

with moderate amounts of total fat, but low in saturated fat and cholesterol, are less effective than their low-fat counterparts.

c. Review papers

Kushi *et.al.* (1999) reviewed the observational data on cereals, legumes and chronic disease reduction. The paper concluded, "Overall, there is substantial epidemiologic evidence that dietary fiber and whole grains are associated with decreased risk of coronary artery disease and some cancers, whereas the role of legumes in these diseases appears promising but as yet inconclusive."

A review of the plausible mechanisms for the protective effect of whole grains (Slavin *et.al.*, 1999) concluded, "Clearly, the range of protective substances in whole grains is impressive and advice to consume additional whole grains is justified. Further study is needed regarding the mechanisms behind this protection so that the most potent protective components of whole grains will be maintained when developing whole grains into acceptable food products for the public."

Anderson *et.al.* (2000) considered the data linking whole grains with CHD risk and concluded, " this meta-analysis of 12 population-based cohort studies indicated that those individuals with the highest intake of whole grains had an adjusted risk for CHD of 0.74 (95% CI, 0.67 to 0.80) compared to individuals with the lowest intake of whole grains. Whole grain intake has a stronger association with protection from CHD than intake of cereal fiber, vegetables or fruits. These studies suggest that the intake of three servings of whole grains per day may have an important cardioprotective effect."

Slavin *et.al.* (2001) summarized the data on whole grain intake and disease prevention as well as factors related to the low intake of whole grains in the U.S. The authors concluded that whole grains are a valuable source of nutrients lacking in the U.S. diet (e.g. dietary fiber, B vitamins, vitamin E, selenium, zinc,

copper, magnesium) as well as phytochemicals, which may reduce the risk of chronic disease. The authors suggest that the 2000 revision of the Dietary Guidelines for Americans and the FDA-authorized health claim for whole grains may help increase consumption.

Three papers (Liu and Manson, 2001; Liu, 2002; Liu and Willett, 2002) reviewed the association between whole grain foods and type 2 diabetes and CHD from a glycemic index perspective. These papers hypothesize that high glycemic index foods contribute to the “metabolic syndrome” characterized by insulin resistance, hyperinsulinemia, dyslipidemia, hypertension and impaired fibrinolysis. The authors note that additional information is needed to understand this possible relationship, but conclude, “Until more definitive data are available, replacing refined grain products and potatoes with minimally processed plant-based foods such as whole grains, fruits, and vegetables, and reducing the intake of high glycemic load beverages may offer a simple strategy for reducing the incidence of coronary heart disease.”

The relationship between cereal grains and CHD was the subject of a comprehensive review of the literature by Truswell (2002). This review drew the following conclusions:

- Total cereal consumption is not clearly linked to CHD in studies conducted throughout the world
- Oatmeal and oat bran have been convincingly shown to cause modest reductions in total- and LDL-C, but studies with purified fibers have been inconsistent
- Observational data associating the consumption of whole grain products with reduced incidence of CHD is consistent and suggests other factors besides cholesterol-lowering are involved
- Fortification of cereal foods with folic acid may be contributing to their cardio-protective affects

Kris-Etherton *et.al.* (2002) published a review of food-based approaches and dietary patterns designed to reduce the risk of CHD. This paper discussed how

the Dietary Approaches to Stop Hypertension Study, the Lyon Diet Heart Study and other intervention studies have prompted recommendations for the inclusion (rather than exclusion) of foods in the diet. Examples of cardioprotective foods include whole grains, fish, fruits and vegetables and low-fat dairy products and nuts. The authors conclude, “We are transiting an era in which recommendations are being shaped by an inclusionary philosophy (i.e. what foods should be featured in a heart healthy diet). Advances in nutrition research have identified a growing list of foods that confer beneficial effects on heart health. It is evident that an emerging issue that must be resolved is how these foods may be included in a diet that confers the optimal dietary pattern for CHD risk reduction, and does so in a way that promotes a healthy body weight (i.e. does not exceed energy requirements).”

Jones *et.al.* (2002) concluded that the weight of scientific evidence demonstrates that whole grains have beneficial effects on heart disease, diabetes and cancer. Nevertheless, consumption of fiber and whole grain foods in the U.S. is well below recommended amounts, and the author suggests a “call to action” to help Americans increase consumption. The following strategies were suggested to help promote the health benefits of whole grains:

- Maintain whole grains at the base of the Food Guide Pyramid
- Encourage and support whole grain research
- Pursue policy support and funding for whole grains research
- Reach consumers through health professionals and other vehicles
- Develop child-targeted education campaigns
- Encourage the whole grain industry to take action

Hu and Willett (2002) reviewed 147 scientific publications pertaining to diet and CHD including original investigations and reviews of metabolic studies, epidemiologic studies and dietary intervention trials. A synthesis of these data led to the following conclusion, “Substantial evidence indicates that diets using nonhydrogenated unsaturated fats as the predominant form of dietary fat, whole

grains as the main form of carbohydrates, an abundance of fruits and vegetables, and adequate omega-3 fatty acids can offer significant protection against CHD.”

B. Summary of Literature

Forty studies with original data on the effect of whole grain foods or dietary fiber (a marker for whole grains) on the risk or incidence of CHD have been identified. These studies include those cited in *Diet and Health* as well as more recent publications. Thirty-four of these studies provide direct or suggestive support for the notion that whole grain foods are cardioprotective. Only six studies failed to provide direct evidence of this effect – primarily due to design limitations or use of non-healthy populations. Taken together, these studies continue to provide compelling evidence that whole grain foods can reduce the risk of CHD. Furthermore, this comprehensive body of literature provides evidence that the total fat content of fiber or whole-grain containing diets is unrelated to CHD, and provides no persuasive evidence that whole grain diets that are low in saturated fat and cholesterol, but not necessarily low in total fat, are any less effective in reducing the risk of CHD than their low-fat counterparts.

Slightly more than half of these studies are observational in nature.

Observational studies are capable of identifying *associations* between dietary components (e.g. fat) and health outcomes such as CHD, but they are *not* capable of proving a cause and effect relationship. Therefore, by definition, these studies cannot provide conclusive evidence on a possible interaction between dietary fat and whole grains on the risk of CHD. Despite this *a priori* limitation, an analysis of the available observational studies with respect to this question was conducted (see Table 3).

Table 3

Analysis of observational studies with respect to evidence concerning dietary fat and the cardioprotective properties of whole grain and fiber-containing foods

Study finding	Study with whole grain data		Study with dietary fiber data only	
	Number of studies	Reference	Number of studies	Reference
Total fat intake with no apparent association with CHD risk			2	Khaw <i>et.al.</i> (1987) Morris <i>et. al.</i> (1977)
Protective effect remains after adjustment for type of fat	1	Liu <i>et.al.</i> (1999)		
No effect of whole grain/fiber regardless of total dietary fat	2	Gramenzi <i>et.al.</i> (1990) Jacobs <i>et.al.</i> (2000)	2	Kromhout et al (1982) Kushi et al (1985)
Insufficient data to assess (e.g. study provided no data on total dietary fat intake)	8	Burr & Sweetnam (82) Fraser <i>et.al.</i> (1992) Jacobs <i>et.al.</i> (1998) Liu <i>et.al.</i> (2000) McKeown <i>et.al.</i> (2002) Liu <i>et.al.</i> (2003) Hu et al (2000) Michels et al (2002)	4	Liu <i>et.al.</i> (1982) Kromhout <i>et.al.</i> (1984) Rimm <i>et.al.</i> (1996) Pietinen et al (1990) Morris <i>et.al.</i> (1977)
Protective effect no longer significant after adjustment for total fat, but multiple adjustments made simultaneously	2	He <i>et.al.</i> (1995) Jacobs <i>et.al.</i> (1999)	1	Liu <i>et.al.</i> (2002)

Analysis of the observational studies summarized in Table 3 shows that there is no evidence that consumption of moderate-fat whole grain food containing diets, low in saturated fat and cholesterol, would be less cardioprotective than their low-fat counterparts. One study found that total dietary fat was not associated with CHD risk thus providing evidence that the fat content of fiber or whole grain food-containing diets does not alter their cardioprotective properties.

One study found that an inverse association between whole grain foods and CHD remained statistically significant after the data were corrected for total fat intake. This observation essentially means that whole grains were protective at all levels of dietary fat studied, and supports the notion that moderate-fat whole grain diets would be beneficial.

Four studies did not find a direct association between whole grain foods and CHD so that the question of dietary fat becomes moot. Thirteen studies did not provide information on dietary fat or use it to statistically adjust their data. It is not possible, therefore, to assess the impact of fat on the results.⁶ Finally, three studies found that correction of the data for dietary fat as well as multiple confounding factors attenuated the protective association found with the uncorrected data. One of these studies examined dietary fiber and not whole grains (Liu *et.al.*, 2002). The other two studies (He *et.al.*, 1995; Jacobs *et.al.*, 1999) pertained to whole grain foods, but adjusted the data for numerous variables simultaneously so that it is not possible to determine whether total fat or one of the other variables (e.g., saturated fat) was responsible for eliminating the statistical significance of the association.

Dietary intervention studies *do* have the capability to demonstrate a cause and effect relationship between a dietary component and a disease outcome or risk factors. An analysis of dietary intervention studies involving fiber or whole-grain containing diets and moderate levels of fat content does not lessen their cardioprotective properties, and there is no compelling evidence to show that it does.

⁶ The fact that total dietary fat was not used to statistically adjust the data in these studies may be due to the fact that it is not regarded as a CHD risk factor other than as a potential carrier of saturated fat (see Part VIII).

Table 4

Analysis of dietary intervention studies with respect to evidence concerning dietary fat and the cardioprotective properties of whole grain and fiber-containing foods.

Study finding	Study with whole grain data		Study with dietary fiber data only	
	Number of studies	Reference	Number of studies	Reference
No effect regardless of dietary total fat intake			1	Judd and Truswell (1981)
Total fat similar in experimental and control diets	6	Fraser <i>et.al.</i> (1981) Anderson <i>et.al.</i> (1986) Van Horn <i>et.al.</i> (1986) Davidson <i>et.al.</i> (1991) Johnston <i>et.al.</i> (1998) Jang <i>et.al.</i> (2001)	2	Grande <i>et.al.</i> (1965) Karlstrom <i>et.al.</i> (1984)
Insufficient data to assess (e.g. study provided no data on dietary fat intake)	3	De Groot <i>et.al.</i> (1963) Van Horn <i>et.al.</i> (1988) Jacobs <i>et.al.</i> (2002)	2	Challen <i>et.al.</i> (1983) Burr <i>et.al.</i> (1989)
Multiple dietary differences make it impossible to assess the impact of dietary fat	4	Van Horn <i>et.al.</i> (1991) Keys et al (1960) Schweizer et al (1983) Kay et al (1985)		

Eight studies used diets with the same fat content for all interventions. Total dietary fat is not a variable in such studies so they cannot be used to assess its potential interaction with the cardioprotective properties of whole grain foods. Five studies did not provide information on the fat content of their diets, and four studies had small but statistically significant differences in multiple dietary components between the control and experimental diets so that it is not possible to assess the impact of dietary fat *per se*.

In conclusion, as noted above, the available literature supports a conclusion that the total fat content of fiber or whole grain food-containing diets is unrelated to CHD, and provides no evidence that diets low in saturated fat and cholesterol, but not necessarily low in total fat, are any less effective in reducing the risk of CHD than their low-fat counterparts.

VIII. ADDITIONAL EVIDENCE IN SUPPORT OF THE CLAIM

As discussed previously, the proposed claim and eligibility criteria are based upon, and consistent with, the major findings presented in *Diet and Health*. The proposed claim and eligibility criteria are also consistent with the underlying studies that provided the basis for the whole grains statement made in *Diet and Health*. Since publication of *Diet and Health*, numerous recommendations and other evidence concerning whole grains, saturated fat, cholesterol, and total fat have emerged. These recommendations and related evidence confirm that (1) continued emphasis should be placed on diets low in saturated fat and cholesterol, and (2) whole grains continue to be a public health priority.

A. Recommendations regarding fat intake

Diet and Health reflected significant scientific agreement that total fat intake may influence CHD risk to the extent that it influenced saturated fat intake. According to the FNB, “[intake of total fat *per se*, independent of the relative content of the different types of fatty acids, is not associated with high blood cholesterol levels and coronary heart disease.” (*Diet and Health*, at 7). Since the FNB issued this finding, additional support for this conclusion has steadily amassed, resulting in significant shifts in dietary recommendations and policy.⁷ These shifts are reflected in current nutrition science, nutrition public policy, and regulatory precedent.

⁷ These shifts have resulted in a moderation of recommendations concerning the percent of energy that should be obtained from fat. At the time of *Diet and Health*, it was suggested that no more than 30% of calories should be obtained from fat; under current recommendations, low-saturated fat diets with moderate amounts of total fat (up to 35% of total energy) are recognized as healthful and appropriate. The recognition that moderate fat diets may be appropriate does not affect the principles outlined in *Diet and Health* regarding whole grains, saturated fat, and cholesterol, but it does further support the proposition that foods containing moderate amounts of fat may be included as part of a healthy diet.

1. Current nutrition science

Serum total cholesterol (T-C) and low-density lipoprotein cholesterol (LDL-C) are well-accepted biomarkers for predicting the risk of CHD. Many of today's dietary recommendations are based on lowering the concentration of these factors in the population. The effect of diet on CHD biomarkers has been studied for many years. Keys (1984) and Hegsted (1986) analyzed data from dietary interventions studies and developed equations that can be used to predict the effect of dietary fats on T-C. These equations reflect the evidence showing that dietary saturated fatty acids (and to a lesser extent cholesterol) increase the concentration of T-C while unsaturated fatty acids (especially polyunsaturated fatty acids) lower it. Total fat would not be expected to influence T-C based on these equations. Epidemiologic studies have repeatedly shown that saturated fat, but not total fat, is associated with reduced incidence of CHD in humans, and numerous clinical trials have confirmed these observations (Hu *et. al.* 2000).

2. Nutrition public policy

Public health authorities have long recommended a low-fat, high carbohydrate diet as a means to reduce the risk of CHD. Such recommendations were made explicitly in the fourth edition of the Dietary Guidelines for Americans (U.S. Department of Agriculture, U.S. Department of Health and Human Services, 1995), which stated, "Choose a diet low in fat, saturated fat, and cholesterol." Similar recommendations were a cornerstone of the second report of the National Cholesterol Education Program (1994).

Evolving science regarding the role of saturated fat versus total fat on the risk of CHD has caused these (and other) public health recommendations to be updated. Current policy statements from governmental and quasi-governmental authorities universally recognize the appropriateness of low-saturated fat diets with

moderate amounts of total fat (i.e. up to 35% of total energy) as alternatives to low-fat, high-carbohydrate diets for the management of CHD.

a. The Dietary Guidelines for Americans

The Dietary Guidelines for Americans represent official nutrition policy of the U.S. government, and guide all federal activities relating to human nutrition. A significant shift in policy regarding total fat occurred in the latest edition of the Guidelines (U.S. Department of Agriculture and the U.S. Department of Health and Human Services, 2000). Americans are now advised to “Choose a diet that is low in saturated fat and cholesterol and *moderate* (emphasis added) in total fat,” rather than the low-fat diet that was previously recommended.

b. The National Institutes of Health

The National Heart Lung & Blood Institute (NHLBI) has also concluded that total fat is not related to CHD risk. Recently updated recommendations to health professionals from this organization were published in a report entitled “Adult Treatment Panel III” (ATP III) (National Cholesterol Education Program, 2001). This report states,

Among the fatty acids that make up the total fat in the diet, only saturated fatty acids and *trans* fatty acids raise LDL cholesterol levels. Thus, serum levels of LDL cholesterol are independent of intakes of total fat *per se*. ATP II (National Cholesterol Education Program 1993, 1994) advised limiting total fat in Step I and Step II (TLC) diet to ≤ 30 percent of calories primarily as a means of achieving lower intakes of saturated fatty acids. The focus of the dietary approach to reducing CHD risk then and now is on dietary fatty acids that raise LDL cholesterol concentrations.

The report also makes the following recommendation:

Recommendation: *It is not necessary to restrict total fat intake for the express purpose of reducing LDL cholesterol levels, provided saturated fatty acids are reduced to goal levels.*

This conclusion is reflected in new dietary recommendations from this group, which increase the upper range of acceptable fat intake from 30 to 35 percent of total calories. These guidelines also reduced recommendations for dietary saturated fat from ten to seven percent of energy consumed.

c. The National Academy of Sciences/Food and Nutrition Board

NHLBI's conclusions are consistent with those provided in the recent "Macronutrient" report from the Institute of Medicine of the National Academy of Sciences (Food and Nutrition Board, 2002). This report concludes that total fat, *per se*, is not associated with the incidence of CHD, but that diets with more than 35% energy from fat tend to provide excessive amounts of saturated fatty acids:

Conclusions. A few case-control studies have shown an association between total fat intake and risk for CHD. However, a detailed evaluation of these studies shows that it is not possible to separate total fat intake from saturated fatty acid intake, which is known to raise LDL cholesterol concentrations. Unsaturated fatty acids, which do not raise LDL cholesterol concentrations compared to carbohydrate, have not been implicated in risk for CHD through adverse effects on lipids or other risk factors. Nonetheless, practical efforts to create "heart-healthy" menus reveal that intakes of total fat exceeding 35 percent of total energy result in unacceptably high intakes of saturated fatty acids. Moreover, there is the possibility that higher fat intakes may enhance a prothrombotic state, although the evidence to support this mechanism for enhancing CHD risk is not strong enough alone to make solid recommendations.

The Macronutrient Report established recommendations, in the form of an “Acceptable Macronutrient Distribution Range” (AMDR), for total fat for adults of 20 to 35 percent of energy. The upper range of the AMDR was intended to accommodate diets low in saturated fat, but moderate in total fat (predominantly from unsaturated fatty acids) which have been shown to have a beneficial affect on CHD.

These recommendations provide a compelling scientific basis for authorizing use of an appropriate whole grain health claim for foods that are low in saturated fat and cholesterol, but that do not necessarily meet the technical definition of “low fat” as defined by FDA.

3. Regulatory precedent

The shift in U.S. nutrition policy toward moderate fat diets is reflected in several recent rulemakings for CHD-related health claims. For example, the agency concluded that spreads and salad dressings should not be required to comply with the total fat disqualifier level in order to qualify for the sterol/stanol ester and CHD health claim (65 Fed. Reg. 54686, 54709 (Sept. 8, 2000)). In doing so, FDA observed:

Although diets high in saturated fat and cholesterol are implicated in CHD, current scientific evidence does not indicate that diets high in unsaturated fat are associated with CHD (Refs. 103 and 108). Furthermore, the 2000 Dietary Guidelines Advisory Committee concluded that the scientific evidence on dietary fat and health supports assigning first priority to reducing saturated fat and cholesterol intake, not total fat intake (Ref 108). In fact, the new guideline for fat intake in the Dietary Guidelines for Americans, 2000 (Ref 103) states, “Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.”

FDA recently extended this approach to a proposal to expand the interim health claim concerning sterol and stanol esters and CHD to cover vegetable oils for

home use. In a February 14, 2003 letter, FDA expressed its intent to allow, pending publication of a final rule, the stanol/sterol health claim to appear on vegetable oils for home use, even though such oils exceed the total fat disqualifier level (Letter from C. L. Taylor, Ph.D., to F. L. Shinnick, Ph.D.). FDA stated that it would consider the exercise of enforcement discretion with respect to vegetable oils that bear the health claim so long as the labels contained a disclosure statement that complies with 21 C.F.R. § 101.13(h).

Similarly, in identifying the foods that qualify for a health claim concerning soy protein and CHD, the agency recognized the health benefits of foods made from whole soybeans and that contain no added fat (64 Fed. Reg. 67700, 67717 (Oct. 26, 1999)). The agency allowed such foods to bear the CHD health claim even though they may not meet the technical regulatory definition for “low fat” foods. FDA reasoned that the amount by which these foods would exceed the “low fat” criterion was small. The agency also characterized such foods as useful sources of soy protein that could appropriately be included in a low fat diet.

These regulatory decisions provide a clear precedent for this proposal to use an appropriate whole grain health claim for foods that are low in saturated fat and cholesterol, but not necessarily “low” in total fat as that term has been defined by FDA.

B. Whole grains as a public health priority

1. Recommendations for whole grain intake

The scientific information documenting the health benefits of whole grains has prompted public health officials, professional organizations and academic experts to place increased emphasis on recommendations intended to increase the consumption of these foods. Recommendations for consumption of whole grain foods are included in the Dietary Guidelines for Americans, the Food Guide Pyramid for Young Children, and Healthy People 2010, as well as guidelines of

the American Cancer Society, American Diabetes Association, American Dietetic Association, and American Heart Association.

a. The Dietary Guidelines for Americans

The nutritional benefits of whole grains prompted the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (USDHHS) to modify the “Dietary Guidelines for Americans” to include a guideline specifically devoted to grains (including whole grains) for the first time in 2000 (USDA/USDHHS, 2000). The 1995 guideline, “Choose a diet with plenty of grain products, vegetables and fruits” was divided into separate guidelines for fruits and vegetables and another for grains. The new guideline for grains states, “Choose a variety of grains daily, especially whole grains.” The text of the Dietary Guidelines advises Americans to consume “several servings of whole grain foods” daily to help protect against “many chronic diseases”.

b. The Food Guide Pyramid for Young Children

The Food Guide Pyramid for Young Children 2 to 6 Years Old was released by USDA in 1999. The purpose of this educational tool is to communicate the same general messages as the adult Food Guide Pyramid using foods and servings sizes more appropriate for young children. Whole grains are prominently pictured on the Pyramid graphic, and the accompanying text includes the following recommendation, “Offer whole or mixed grain products for at least three of the six grain group choices the Pyramid recommends each day.”⁸

⁸ The Food Guide Pyramid for adults booklet (USDA, 1996) also specifically advises Americans to consume whole grains. This booklet states, “To get the fiber you need, choose several servings a day of foods made from whole grains, such as whole wheat bread and whole grain cereals.” USDA has announced that it is likely to revise the Food Guide Pyramid shortly after revision of the Dietary Guidelines for Americans in 2005, and it is likely that whole grains will be given greater prominence.

c. **Healthy People 2010**

The purpose of the “Healthy People” publications (U.S. Department of Health and Human Services, 1990, 2000) is to define a national strategy for significantly improving the health of the nation. The first publication (Healthy People 2000) did not specifically address whole grain intake, but included the following broad objective:

Objective 2.6 and 16.8

Increase complex carbohydrate and fiber-containing foods in the diets of adults to 5 or more daily servings for vegetables (including legumes) and fruits, and to 6 or more daily servings for grain products. (Baseline: 2 ½ servings of fruits and vegetables and 3 servings of grain products for women aged 19 through 50 in 1985)

This objective was revised in Healthy People 2010 to reflect a greater understanding of the relationship between whole grain consumption and public health as reflected in the 2000 Dietary Guidelines for Americans.

Objective 19-7

Increase the proportion of persons aged 2 years and older who consume at least six daily servings of grain products, with at least three being whole grains.

Target: 50 percent

Baseline: 7 percent of persons aged 2 years and older consumed at least six daily servings of grain products, with at least three being whole grains in 1994-96 (age adjusted to the year 2000 standard population).

d. The American Cancer Society

Guidelines for the prevention and early detection of cancer from the American Cancer Society (2002) recommend whole grains:

Choose whole grains in preference to processed (refined) grains and sugars. Choose whole grain rice, bread, pastas and cereals.

e. The American Diabetes Association

The American Diabetes Association's (2003) most current recommendations for the treatment and prevention of diabetes emphasize the importance of whole grains in the diet of all Americans:

As for the general population, people with diabetes are encouraged to choose a variety of fiber-containing foods, such as whole grains, fruits and vegetables, because they provide vitamins, minerals, fiber, and other substances important for good health.

f. The American Dietetic Association

The American Dietetic Association (2002) recently emphasized the importance of whole grain foods in its position statement on dietary fiber:

There is substantial scientific evidence suggesting that vegetables, fruits and whole grains reduce risk of chronic diseases, including cancer and heart disease. Additionally, recent studies suggest that whole foods offer more protection against chronic diseases than dietary fiber, antioxidants, or other biologically active components in foods.

g. The American Heart Association

Revised dietary guidelines from the American Heart Association (Krauss *et.al.*, 2000) specifically recommend frequent consumption of whole grain foods:

Consume a variety of grain products, including whole grains; choose 6 or more servings per day.

Grain products provide complex carbohydrates, vitamins, minerals, and fiber. Dietary patterns high in grain products and fiber have been associated with decreased risk of cardiovascular disease.

In summary, whole grains have been given increasingly greater prominence in guidelines and recommendations from public health authorities. This higher priority reflects an increased understanding of the ability of whole grains to reduced risk of chronic diseases, coupled with a lack of understanding of these benefits by many Americans.

2. Inadequate whole grain consumption in the United States

Despite the considerable evidence that regular consumption of whole grains can reduce the risk of CHD and other chronic diseases, most Americans appear unaware of these benefits and the intake of whole grain products remains well below current dietary recommendations (Jones *et.al.*, 2002). An analysis of data from the 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) found that average consumption of whole grains among U.S. adults was only one serving per day, and only eight percent of this group met the current recommendation to eat at least three servings per day (Cleveland *et.al.*, 2000).

Whole grain consumption also differs by demographic group. Kantor *et.al.* (2001) reported that the mean number of servings of whole grains eaten per day tends to be higher among U.S. Caucasians (1.1) compared to non-Native

American minorities (0.7). In addition, whole grain intake was associated with education level (1.2 servings/d for people with post-high school education vs. 0.8 for those who did not finish high school) and household income (0.8 vs. 1.2 servings/d for people with incomes <130% of the poverty level compared to those with >350%, respectively). Cleveland *et.al.* (2000) found that health conscious consumers (e.g. exercisers, non-smokers, vitamin and/or mineral supplement users and non-overweight individuals) tended to eat more servings of whole grains than their less health conscious counterparts. These findings suggest that a significant portion of the population stands to benefit from increased consumption of whole grain foods.

3. Barriers to whole grain consumption

The most frequently cited barriers to increased consumption of whole grain foods by U.S. consumers are low awareness of their benefits, inability to identify such foods in the marketplace and unwillingness to sacrifice good taste (Adams and Engstrom, 2000; Kantor *et.al.*, 2001). Nevertheless, consumers are receptive to messages about nutrition and health. A recent survey (IFIC, 2002) found that 93% of Americans believe that some foods have health benefits beyond basic nutrition (i.e. vitamins and minerals), and 85% are interested in learning more about such foods. These results suggest that consumers may respond to compelling messages about whole grains that address the existing barriers to increased consumption. Increased consumer and health professional education and increased availability of better-tasting products have been identified as strategies to increase the consumption of whole grain foods (Adams and Engstrom, 2000). Kantor *et.al.* (2001) concluded that the FDA-sanctioned health claims have the potential to address all three of these strategies.

Taste is considerably influenced by fat, a major contributor to the palatability of many foods, including whole grains. In addition to bringing out the flavor of such products, fat contributes significantly to their texture and mouth feel and results in improved consumer acceptability.

Fat is especially important in processing crackers and other baked products with significant whole grain content:

- Fat is needed to process and sheet the dough
- Low fat, whole grain dough will not flow and become dry and crumbly
- The fiber in whole grain has binding properties for both water and fat
- Adding more water does not aid in processing because the dough becomes very sticky and the increased bake time to eliminate the additional water leads to a very dry hard texture that is unacceptable to consumers

Use of a whole grains health claim on popular products that contain moderate amounts of fat, such as nut-containing cereals, Triscuit™ brand whole grain crackers, and other whole grain foods would expose more consumers to the benefits of whole grains. It also would call attention to additional dietary sources of whole grains that may previously have been unrecognized.

In summary, consumption of a diet rich in whole grains is widely recommended, but intake of whole grain foods in the United States continues to fall below recommended levels. Exposure of consumers to a variety of whole grain foods, including foods that may currently be unrecognized as containing whole grains, is one strategy for furthering public health goals concerning diets rich in whole grains.

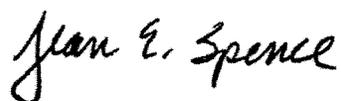
IX. SUMMARY AND CONCLUSIONS

In summary, the greatest possible benefit for all stakeholders is made possible by a health claim that focuses on the relationship between CHD and diets rich in whole grains but low in saturated fat and cholesterol. Such a claim reflects not

only *Diet and Health*, but also the latest nutrition science confirming that saturated fat intake (and to a lesser extent cholesterol) is related to CHD risk factors, but that dietary total fat, *per se*, is not. It is also consistent with government nutrition policy concerning such science, mirrors statements from scientific and professional organizations, follows precedent established by FDA for other CHD-related health claims, and would have a minimal effect on total dietary fat intake.

Furthermore, use of the claim on products that are low in saturated fat and cholesterol, but not necessarily low in total fat, will provide food manufacturers with greater opportunities to increase whole grain consumption. Use of the claim on a wider range of products will help educate consumers about the benefits of whole grains, and availability of the claim for slightly higher fat products will provide industry with the opportunity and additional incentives to develop new and better tasting whole grain foods.

Respectfully submitted,

A handwritten signature in black ink that reads "Jean E. Spence". The signature is written in a cursive, flowing style.

Jean E. Spence
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X. LITERATURE CITATIONS

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APPENDIX – B

Whole Grain Foods Authoritative Statement Claim Notification 1999

APPENDIX – C

Survey of whole grain and non-whole grain products

Market Survey of Grain Products*
Whole Grain Cereals
30 g RACC

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Cheerios	Gen Mills	30	30	2	2.0
Multi-Grain Cheerios Plus	Gen Mills	30	30	1	1.0
Wheaties	Gen Mills	30	30	1	1.0
Whole Grain Total	Gen Mills	30	30	1	1.0
Complete Wheat Bran Flakes	Kellogg	30	29	0.5	0.5
Cinnamon Life	Quaker	30	32	1	0.9
Life	Quaker	30	32	1.5	1.4
Post Grape Nuts Flakes	Kraft	30	29	1	1.0
Average					1.1
Range					0.5- 2.0

*Products meet the existing criteria for the whole grain health claim with the possible exception of "low fat"

*Survey determined whole grain status based on whole grain flour being primary ingredient and fiber content

Market Survey of Grain Products
Other Cereals
30 g RACC

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Apple Cinnamon Cheerios	Gen Mills	30	30	1.5	1.5
Berry Berry Kix	Gen Mills	30	30	1.5	1.5
Boo Berry	Gen Mills	30	30	1	1.0
Cinnamon Grahams	Gen Mills	30	30	1	1.0
Cinnamon Toast Crunch	Gen Mills	30	30	3.5	3.5
Cocoa Puffs	Gen Mills	30	30	1	1.0
Cookie Crisp	Gen Mills	30	30	1	1.0
Corn Chex	Gen Mills	30	30	1	1.0
Count Chocula	Gen Mills	30	30	1	1.0
Country Corn Flakes	Gen Mills	30	30	0	0.0
Fiber One	Gen Mills	30	30	1	1.0
Franken Berry	Gen Mills	30	30	1	1.0
French Toast Crunch	Gen Mills	30	30	1	1.0
Frosted Cheerios	Gen Mills	30	30	1	1.0
Frosted Wheaties	Gen Mills	30	30	0	0.0
Golden Grahams	Gen Mills	30	30	1	1.0
Honey Nut Cheerios	Gen Mills	30	30	1.5	1.5
Honey Nut Chex	Gen Mills	30	30	0.5	0.5
Kaboom	Gen Mills	30	30	1	1.0
Kix	Gen Mills	30	30	0.5	0.5
Lucky Charms	Gen Mills	30	30	0.5	0.5
Reese's Peanut Butter Puffs	Gen Mills	30	30	3	3.0
Rice Chex	Gen Mills	30	31	0	0.0
Team Cheerios	Gen Mills	30	30	1	1.0
Total Corn Flakes	Gen Mills	30	30	0	0.0
Trix	Gen Mills	30	30	1	1.0
All-Bran	Kellogg	30	31	1	1.0
All-Bran Buds	Kellogg	30	30	0.5	0.5
All-Bran with Extra Fiber	Kellogg	30	26	1	1.2
Apple Jacks	Kellogg	30	33	0	0.0
Cocoa Frosted Flakes	Kellogg	30	31	0	0.0
Cocoa Krispies	Kellogg	30	31	1	1.0
Complete Oat Bran Flakes	Kellogg	30	30	1	1.0
Corn Flakes	Kellogg	30	28	0	0.0
Corn Pops	Kellogg	30	31	0	0.0

Market Survey of Grain Products

Other Cereals

30 g RACC

Crispix	Kellogg	30	29	0	0.0
Froot Loops	Kellogg	30	32	1	0.9
Frosted Flakes	Kellogg	30	31	0	0.0
Honey Crunch Corn Flakes	Kellogg	30	30	1	1.0
Marshmallow Blasted Froot Loops	Kellogg	30	30	0.5	0.5
Product 19	Kellogg	30	30	0	0.0
Razzle Dazzle Rice Krispies	Kellogg	30	28	0	0.0
Rice Krispies	Kellogg	30	33	0	0.0
Rice Krispies Treats Cereal	Kellogg	30	30	1.5	1.5
Smacks	Kellogg	30	27	0.5	0.6
Special K	Kellogg	30	31	0	0.0
Post 100% Bran	Kraft	30	29	0.5	0.5
Post Cocoa Pebbles	Kraft	30	29	1	1.0
Post Fruity Pebbles	Kraft	30	27	1	1.1
Post Golden Crisp	Kraft	30	27	0	0.0
Post Honey Bunches Of Oats Honey-Roasted	Kraft	30	30	1.5	1.5
Post Honey Bunches Of Oats with Almonds	Kraft	30	31	2.5	2.4
Post Honey Comb	Kraft	30	29	0.5	0.5
Post Marshmallow Alpha Bits	Kraft	30	29	1	1.0
Post Oreo O's	Kraft	30	27	2.5	2.8
Post Premium Bran Flakes	Kraft	30	30	0.5	0.5
Post Toasties Corn Flakes	Kraft	30	28	0	0.0
Post Waffle Crisp	Kraft	30	30	2.5	2.5
Apple Zaps (bagged)	Quaker	30	30	1	1.0
Cap'n Crunch	Quaker	30	27	1.5	1.7
Cap'n Crunch Crunch Berries	Quaker	30	26	1.5	1.7
Cap'n Crunch's OOPS! All Berries	Quaker	30	32	1.5	1.4
Cap'n Crunch's Peanut Butter Crunch	Quaker	30	27	2.5	2.8
Cinnamon Crunch (bagged)	Quaker	30	30	2	2.0
Cocoa Blasts (bagged)	Quaker	30	33	1	0.9
Crunchy Corn Bran	Quaker	30	27	1	1.1
Frosted Flakers	Quaker	30	31	0	0.0
Frosted Oats (bagged)	Quaker	30	28	1.5	1.6
Fruitangy Ohs (bagged)	Quaker	30	31	0	0.0
Honey Crisp Corn Flakes (bagged)	Quaker	30	31	0	0.0
Honey Graham Oh's	Quaker	30	27	2	2.2
Honey Grahams (bagged)	Quaker	30	28	1.5	1.6

Market Survey of Grain Products
Other Cereals
30 g RACC

Honey Nut Oats (bagged)	Quaker	30	28	1	1.1
King Vitaman	Quaker	30	31	1	1.0
Marshmallow Safari (bagged)	Quaker	30	30	1.5	1.5
Sweet Crunch (bagged)	Quaker	30	27	1.5	1.7
Sweet Puffs (bagged)	Quaker	30	34	1	0.9
Toasted Oats (bagged)	Quaker	30	30	1.5	1.5
Average					1.0
Range					0 - 3.5

Market Survey of Grain Products*
Whole Grain Cereals
55 g RACC

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Oatmeal Crisp Almond	Gen Mills	55	55	4.5	4.5
Oatmeal Crisp Apple Cinnamon	Gen Mills	55	55	2	2.0
Oatmeal Crisp Raisin	Gen Mills	55	55	2	2.0
Wheat Chex	Gen Mills	55	50	1	1.1
Apple Cinnamon Mini-Wheats	Kellogg	55	55	1	1.0
Blueberry Mini-Wheats	Kellogg	55	54	1	1.0
Frosted Mini-Wheats	Kellogg	55	55	1	1.0
Frosted Mini-Wheats Bite Size	Kellogg	55	51	1	1.1
Raisin Mini-Wheats	Kellogg	55	53	1	1.0
Strawberry Mini-Wheats	Kellogg	55	50	1	1.1
Post Banana Nut Crunch (Selects)	Kraft	55	59	6	5.6
Post Great Grains - Crunchy Pecan (Selects)	Kraft	55	53	6	6.2
Post Great Grains - Raisin, Date, Pecan (Selects)	Kraft	55	54	4.5	4.6
Post Honey Nut Shredded Wheat Bite Size	Kraft	55	52	1.5	1.6
Post Shredded Wheat	Kraft	55	46	0.5	0.6
Post Shredded Wheat 'N Bran	Kraft	55	59	1	0.9
Post Grape Nuts	Kraft	55	58	1	0.9
Toasted Oatmeal Honey & Nut	Quaker	55	49	2.5	2.8
Toasted Oatmeal Squares	Quaker	55	56	2.5	2.5
Average					2.2
Range					0.6 - 6.2

*Products meet the existing criteria for the whole grain health claim with the possible exception of "low fat"

*Survey determined whole grain status based on whole grain flour being primary ingredient and fiber content

Market Survey of Grain Products
Other Cereals
55 g RACC

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Basic 4	Gen Mills	55	55	3	3.0
Honey Nut Clusters	Gen Mills	55	55	2	2.0
Multi-Bran Chex	Gen Mills	55	59	1.5	1.4
Raisin Nut Bran	Gen Mills	55	55	4	4.0
Total Raisin Bran	Gen Mills	55	55	1	1.0
Healthy Choice Almond Crunch with Raisins	Kellogg	55	58	2.5	2.4
Healthy Choice Low Fat Granola without Raisins	Kellogg	55	60	3	2.8
Healthy Choice Low-Fat Granola with Raisins	Kellogg	55	49	3	3.4
Just Right Fruit and Nut	Kellogg	55	60	2	1.8
Raisin Bran	Kellogg	55	59	1.5	1.4
Raisin Bran Crunch	Kellogg	55	53	1	1.0
Smart Start	Kellogg	55	50	0.5	0.6
Post Blueberry Morning (Selects)	Kraft	55	55	2.5	2.5
Post Cranberry Almond Crunch (Selects)	Kraft	55	55	3	3.0
Post Premium Raisin Bran	Kraft	55	59	1	0.9
Oat Bran	Quaker	55	57	3	2.9
Toasted Oatmeal	Quaker	55	49	2.5	2.8
Average					2.2
Range					0.6 - 4.0

Market Survey of Grain Products*
Whole Grain Crackers

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Natural Ry Krisp	Bremner, Inc.	15	15	0	0.0
Sesame Ry Krisp	Bremner, Inc.	15	15	1.5	1.5
Meijer Woven Wheat	Miejer (distributor)	30	31	5	4.8
Reduced Fat Triscuits	Nabisco	30	29	3	3.1
Triscuits	Nabisco	30	31	5	4.8
Wasa Fiber Rye Crisp	Wasa GmbH (Germany)	15	10	1	1.5
Average					2.6
Range					0 - 4.8

*Products meet the existing criteria for the whole grain health claim with the possible exception of "low fat".
 *Survey determined whole grain status based on whole grain flour being primary ingredient and fiber content

Market Survey of Grain Products Other Crackers

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Carr's Whole Wheat	Carr's of Carlisle (UK)	15	17	3.5	3.1
Delicious Hearty Wheat	Delicious Frookie Co.	30	31	6	5.8
Cinnamon Crisp Grahams	Keebler	30	30	3	3.0
Club Original	Keebler	15	14	3	3.2
Club, Reduced Fat	Keebler	15	16	2	1.9
Harvest Baked Rye	Keebler	15	16	3.5	3.3
Hi-Ho	Keebler	15	16	4.5	4.2
Hi-Ho Reduced Fat	Keebler	15	15	2.5	2.5
Sunshine Krispe Original Salteens	Keebler	15	15	1.5	1.5
Sunshine Krispe Whole Wheat Salteens	Keebler	15	15	1.5	1.5
Sunshine Krispee Fat-Free Salteens	Keebler	15	14	0	0.0
Toasted Buttercrisp	Keebler	15	16	3.5	3.3
Wheatables 7 Grain	Keebler	30	30	6	6.0
Wheatables Honey Wheat	Keebler	30	30	6	6.0
Wheatables Original Wheat	Keebler	30	30	6	6.0
Wheatables Reduced Fat	Keebler	30	31	4	3.9
Low Fat Honey Maid Grahams	Nabisco	30	31	1.5	1.5
Reduced Fat Wheat Thins	Nabisco	30	29	4	4.1
Ritz	Nabisco	15	16	4	3.8
Ritz with Whole Wheat	Nabisco	15	15	2.5	2.5
Sociables	Nabisco	15	14	3.5	3.8
Wheat Thins	Nabisco	30	29	6	6.2
Zesta Salteens	Nabisco	15	15	1.5	1.5
Average					3.4
Range					0 - 6.2

Market Survey of Grain Products*
Whole Grain Bread

Product	Source	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Bread, whole wheat, commercially prepared	Handbook #8	50	28	1.2	2.1
Bread, whole wheat, from recipe	Handbook #8	50	28	1.5	2.7
Mixed grain	Handbook #8	50	28	1.1	2.0
Pumpemickel	Handbook #8	50	28	0.9	1.6
Rye	Handbook #8	50	28	0.9	1.6
Rye, reduced calorie	Handbook #8	50	28	0.8	1.4
Wheat, reduced calorie	Handbook #8	50	28	0.6	1.1
Average					1.8
Range					1.1 - 2.7

**Market Survey of Grain Products
Other Breads**

Product	Source	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Cracked wheat	Handbook #8	50	28	1.1	2.0
French or Vienna	Handbook #8	50	28	0.8	1.4
Italian	Handbook #8	50	28	1	1.8
White, commercially prepared	Handbook #8	50	28	1	1.8
White, prepared from recipe	Handbook #8	50	28	1.6	2.9
Average					2.0
Range					1.4 - 2.9

Market Survey of Grain Products*
Snack Mixes

Product	Manufacturer	RACC	Serving size	Fat (g/svng)	Fat (g/RACC)
Chex Snack Mixes, Traditional	General Mills	30	30	4	4.0
Chex Snack Mixes, Party Blend	General Mills	30	30	6	6.0
Chex Snack Mixes, Honey Nut	General Mills	30	30	4	4.0
Chex Snack Mixes, Hot n Spicky	General Mills	30	30	4.5	4.5
Chex Snack Mixes, Nacho Fiesta	General Mills	30	30	3.5	3.5
Ches Snack Mixes, Peanut Lovers	General Mills	30	30	6	6.0
Gardettos Deli Style Mustard	General Mills	30	30	2	2.0
Gardettos Italian Cheese Blend	General Mills	30	30	5	5.0
Gardettos Reduce Fat Original Recipe	General Mills	30	30	6	6.0
Gardettos Sour Cream & Onion	General Mills	30	30	4	4.0
Gardettos Special Italian Recipe	General Mills	30	30	6	6.0
Average					4.6
Range					2.0 - 6.0

*Current products in snack mix category do not meet existing requirements for whole grain health claim

APPENDIX – D

Label Examples for Cereal and Cracker Products

NUT CONTAINING WHOLE GRAIN CEREAL EXAMPLE

N u t r i t i o n F a c t s			
Serving Size 1 cup (59g)			
Servings Per Container (15.5 oz) about 7			
Amount Per Serving	Cereal	Cereal with 1/2 cup Fat Free Milk	
Calories	240	280	
Calories from Fat	50	50	
% Daily Value**			
Total Fat 6g*	9%	9%	
Saturated Fat 0.5g	3%	3%	
Trans Fat 0g			
Polyunsaturated Fat 2.5g			
Monounsaturated Fat 2.5g			
Cholesterol 0mg	0%	0%	
Sodium 250mg	10%	13%	
Potassium 200mg	6%	11%	
Total Carbohydrate 44g	15%	17%	
Dietary Fiber 5g	20%	20%	
Sugars 11g			
Other Carbohydrate 28g			
Protein 5g			
Vitamin A	15%	20%	
Vitamin C	0%	0%	
Calcium	0%	15%	
Iron	25%	25%	
Vitamin D	10%	25%	
Thiamin	25%	30%	
Riboflavin	25%	35%	
Niacin	25%	25%	
Vitamin B ₆	25%	25%	
Folic Acid	50%	50%	
Vitamin B ₁₂	25%	35%	
Phosphorus	15%	25%	
Magnesium	15%	20%	
Zinc	10%	15%	
Copper	8%	8%	
* Amount in Cereal. One half cup fat free milk contributes an additional 40 calories, 65mg sodium, 200mg potassium, 6g total carbohydrate (6g sugars), and 4g protein.			
** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
		Calories:	
		2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Whole Wheat Cracker Label Example

Nutrition Facts			
Serving Size 7 crackers (31g)			
Servings Per Container			
Amount Per Serving			
Calories 140	Calories from Fat 45		
%Daily Value *			
Total Fat 5g			8%
Saturated Fat 1g			4%
Trans Fat 0g			
Polyunsaturated Fat 2.5g			
Monounsaturated Fat 1g			
Cholesterol 0mg			0%
Sodium 200mg			8%
Total Carbohydrate 21g			7%
Dietary Fiber 3g			12%
Sugars 0g			
Protein 3g			
Vitamin A 0% • Vitamin C 0% • Calcium 0%			
Iron 6%			
*Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g