable contribution of the disqualifying substance to increasing the risk of disease;*
- 4) the risk of the disease that is the subject of the health claim to the population targeted by the claim compared with the risk to the general population of the disease to which the disqualifying nutrient contributes;*
- 5) the improvement in public health that could result from dietary changes brought about by the approval of the health claim; and*
- 6) the target and general population's understanding of the association between the disqualifying nutrient and the diseases to which it may contribute.*

The Dialogue Group agrees that health claims are not appropriate on some foods. In attempting to prevent these foods from being eligible to bear health claims, however, the "jelly bean" rule excludes a range of foods that may be

appropriate vehicles for health claims, such as grains, whose more frequent consumption is encouraged by the *Food Guide Pyramid*⁷ and the *Dietary Guidelines for Americans*.⁸

The Dialogue Group discussed other circumstances in which fortification and the use of health claims on the labels or in the labeling of fortified foods may be appropriate for making incremental improvements in the diets of at-risk populations. The “jelly bean” rule requires that foods have some minimum nutritive value prior to any fortification to qualify for bearing a health claim. After considerable discussion, the Dialogue Group supported the general rationale for that rule, but thought that some modifications might be desirable so as not to exclude foods that could contribute to a healthful diet from bearing health claims.

RECOMMENDATION: The Dialogue Group recommends that FDA reexamine the “jelly bean” rule. Possible approaches include 1) exempting certain categories of foods (e.g., vegetables, fruits, and certain grain products), 2) expanding the list of nutrients that would qualify foods to bear a health claim under the “jelly bean” rule, and 3) reexamining the current fortification policy, particularly to ensure that foods specifically fortified consistent with dietary recommendations are not precluded from eligibility to carry a health claim.

Even if the regulations were changed, the Dialogue Group recognizes that some food products will not meet the criteria for waiving the disqualification requirements and will not be exempt from the “jelly bean” rule. The Dialogue Group emphasizes that, where appropriate, these

foods are still able to carry important information to consumers through the use of nutrient content claims on labels and in labeling.

RECOMMENDATION: The Dialogue Group recommends that food companies take full advantage of opportunities to make approved nutrient content claims on the labels and in the labeling of their products.

Messages on Food Labels

Health Claims

A critical issue that the Dialogue Group discussed extensively is how to make the wording of health claims more effective. The Dialogue Group identified the different objectives of health claims and then sought to meet those objectives with recommendations that would encourage the most effective means of communicating the relationship between a food substance and a disease or health-related condition.

Communicating the healthful benefits of foods raises difficult issues. If the health claim statement includes an extensive amount of information, the language may become too complicated and cumbersome. On the other hand, if the health claim statement contains only a limited amount of information, consumers may be unable to understand it well enough to make informed food choices. The Dialogue Group’s recommendations are targeted toward improving communication by achieving balance between too much and too little information. All Dialogue Group members agree that health claim messages should be scientifically valid, nonmisleading, and compelling.

⁷ U.S. Department of Agriculture (USDA). Human Nutrition Information Service (HNIS). Food Guide Pyramid. Home and Garden Bulletin, no. 252, Washington, DC, 1992. 30 pp.

⁸ USDA and DHHS. Nutrition and Your Health: Dietary Guidelines for Americans. Home and Garden Bulletin, no. 232, Washington, DC, 1995. 45 pp.

In thinking about health claim language, it should be remembered that food products that bear authorized health claims already are subject to rigorous regulatory control. As discussed above, a product is eligible to bear a health claim only if it meets certain requirements. If a product meets these pertinent compositional requirements, additional regulations relating to the health claim language itself must be followed. Health claim language must be placed in the context of the total diet and must be nonmisleading. In addition, FDA has required that statements be generic and nonproprietary. In accordance with these parameters, the Dialogue Group concentrated its efforts on determining whether food companies should have more flexibility in communicating a health claim on the label or in labeling.

The Dialogue Group was hindered in its recommendations by the lack of information on consumers' interpretation of food and nutrition information, especially health claims. Although consumer research is being conducted by the U.S. Department of Health and Human Services (DHHS), the Dialogue Group could not await its completion. Consequently, some of the Dialogue Group's recommendations for improving health claims offer thoughtful suggestions for change, but require additional information about consumer knowledge and behavior to confirm the direction in which health claim language should move.

RECOMMENDATION: To create the most effective health claim messages that are scientifically valid, nonmisleading, and compelling, the Dialogue Group recommends reexamination of the regulations to 1) improve flexibility in wording, 2) evaluate whether any of the elements that are currently required should be made optional, and 3) evaluate whether abbreviated claims may be used on the principal display panel with appropriate reference to the full claim on the back panel or another prominent position if

the package does not contain a back panel. The Dialogue Group also recommends that mechanisms for enhancing the credibility of health claims be explored. The Dialogue Group believes that FDA should take a leadership role in facilitating this public process. Other interested parties (e.g., industry, consumer groups, and academia) should assist the agency and should participate in this process by designing and performing consumer research, submitting data, and suggesting decision-making criteria to assist FDA in reaching a final decision concerning health claim language.

Consumers need more information about nutrition labeling in general to receive its full benefit. Qualitative research recently conducted by DHHS suggests that consumers may be unaware that nutrient content and health claims are strictly regulated by the federal government. The Dialogue Group believes that additional research should be conducted to explore consumer perceptions of health claims and that appropriate measures should be taken to address the credibility of such claims.

RECOMMENDATION: The Dialogue Group recommends that resources be provided for a federal initiative designed to help consumers understand, trust, and use NLEA-regulated information. This initiative should give proper emphasis to the fact that nutrient content and health claims are strictly regulated and that they provide important information about the foods that bear them.

Dietary Guidance

The Dialogue Group also discussed communication mechanisms other than health claims on labels or in labeling. Consumers' ability to make informed food choices can be enhanced through many means of communicating infor-

mation and is affected by the many variables involved in consumers' recognition and use of new information about diet and health. To help encourage greater dissemination of dietary guidance information, the Dialogue Group thought that model dietary guidance statements and suggestions about mechanisms for conveying such statements should be developed. Furthermore, the Dialogue Group thought that these suggestions could be developed most effectively through a cooperative public-private partnership.

RECOMMENDATION: The Dialogue Group recommends that a public-private partnership develop a user's guide to assist and encourage the food industry in the creative use of dietary guidance tools (such as the Food Guide Pyramid) on labels and in labeling and advertising.

Health Claims in the Future

The Dialogue Group recognized that new issues may emerge when health claims are authorized in the future. Issues may arise from the discovery of new healthful food substances, findings regarding new diseases with which a food substance has a relationship, and new challenges in conveying this information in proposed health claim messages. There are two broad categories of future health claims: 1) refinements or additions to current claims and 2) new claims. Future issues will arise from review of the scientific literature, marketing research, and scientific research. The Dialogue Group discussed the overall impact of consuming foods for the purpose of achieving the benefit stated in health claims and the potential risks involved from increased exposure to various food substances.

Particularly interesting new areas of research involve safety and target populations. Safety issues are raised when 1) food substances that are safe in whole foods may no longer be safe in their isolated form when they are added

to foods to take advantage of health claims and 2) concentrates increase the level of exposure of the overall population to a specific substance. Although mechanisms currently exist to evaluate the safety of a substance, they do not include possible increases in exposure for generally recognized as safe (GRAS) nutrients, food additives, and prior sanctioned nutrients.

RECOMMENDATION: The Dialogue Group recommends that FDA develop and implement a decision-making mechanism to address potential safety issues that may be raised in the process of authorizing future health claims, with particular regard to isolated and concentrated substances.

Review of the scientific literature may unveil new claims or may help to refine currently approved claims. The current literature is flawed in that it does not provide the essential information needed to firmly establish relationships between food substances and diseases or other health-related conditions because the studies were not designed to address or support the authorization of health claims. Under NLEA, existing information could provide the direction in which new scientific research could go. With the enactment of NLEA, new scientific research may be specifically tailored toward answering the requirements of the Act.

Market research issues related to improving health claim messages need to be addressed immediately to ensure that future health claim messages are used in a manner that creates scientifically valid, nonmisleading, and compelling messages. Without such research, it is not possible to evaluate the extent to which consumers are reading, understanding, and using health claims on labels and in labeling to make informed food choices.

The future of health claims also may involve incentives for reformulating existing products or developing new ones. Factors that influence the development of new or reformulated products include consumer demand, responsible media attention, competitive pressure and profitability, advances in food technology, and flexibility in labeling language. The Dialogue Group believes that an essential part of creating a healthy diet is to have healthful food alternatives from which to choose. The development of new or reformulated foods requires research, which in turn requires funding.

RECOMMENDATION: The Dialogue Group recommends that scientific and marketing research into the relationships among foods, food substances, diet, and disease be increased and that more private and public sector funding be made available for this purpose.

The Dialogue Group did not reach a consensus as to the particular mechanism that should be used to stimulate research. The Dialogue Group did, however, identify several possible avenues for encouraging private and public investment and for removing barriers to research. The private sector incentives discussed were primarily related to economic factors. A discussion of these potential economic incentives includes comments on their advantages and disadvantages. Public sector incentives focused less on economic approaches and more on prestige and recognition for research accomplishments, in addition to improving public welfare.

RECOMMENDATION: The Dialogue Group recommends that the potential for providing various economic incentives be explored as a means of stimulating private investment in research that could establish relationships between food substances and the reduction of disease risk.

COMPARISON OF LABELING AND ADVERTISING POLICIES

Statutory authority and regulations for nutrition-related messages are different for advertising than they are for labels and labeling. At the federal level, FTC, FDA, and the U.S. Department of Agriculture (USDA) share jurisdiction over claims made by food manufacturers under a regulatory scheme established by the U.S. Congress through several complementary laws. In addition, the state attorneys general share enforcement jurisdiction with the federal agencies. All federal and state agencies share the goal of protecting consumers from false and misleading nutrient content and health claims. Because these different entities operate under different statutory mandates and policies, with different enforcement tools, uniformity of regulations is not possible. However, these agencies should strive to achieve consistent results in the regulation of nutrient content and health claims.

Dialogue Group members differ in the approaches that they believe can be used to achieve consistent results in the regulation of health and nutrient content claims in labeling and advertising, specifically, whether the differences between advertising and labeling warrant different regulatory approaches. Some members believe that the differences between the roles of advertising and labeling are insignificant and irrelevant from the standpoint of public health and consumer protection and, thus, that there should be greater uniformity in advertising and labeling regulation. Others believe that the differences between the two media argue for a more flexible, less standardized approach for advertising. Regardless of the different points of view concerning the rationale, Dialogue Group members could agree that the objective of "harmonization," in terms of achieving consistent results in the implementation of these agencies' policies and regulations, merited a recommendation. Harmonization does not imply a merging of these policies or an attempt to

achieve uniformity of language between advertising and labeling regulations.

RECOMMENDATION: Recognizing the importance of consistency, but given the different statutory mandates and policies, the Dialogue Group recommends that the regulation of health and nutrient content claims in food labeling and advertising by FDA, USDA, FTC, and the states be harmonized to the fullest extent feasible.

COMMUNICATING EMERGING SCIENTIFIC INFORMATION

Although considerable attention was focused on authorized health claims on labels and their counterparts in advertising, Dialogue Group members also explored other formats and vehicles in which useful health and nutrition information might be conveyed to help consumers make more informed dietary choices. Dialogue Group members are in agreement that public health could be improved if the amount of useful, nonmisleading information that gets to consumers is maximized. There is no agreement, however, concerning whether claims based on emerging scientific information are inherently misleading or whether consumers could benefit from mechanisms that would formalize consumer access to the most recent information on the links between diet and disease or other health-related conditions.

“Emerging scientific information” refers to the incremental increase in knowledge generated by new research findings or new interpretations of existing research data. Significant controversy exists regarding the most appropriate and effective means of communicating emerging scientific information and the most effective vehicle (e.g., labels, labeling, advertising, and media) for delivering this information. Although some members favor increasing the opportunities for the responsible dissemination of emerging scientific information

in the regulated vehicles (i.e., labeling and advertising), other members firmly believe that such information could not be appropriately evaluated by the general public and therefore that such information would not assist consumers in making rational decisions about their diets.

It is generally agreed within the Dialogue Group that each means of communication has some role to play in helping consumers make informed food choices. Some members believe that these roles would be enhanced by allowing additional emerging scientific information to appear in regulated channels, such as advertising and off-package educational materials (labeling). These participants believe that such messages would be regulated to avoid misleading consumers, and therefore that the reliability and usefulness of the total body of information available to consumers would be increased. These members would encourage FDA to allow claims that reflect more preliminary or controversial scientific findings as long as such claims are qualified to appropriately reflect the state of the scientific evidence.

Other Dialogue members believe that such a policy would lead to a preponderance of unreliable claims, consumers would have difficulty distinguishing between them and the relatively enduring health claims that are authorized under NLEA, and allowing emerging scientific messages in the regulated arenas would jeopardize consumer confidence in the reliability of NLEA-authorized claims. In addition, these Dialogue members believe that consumers could be physically harmed if they act on emerging scientific information in lieu of relying on more proven therapeutic approaches. These Dialogue members further believe consumers could be harmed economically if they purchase products purporting to have a health benefit based on emerging scientific information that later is invalidated.

Although consensus was not reached on whether emerging scientific information

should be allowed in regulated channels, there was agreement concerning the need for providing an appropriate context for explaining emerging scientific information wherever it may appear. The Dialogue Group members had extensive discussions regarding the best strategies for improving the reliability and consistency of the messages and information regarding emerging scientific issues reaching health and nutrition professionals, journalists, and the public. Although Dialogue Group members were not in agreement as to what and where emerging scientific information is appropriate, the Group developed considerations that should govern any communication of preliminary scientific developments.

RECOMMENDATION: To ensure that the information about emerging scientific information disseminated to the public is not misleading or confusing, the Dialogue Group recommends that any entities disseminating such information do so in a manner that 1) protects consumers from harm, 2) empowers consumers to choose foods that contribute to a healthful diet, 3) preserves scientific accuracy, and 4) does not diminish the credibility of authorized health claims.

In addition to these considerations, the Dialogue Group discussed several strategies for improving the communication of emerging scientific information. Ultimately, no consensus was reached on a specific approach. However, there was a common view that the provision of balanced, reliable information on emerging scientific issues remains a critical need. Partnership efforts to improve awareness, increase access, and broaden the dissemination of information from these resources would be of considerable value.

RECOMMENDATION: The Dialogue Group recommends advancements in the communication of emerging scientific information in the unregulated

arena through three strategies: 1) improving access to reliable information that explains the new finding in the context of the broader base of scientific knowledge, 2) convening consensus-building conferences on issues of emerging scientific information, when appropriate, and 3) conducting research on the public's exposure to and understanding of emerging scientific issues. The Dialogue Group further recommends that partnership efforts be encouraged to pursue these strategies.

Improving access to reliable and consistent information is challenging. Many organizations in government, the private sector, and academic institutions have information relating to emerging scientific issues in food, nutrition, and health, but there is no single repository or data bank dedicated to tracking such information. The Dialogue Group discussed the value of and challenges associated with establishing a central information resource that could provide reliable information to professionals, the media, and the general public. Two models discussed by the Group included the creation of a new organization or reshaping an existing organization as a clearinghouse for information and forming a food and nutrition science council. Although it was very informative and creative, this discussion did not result in consensus recommendations for a particular organization model.

Many professional organizations and government health agencies sponsor individual workshops, conferences, and colloquia at which published information on nutrition research is reviewed and interpreted. These meetings serve to build consensus on key issues of emerging scientific information. The Dialogue Group members agree that it would be useful to have in place a responsible body with scientific expertise to review this emerging information in a timely manner and provide context to its communication.

Objective data on consumers' knowledge, attitudes, and practices regarding food and nutrition issues are quite limited. In response to this fact, Dialogue Group members considered ways to better assess the public's perceptions of emerging scientific issues and changes in dietary behavior that may be related to those perceptions. The most direct approach was considered to be broad-based consumer research to assess public knowledge, attitudes, and practices and the public's interpretation of and response to nutrition and food messages.

The Dialogue Group members believe that a partnership approach for all of these strategies, whether consumer research, scientific review, or information dissemination, would be the most effective because this approach would give the information more credibility and would make it available to all interested parties.

DIETARY INFORMATION AND BEHAVIORAL CHANGE

Determining what constitutes "credible and consistent" information and the best means of presenting that information is a challenge that the Dialogue Group discussed throughout the project. The Dialogue Group members noted that credible information is important not only for emerging scientific information but also for any messages concerning the relationships among food, diet, and health.

The Dialogue Group believes that partnerships among public and private agencies, similar to several partnerships already in place, can play a significant role in providing dietary information and increasing the credibility of that information. A partnership approach is appealing for general dietary information for many of the same reasons that partnership efforts are appealing for handling emerging scientific information. Partners may share the costs for market research to define target groups and the best messages and channels for reaching the targeted populations. Multiple

partners can also increase the visibility and exposure of a message beyond what any individual agency or company could achieve. The messages associated with a consortium of partners may also be more credible than those from a single source.

***RECOMMENDATION:** The Dialogue Group recommends that public-private partnership efforts be encouraged, with the goals of providing balanced and consistent information on food and nutrition issues to the public, the media, and food, nutrition, and health professionals and assisting consumers in making healthful dietary changes.*

Part of the goal of providing food, nutrition, and health information to consumers is to encourage consumers to make informed food choices or behavioral changes that result in more healthful diets. Applying behavioral change theories to these informational efforts is an important part of encouraging action as a result of the information. The Dialogue Group briefly discussed theories of behavior and their relevance to the many mechanisms and approaches used to communicate health information. Although Dialogue Group members were not specific in terms of how theories of behavior should be applied to particular mechanisms for communicating nutrition information, they believe that it is an important area for research.

***RECOMMENDATION:** The Dialogue Group recommends that research into the application of theories of behavior to community-based nutrition interventions and programs be a priority for public and private funding and that partnership efforts that promote positive dietary changes be supported and expanded at the national, state, and community levels.*

THE FINAL REPORT

The recommendations and discussion in this Executive Summary are meant to highlight the culmination of 2 years of work by participants in the Keystone National Policy Dialogue on Food, Nutrition, and Health. However, the value of the significant information exchange and mutual education among decision makers with very different perspectives can only be truly appreciated by reading the full Final Report. Ultimately, it is the enhanced communication among these decision makers that constitutes the real value of these Dialogues. Although this particular Dialogue has completed its charge, many questions remain unanswered. It is still unclear how public policy should be forged in areas where consensus has not been reached, as well as how to prioritize and ensure funding in some of the areas in which consensus recommendations have been made. The members of this Dialogue hope that this Report will stimulate continuing discussions to advance public understanding and decision making on these important issues.

CHAPTER 5

MESSAGES ON FOOD LABELS

This chapter focuses on two types of health messages that may appear on food labels: authorized health claims and dietary guidance. Health claims on food labels may be powerful communications vehicles and may have great potential for disseminating nutrition information and communicating the relationship between diet and disease. Translating a scientifically valid diet-disease relationship into health claim language that is both nonmisleading and compelling is a significant challenge. The first part of this chapter explores the extent to which authorized health claims are being used on food labels, the factors limiting their use, the required information health claim language must contain, and how it must be stated, the use of FDA's model statements, and possible improvements to model language.

Dietary guidance is another powerful communications mechanism that, unlike authorized health claims, was not affected by NLEA. Dialogue Group participants believed that dietary guidance warranted discussion because it has great (and underused) potential to help fulfill two Dialogue goals: to promote the consumption of currently available foods that advance health and to promote consumers' ability to make informed food choices. This chapter discusses and makes recommendations regarding the use of health claims and dietary guidance on labels.

HEALTH CLAIMS

To date, eight health claims related to seven diet-disease relationships have been authorized by FDA. No comprehensive research has been done to determine how many food product labels bear these claims. Nonetheless, it is known that several food companies are using authorized health claims on a variety of different products, including breakfast cereals, fat-free brownies, pasta sauces, egg substitute products, and frozen fruit bars. (See Appendix B for examples of health claims currently used on food labels.) The particular claim used varies with the type of food product involved. A segment of the fruit juice industry has used claims regarding the relationship between decreased cancer risk and diets rich in low-fat foods that contain certain vitamins. A leading cereal company has used claims on the relationship between a high-fiber, low-fat diet and a reduced risk of certain forms of cancer. Another major breakfast cereal company is using a message on the relationship between the reduced risk of cardiovascular disease and diets that are low in fat and high in fiber. In addition, a calcium supplement product has used a claim regarding the relationship between calcium consumption and the reduced risk of osteoporosis. Many authorized health claims now in use appear along with third-party endorsements, a practice permitted under FDA regulations. The use of an endorsement from a third party such as a nationally recognized health organization, in conjunction with an authorized health claim, may help consumers identify a product as healthful.

Some Dialogue Group members believe that health claims are being used to a significant degree, whereas other members believe that health claims are significantly underused because of constraints on the wording of the health claim messages and other requirements under NLEA.

Regardless of different perspectives concerning the adequate use or quantity of health claims, the Dialogue Group members held a common interest in maximizing the amount of scientifically valid, nonmisleading, and compelling information disseminated to consumers. Dialogue Group members agree that consumers should be encouraged to adopt a healthful diet through clear and effective health claims. However, the integrity of health claim messages must be conscientiously maintained, and their ability to communicate the relationship between diet and disease should not be enhanced at the expense of their obligation to provide nonmisleading and scientifically valid information. Given this understanding, participants believe that the use of authorized health claims on eligible products can and should be increased.

Factors Limiting the Use of Health Claims on Labels

The Dialogue Group examined factors that may discourage food companies from using authorized health claims. One factor is the newness of FDA's regulations for NLEA. The Dialogue Group believes that the Keystone process and this Report will help to explain how health claims can be made under existing regulations. However, a more pervasive obstacle is that most food manufacturers contend that they are unable to craft compelling messages under existing regulations. These regulations require that multiple elements be mentioned for each claim (e.g., 5 elements for sodium intake and hypertension and 10 elements for folic acid intake and neural tube birth defect claims; Table 2). As a result, the model language for authorized health claims can be wordy and complex.

FDA encountered several difficulties in drafting model language for the eight authorized health claims. Existing scientific studies on the diet-disease relationships for which health claims have been authorized had not been designed for the purpose of supporting health claims applicable to specific food substances. Many scientific studies that were reviewed did not adequately document or identify the specific intervention, such as the type of fiber or antioxidant used. The studies also did not always assess the exact outcome, such as heart disease, cholesterol level, or cancer incidence, that was to be the subject of the claim. In the future, health claims can be crafted around either existing evidence or studies designed to support particular health claims. In the latter case, improvement in the health claim's specificity should be possible.

Understanding these difficulties, the Dialogue Group conducted an exercise to test the validity of the contention that the health claim language requirements are too cumbersome. First, the Group developed a list of commonly accepted communications factors that are characteristic of the type of compelling, understandable messages most likely to be used by food manufacturers. The Dialogue Group concluded that messages should be 1) simple, 2) concise, 3) at a reading level appropriate to the audience, 4) compelling, 5) credible, and 6) memorable, and should 7) encourage action, and 8) contain a single message or a limited number of concepts.

The Dialogue Group then compared the FDA model statements against these criteria. The conclusion was that the model statements were unlikely to be effective from a communications standpoint. Next, the Dialogue Group attempted to reword the model statements, which is permitted under the existing regulations. Once again, the resulting statements failed to meet the criteria for effective communication in almost every case. Subsequently, qualitative research also suggested that the model health claim statements, no matter how they are worded, may not be seen by consumers as credible or authoritative. (See Appendix D).

TABLE 2: CURRENT REQUIRED ELEMENTS FOR HEALTH CLAIM MESSAGES

	Fat & Cancer	Saturated Fat, Cholesterol & Coronary Heart Disease	Fiber & Cancer	Soluble Fiber & Coronary Heart Disease	Sodium & High Blood Pressure	Calcium & Osteoporosis	Fruits, Vegetables & Cancer	Folic Acid & Neural Tube Defects
Identify Food Substance & Disease	Req.	Req.	Req.	Req.	Req.	Req.	Req.	Req.
State "Some Types" of Disease	Req.		Req.				Req.	Req.
Place in Dietary Context	Req.	Req.	Req.	Req.	Req.	Req.	Req.	Req.
Specify "May or Might Reduce the Risk of"	Req.	Req.	Req.	Req.	Req.	Req.	Req.	Req.
Note Multifactorial Etiology	Req.		Req.					Req.
Specify That Diet Must Have Certain Characteristics	Req. (must be low in fat)	Req. (must be low in fat)	Req. (must be low in fat)	Req. (must be low in saturated fat & cholesterol)			Req. (must be low in fat)	
Specify That Foods Must Contain Particular Nutrients			Req. (fiber containing grain products, fruits, & vegetables)	Req. (fiber containing grain products, fruits, & vegetables)			Req. (fruits and vegetables low in fat and are good source of vitamins A and C or fiber)	
List Populations at Risk					Req.			
State that Exercise and Healthful Diet are Important					Req.			
State When Intake Is Effective						Req. (importance of adequate calcium throughout life)		Req. (adequate intake during childbearing years)
State Limitation on Effect of High Level of Nutrient						Req. if > 40% DV		
State Safe Upper Limit								Req. if > 25% DV
State Prevalence of Disease								Req.
Describe Diets Rich in the Nutrient								Req.

Health Claim Language Requirements

Food products bearing authorized health claims are subject to rigorous regulatory control. A product is eligible for a health claim only if it contains an appropriate amount of the food component that is the subject of the health claim. In addition, the product must not contain certain other food components above levels that increase the risk of another disease or condition, which would disqualify the product from bearing a health claim, and food products that do not contain a minimum nutrient composition are also ineligible to bear health claims. These controls help to ensure that the benefit described in the health claim can truly be achieved by incorporating the food into a healthful diet.

Once a product meets these scientific requirements, additional regulations relating to the health claim language itself must be met. Specifically, health claim language must be generic and nonproprietary, placed in the context of the total diet, and nonmisleading. (See Table 1 in Chapter 4).

Generic, nonproprietary terminology must be used to describe an authorized relationship between a food substance and a disease. In other words, the health claim language should not imply that the claim is specific to a single product if it could apply to several products. Although the generic nature of claims is not explicitly stated in NLEA, FDA's implementation of the law includes this requirement. This issue was not considered in the first 10 diet-disease relationships, but it may become important in the future if research supports a specific claim for a specially formulated food product.

Furthermore, NLEA requires that the food substance be placed in the context of the total daily diet.¹³⁸ In order for the health claim to be understood in the context of the total diet, the substance must first be recognized as a food and must retain its food attributes when it is consumed at the levels that are necessary to justify the claim. The health claim must communicate to the public that the effect on disease or a health-related condition is achieved when the product is ingested as a food (i.e., consumed for taste, aroma, nutritive value, or other technical effect listed in the regulations).¹³⁹

The Dialogue Group believes that when the scientific basis for significant agreement demonstrates a link between a disease or health-related condition and *total diet*, it is appropriate policy to include reference to *diet* in the primary claim, the "primary claim" being the statement made in the most prominent position on the label, such as the front panel. A "secondary claim" would be statements found in another portion of the package with additional information concerning the diet-disease relationship. The Dialogue Group discussed the concept of split claims and concluded that more consumer research would need to be conducted before split claims could be considered. If research establishes, to a level of significant scientific agreement, that a specific product or food substance is responsible for the health benefit, then the primary claim may not need to refer to the total diet. Then the supporting information provided elsewhere on the package can refer generically to the importance of the total diet in promoting good health.

¹³⁸ U.S.C. § 343(r)(3)(B)(iii) (1994).

¹³⁹ DHHS. FDA. Food Labeling; General Requirements, *supra* note 52.

A health claim also must be scientifically valid and nonmisleading. This requirement arises from NLEA and the general provisions of FDCA, which require that labeling not be false or misleading in any particular.¹⁴⁰ Communication of the underlying science requires both an accurate appraisal of the science and a simple restatement of the scientific conclusions in a format that is comprehensible to the greatest number of consumers who are actually at risk. However, many consumers are not aware of the regulatory requirements for a health claim, and, therefore, consumers may be skeptical about the credibility of this information on food labels.

Improving Health Claim Language on Labels

To improve health claim language on labels without compromising scientific validity, Dialogue Group members outlined principles for health claim language, general opportunities to strengthen those messages, and specific areas where additional research and consideration are warranted.

Principles for Health Claim Language

The Dialogue Group identified the following set of principles that it agreed must be addressed to ensure that health claim messages are appropriate:

- **Scientifically valid.** The claim must not misrepresent the scientific underpinnings of the diet-disease relationship.
- **Nonmisleading.** 1) The claim must place the health benefit in the appropriate *dietary context* (i.e., consumers should not conclude that eating more of a specific food will provide the health benefit if a more comprehensive modification of the total diet is necessary). 2) The claim should not convey unrealistic expectations about the *magnitude* of the health benefit (i.e., consumers should not conclude that dietary intervention eliminates the need to address other risk factors such as smoking or physical inactivity). 3) The claim should not convey unrealistic expectations about the *scope* of the health benefit (i.e., consumers should not conclude that dietary intervention will reduce the risk of *all* forms of cancer). 4) The claim should not convey unrealistic expectations about the therapeutic value of dietary modification (e.g., consumers should not conclude that dietary intervention will *cure* an existing condition or eliminate the need for conventional health care).
- **Compelling.** The claim must capture consumers' attention so that the information will be read and result in an action based on that information (e.g., including more fiber in the diet).

Opportunities to Strengthen the Message

The Dialogue Group also identified broad, general measures that may significantly strengthen the ability of health messages to inform consumers if the messages are implemented in accordance with the principles given above. To further confirm the anticipated positive impact of efforts to make scientifically valid and nonmisleading messages also compelling, the Dialogue Group strongly urged that consumer research be conducted on the following:

¹⁴⁰ 21 U.S.C. § 343(a)(1) (1994).

- “Abbreviated” health claims on the principal display panel of packages. At a minimum, such abbreviated claims would be required to include the disease, the nutrient, a qualifying word (e.g., “may” or “might”), and a referral statement indicating the location of the full claim elsewhere on the package.
- Simplified health claims. The Dialogue Group agrees that health claims would be more effective from a communications standpoint if they could be simplified by making optional any currently required element that is not absolutely necessary to prevent the consumer from being misled and to maintain scientific validity (see Table 3 for potential areas that could be evaluated).
- Flexible health claim wording. The Dialogue Group agrees that additional flexibility in the wording of health claims could increase their appeal to consumers and manufacturers and enable the claims to be more compelling.
- Enhancing the credibility of health claims. The Dialogue Group believes that the credibility of health claims may be accomplished by references to government oversight either on labels or in information campaigns.

Areas Requiring Additional Data

A suggested matrix of required and *potentially* optional elements is presented in Table 3. Specific guidelines on which of the currently required health claim elements should be considered for additional flexibility are provided. Examples of changes that might be implemented following consumer testing are contained in Appendix C. Dialogue Group members agree that more information is needed to confirm that the health claim elements identified in Table 3 can be eliminated without violating the principles given above. Both communications and scientific issues need to be considered in making this determination. The communications issues are best resolved by conducting consumer research, and the scientific issues are best addressed by qualified scientific experts.

RECOMMENDATION: To create the most effective health claim messages that are scientifically valid, nonmisleading, and compelling, the Dialogue Group recommends reexamination of the regulations to 1) improve flexibility in wording, 2) evaluate whether any of the elements that are currently required should be made optional, and 3) evaluate whether abbreviated claims may be used on the principal display panel with appropriate reference to the full claim on the back panel or another prominent position if the package does not contain a back panel. The Dialogue Group also recommends that mechanisms for enhancing the credibility of health claims be explored. The Dialogue Group believes that FDA should take a leadership role in facilitating this public process. Other interested parties (e.g., industry, consumer groups, and academia) should assist the agency and should participate in this process by designing and performing consumer research, submitting data, and suggesting decision-making criteria to assist FDA in reaching a final decision concerning health claim language.

Participants in this process could submit scientific or consumer data that demonstrate that the required elements are no longer necessary or can be modified, including data that elucidate whether changes in the authorized claim language will promote the objectives of the Dialogue Group. FDA recently initiated a rulemaking on several issues closely related to this recommendation.¹⁴¹

¹⁴¹ DHHS. FDA. Food Labeling; Nutrient Content Claims, General Principles; Health Claims, General Requirements, *supra* note 10.

TABLE 3: POTENTIAL OPPORTUNITIES TO SIMPLIFY HEALTH CLAIM MESSAGES

	Fat & Cancer	Saturated Fat, Cholesterol & Coronary Heart Disease	Fiber & Cancer	Soluble Fiber & Coronary Heart Disease	Sodium & High Blood Pressure	Calcium & Osteoporosis	Fruits, Vegetables & Cancer	Folic Acid & Neural Tube Defects
Identify Food Substance & Disease	Req.	Req.	Req.	Req.	Req.	Req.	Req.	Req.
State "Some Types" of Disease	Opt.-F		Opt.-F				Opt.-F	Opt.-F
Place in Dietary Context	Opt.-F	Opt.-F	Opt.-F	Opt.-F	Opt.-F	Opt.-F	Opt.-F	Opt.-F
Specify "May or Might Reduce the Risk of"	Req.	Req.	Req.	Req.	Req.	Req.	Req.	Req.
Note Multifactorial Etiology	Opt.	Opt.	Opt.	Opt.	Opt.		Opt.	Opt.
Specify That Diet Must Have Certain Characteristics	Opt.-F (must be low in fat)	Opt.-F (must be low in fat)	Opt.-F (must be low in fat)	Opt.-F (must be low in saturated fat & cholesterol)			Opt.-F (must be low in fat)	
Specify That Foods Must Contain Particular Nutrients			Opt.-F (fiber containing grain products, fruits, & vegetables)	Opt.-F (fiber containing grain products, fruits, & vegetables)			Opt.-F (fruits and vegetables low in fat and are good source of vitamins A and C or fiber)	
List Populations at Risk						Opt.		
State that Exercise and Healthful Diet are Important						Opt.		
State When Intake Is Effective						Opt. (importance of adequate calcium throughout life)		Opt. (adequate intake during childbearing years)
State Limitation on Effect of High Level of Nutrient						Opt.		
State Safe Upper Limit								Opt.
State Prevalence of Disease								Opt.
Describe Diets Rich in the Nutrient								Opt.

NOTES:
Req.= Should be unconditionally required on front and back panels (same as current regulation)

Specific areas requiring additional information are enumerated below. General issues are described first; this is followed by a more specific accounting of the research needs for three of the authorized health claims. DHHS is conducting research on some aspects of consumers' response to health claim language. Appendix D provides information on that effort, including a summary of the lessons learned from the focus groups.

Research is needed on the following:

- Abbreviated Front-Panel Messages. Under the current regulations, manufacturers can provide the statement, "See [side/back] panel for information on the relationship between [nutrient] and [disease]."¹⁴² Currently, health claims must state the nature of the diet-disease relationship within the context of the entire claim. As noted above, the Dialogue Group agrees that the ability of health claim messages to attract the attention of consumers could be greatly enhanced if the claims could be provided in abbreviated form on the principal display panel. The most straightforward approach would be to require claims on the principal display panel to include a qualifying word (e.g., "may" or "might"), along with the relationship between the nutrient and disease and a referral statement indicating the location of the full claim.
- Multifactorial Etiology. Dialogue Group members suspect that most consumers have learned that most nutritionally related diseases are multifactorial in nature and that few would conclude that dietary modification is *all* that is necessary to reduce risk. There may be alternative ways to inform consumers of this principle. For example, including qualifying terminology such as "some cancers," "may reduce the risk of," or "help lower the chance of" may prove to be as effective as the currently required wording, which includes phrases such as "cancer, a disease associated with many factors" and "development of heart disease is caused by many factors."
- Reduction of Health Risk. Little is known about how best to communicate the concept of health risk reduction associated with eating a healthy diet. Consumers may not distinguish among terms such as "reduce the risk of," "mitigate," "avoid," "lessen the chances of," or "help prevent." Under the current regulations, the term "prevent" is not permitted in health claims because it is a component of the legal definition of a drug. In the scientific sense, "prevent" means reducing risks to zero or virtually zero, whereas "reduce the risk" means reducing the probabilities of the adverse event by some measurable amount. Consumers may be unaware of either the legal or the scientific definitions of these concepts, particularly when accompanied by a qualifier such as "may help," or the concepts of probability as they apply to health risk. It is possible that consumers regard "reduce the risk of" and "help prevent" as similar concepts. Additional information is needed to determine how best to communicate to consumers the degree of potential risk reduction associated with altering the diet in response to a health claim and how much flexibility can be allowed in the language without violating the principles.
- Risk Reduction Versus Treatment. The Dialogue Group agrees that phrases such as "helps fight cancer" may be powerful attention-getters. However, there is also concern

¹⁴² DHHS. FDA. Food Labeling; General Requirements, *supra* note 52.

that such phrases may cause consumers to erroneously conclude that dietary intervention could be used to *treat* an existing condition. Consumer testing is recommended to determine whether adjectives such as “fight” or phrases such as “low-fat foods are a powerful weapon against heart disease” can be used in health claims without implying that the dietary intervention will have a therapeutic effect.

- Individual Foods Versus Total Diet. Some Dialogue Group members believe that the effectiveness of health claims and the likelihood that they will be used by food companies would be increased if the claims were permitted to mention specific foods in the context of the total diet (e.g., “high-calcium foods like this one may reduce the risk of osteoporosis”). Although there is consensus that health claims should be placed in the context of the total diet, the most effective and efficient wording necessary to convey this concept to consumers is unknown.

It is possible that, in some cases, individual foods could be appropriately emphasized in health claims recommending positive action (e.g., folic acid-neural tube birth defects and calcium-osteoporosis) because consuming a variety of foods that are good or excellent sources of these nutrients would provide the beneficial effect. However, claims that recommend avoidance (e.g., fat, saturated fat, and cholesterol in relation to heart disease) must rely more heavily on references to total diet because all foods in the diet contribute to the total intake of the nutrient in question.

Even in claims recommending positive action, the Dialogue Group agrees that no health claim should convey the impression that any particular brand of a food is more effective than another in providing health benefits, unless the relationship is supported by significant scientific agreement. For example, Brand X vegetables should not be implied to be of more value in reducing the risk of some cancers than Brand Y of a comparable product.

- Calcium-Osteoporosis Health Claim Elements. Dialogue Group members agree that the following mandatory elements of the calcium-osteoporosis health claim should be evaluated through consumer testing to determine whether they can be made optional without compromising the integrity of the health claim.

- 1) Sex, race, and age must be stated as important factors. According to an NIH consensus conference, calcium consumption is most strongly correlated with bone density during the second and third decades of life.¹⁴³ Nevertheless, the recommendations derived from the conference emphasize the importance of adequate calcium intake for *all* members of the population, including men and postmenopausal women.

Some Dialogue Group members are concerned that inclusion of the currently required reference to “young adult white and Asian women” may create the false impression that adequate calcium intake is unimportant for the rest of the population. Preliminary data collected by DHHS indicate that this reference was not

¹⁴³ DHHS. NIH. NIH Consensus Statement, *supra* note 70.

understood and was actively disliked by many focus group participants, who questioned its validity and saw it as “undemocratic” (see Appendix D). In addition, inclusion of this information may dilute the claim’s primary message to eat more calcium-rich foods. It is recommended that the viability of making this information an optional component of the claim be evaluated by consumer research and scientific experts.

- 2) Exercise and a healthful diet must be stated as important factors. The NIH consensus conference also concluded that the beneficial effects of exercise on bone mass are probably *not* related to calcium intake. The available data have not demonstrated that exercise is necessary for the human body to utilize dietary calcium. Even sedentary individuals would benefit from increasing their calcium intake to optimal amounts.

Some Dialogue Group members are concerned that requiring claims to recommend exercise in addition to adequate calcium intake unnecessarily complicates the message. More importantly, such language could discourage sedentary individuals from attempting to increase their calcium intake on the basis of the erroneous conclusion that it would not be beneficial without regular physical activity.

- 3) Populations at risk must be listed. Some Dialogue Group members believe that identifying populations at particular risk for osteoporosis may imply that other groups need not be concerned with consuming adequate amounts of calcium. The NIH consensus conference concluded that virtually all segments of the U.S. population would benefit from increased calcium intake.
- 4) The importance of calcium throughout life must be stated. Although the goal of encouraging individuals to maintain adequate calcium intakes throughout life is laudable, some Dialogue Group members believe that mandating this element in the claim would be counterproductive. Such information may discourage older individuals who have not concerned themselves with calcium intake to disregard the message on the erroneous assumption that it is too late for them to benefit from additional calcium intake.
- 5) The health claim must state that there is no known benefit to consuming more than 200 percent of the daily value (2,000 milligrams) of calcium per day if the food bearing the claim contains more than 40 percent of the daily value of calcium. The body protects itself from excess calcium by decreasing the efficiency of absorption as dietary intake increases. Reported cases of calcium intoxication have been limited to medically compromised individuals consuming large amounts of supplemental calcium (generally as antacids). No cases of calcium toxicity have been reported among healthy individuals, even with supplemental calcium use. Additional evidence of the safety of dietary calcium is provided by the Masai in Africa, who remain in excellent health, even though they consume approximately 6,000 to 7,000 milligrams of calcium per day.¹⁴⁴

¹⁴⁴ Personal communication. Robert P. Heaney, Creighton University, Omaha, Nebraska.

The NIH consensus conference concluded that virtually all segments of the adult population in the United States would benefit from additional calcium intake. The discrepancies are most dramatic in individuals older than 65 years of age whose actual intakes are approximately one-half of the intakes recommended by NIH. The NIH consensus conference concluded that daily intakes of 2,000 milligrams of calcium are safe for most individuals and that calcium toxicity is most likely caused by the abuse of concentrated, nonfood sources of calcium such as antacids.

Some Dialogue Group members believe that requiring labels for foods that contain more than 40 percent of the daily value to provide information on a maximum effective dose of calcium is counterproductive. Such information may generate undue concern regarding the safety of calcium. In addition, this requirement provides a disincentive to provide health claim information on the labels of foods that contain the most concentrated sources of this important nutrient.

- Fruits and Vegetables-Cancer Health Claim Elements. Dialogue Group members agree that the following mandatory element of the fruits and vegetables-cancer health claim should be evaluated by consumer testing to determine if it can be made optional without compromising the integrity of the health claim.
 - 1) State that vegetables and fruits may contain vitamin A, vitamin C, or fiber. The current regulation requires health claims in this area to specify that the fruits and vegetables be accompanied by the claim “may contain vitamin A, vitamin C, and dietary fiber.” In addition, the claim must identify the content of these nutrients in the specific food bearing the claim (e.g., “Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.”). Some Dialogue Group participants believe that this information is unnecessary and significantly compromises the impact of the claim by making it lengthy and needlessly complex.

The substantial number of approximately 200 studies reviewed in 1992 found a protective correlation between fruits and vegetables intake and the incidence of cancer.¹⁴⁵ The studies included in that review reflected studies of a wide range of foods and were not limited to those containing vitamin A activity (from carotenoids), vitamin C, and/or fiber. Therefore, there is considerable evidence that a much broader array of fruits and vegetables provides beneficial effects and little evidence that pinpoints which components provide the benefits.

Some Dialogue Group members also believe that increased consumption of *any* low-fat fruit or vegetable would contribute to reducing the risk of certain cancers, and the currently required language for this claim may create the impression that only certain foods in this category are of value.

- Folic Acid-Neural Tube Birth Defect Health Claim Elements. Dialogue Group members agree that the following mandatory elements of the folic acid-neural tube birth defect health claim should be evaluated through a combination of consumer research and

¹⁴⁵ Block, G., et al. Fruit, Vegetable, and Cancer Prevention: A Review of the Epidemiological Evidence. *Nutrition and Cancer*, v. 18, 1992. pp. 1-29.

scientific evaluation to determine if they can be made optional without compromising the integrity of the health claim.

- 1) The prevalence of neural tube birth defects must be stated. Some participants believe that requiring such language as “such birth defects, while not widespread” will be counterproductive because consumers may conclude that dietary intervention is unnecessary.
- 2) The language “during childbearing years” must be included in the claim. Some Dialogue Group members believe that this information is unnecessary considering the nature of the claim. It seems obvious that a message concerning birth defects would apply only to women of childbearing age. Furthermore, there would be no risk to men or women of nonchildbearing age who increase their folic acid intake on the erroneous conclusion that it will help them prevent birth defects.
- 3) The health claim must state the safe upper limit if it is more than 25 percent of the daily value. Some Dialogue Group members believe that this information is unnecessary because excessive intakes of folic acid are unlikely to occur from foods, even if they contain more than 25 percent of the daily value. In addition, requiring this information may discourage use of the health claim on products that are the best sources of this nutrient. It may be appropriate to include this information on dietary supplements, which have a greater potential to contribute to excess folic acid intake.
- 4) The health claim must describe diets adequate in folic acid. The current proposed regulation requires that extensive information on the dietary sources of folic acid be provided in the claim. The folic acid claim is unique in this regard. The following is an example of the model health claim language in this area: “adequate amounts of folic acid may be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or from a supplement.” Some Dialogue Group members believe that requiring such language dilutes the message to consumers and provides a disincentive for food manufacturers to use it.

Again, the Dialogue Group believes that these required elements in the health claim language merit further evaluation and research to conclude affirmatively the elements that are necessary or that could be optional in crafting scientifically valid, nonmisleading, and compelling health claims on food labels.

Several studies suggest that consumers need more information about nutrition labeling in general to receive its full benefit.¹⁴⁶ In addition, qualitative research recently conducted by DHHS (see Appendix D) suggests that consumers are unaware that nutrient content and health claims are strictly regulated by the federal government. This research, if confirmed by more extensive study, strongly suggests that the credibility of such claims would be greatly enhanced if consumers were made aware of this fact. FDA should be the lead agency in this effort, but other public and private sector organizations should be encouraged to participate.

¹⁴⁶ Packwood Research Associates. The New “Nutrition Facts” Food Label: Is It Making a Difference? The Prevention Magazine/CNN Poll, Aug. 1994; Food Label Readers Are Checking for Fat. International News on Fats, Oils, and Related Materials (INFORM), v. 6, 1995. pp. 330-340.

RECOMMENDATION: The Dialogue Group recommends that resources be provided for a federal initiative designed to help consumers understand, trust, and use NLEA-regulated information. This initiative should give proper emphasis to the fact that nutrient content and health claims are strictly regulated and that they provide important information about the foods that bear them.

DIETARY GUIDANCE

Dietary guidance is the translation of knowledge about food and nutrient needs into advice for consumers. It includes recommendations and suggestions on dietary intakes of foods and nutrients, recommendations or suggestions about healthy eating patterns (e.g., food guides, dietary advice, and sample menus), and suggestions on how to purchase and prepare foods to achieve and/or maintain good nutrition. This section discusses the use of dietary guidance on labels and in labeling.

Sources of Dietary Guidance

The dietary guidance documents that form the U.S. government's national dietary policy are *Dietary Guidelines for Americans*, the *Food Guide Pyramid*, *Healthy People 2000*, the NAS report *Diet and Health*, the *Surgeon General's Report on Nutrition and Health*, and the U.S. Recommended Daily Allowances (RDAs).¹⁴⁷ The *Dietary Guidelines for Americans*, published by USDA and DHHS, provides recommendations based on current scientific knowledge about how dietary intake can help reduce the risk of major chronic diseases. To implement this provision of the law, USDA and DHHS established in 1993 internal review procedures and a Memorandum of Agreement to ensure that none of its agencies publishes dietary guidance without appropriate review by a Standing Committee consisting of individuals from both departments. The *Food Guide Pyramid*, prepared by USDA, is a pictorial representation of a daily food guide designed to meet the nutrient needs of healthy individuals. *Healthy People 2000*, from DHHS's Office of Disease Prevention and Health Promotion, presents national health promotion and disease prevention objectives that quantify targets for reduction of disease, enabling measurement of progress in meeting dietary goals for the population. The *Surgeon General's Report* and the NAS report *Diet and Health* provide scientific consensus on a number of dietary issues and sets of recommendations to the public consistent with those presented in other dietary guidance documents. The RDAs also play a supporting role in providing dietary guidance by helping to establish the number of servings per food group necessary to maintain good health.

Additional recommendations have come from government agencies, such as NCI, concerned with the nutritional factors related to specific diseases. Voluntary health associations, such as the American Heart Association, the American Cancer Society, and the American Diabetes Association, and professional associations, such as the American Dietetic Association, also provide dietary guidance. Finally, dietary guidance can also come from trade associations, such as the American Dairy Association and the American Meat Institute.

Dietary guidance can be disseminated via all of the communications vehicles discussed in this Report: food labels and labeling, advertising, and the media. Large-scale programs cospon-

¹⁴⁷ USDA and DHHS. *Dietary Guidelines*, *supra* note 67; USDA, *Food Guide Pyramid*, *supra* note 64; DHHS. PHS. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*. DHHS PHS Pub. No. 91-50212. Washington, DC, 1991. 692 pp.; NRC. *Diet and Health*, *supra* note 70; DHHS. PHS. *Surgeon General's Report*, *supra* note 1.

sored by public and private organizations often encourage the dissemination of dietary guidance through various combinations of these mechanisms. The creative use of dietary guidance in these circumstances has been encouraged for its potential to reach millions of consumers with motivating messages regarding healthy diets. Nevertheless, such programs face challenges in disseminating information and achieving the ultimate goal of achieving positive and sustained changes in behavior.

Using Dietary Guidance on Food Labels and in Labeling

An important opportunity exists for accomplishing nutrition education through food labels and labeling. Manufacturers are concerned, however, about using dietary guidance on labels. Specific concerns include the appropriateness of using the *Food Guide Pyramid* on the label of any food, even one that, for example, is high in fat. Does the *Pyramid* imply something about the nutritional value of the product on which it is featured that may work to the detriment of consumers attempting to achieve a healthy diet? How can a product that contains more than one food group be represented in a picture? Furthermore, what is the impact of embellishing or modifying the *Pyramid* in some way? Does graphic or artistic alteration of the *Pyramid* interfere with consumer understanding? Can the food group represented by a product be highlighted in some way without interfering with the basic nutrition messages of the *Pyramid*? Can the brand name of a product be included in the *Pyramid*? Would a *Pyramid* representation of an individual meal confuse consumers?

Questions also exist about the latitude manufacturers have in using the language of dietary guidance documents. *Dietary Guidelines for Americans* refers to “complex carbohydrates,” a term not currently required in FDA food labeling regulations. In citing the *Dietary Guidelines* on the issue of complex carbohydrates, would companies be in violation of labeling laws? Similarly, can information from *Dietary Guidelines* be presented on the label of a product that does not meet the definition for low fat? Is it permissible to talk about products that do not meet the definition for “healthy” in the context of a healthy diet? In addition, what is considered dietary guidance? Do the *Surgeon General’s Report*, National Cholesterol Education Program, or NCI guidelines qualify? Could using these guidelines on labels or in labeling or advertising be construed as a health claim?

To achieve the promise offered by the use of dietary guidance on food labels and in labeling, these types of concerns must be addressed so that manufacturers know the boundaries for using dietary guidance.

RECOMMENDATION: *The Dialogue Group recommends that a public-private partnership develop a user’s guide to assist and encourage the food industry in the creative use of dietary guidance tools (such as the Food Guide Pyramid) on food labels and in labeling and advertising.*