Food Laws and the Consumer:
Health Claims in Labeling of Food Products

by

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B.S., Kansas State University, 1986

A MASTER'S REPORT

submitted in partial fulfillment of the

requirements for the degree

MASTER OF SCIENCE

FOOD SCIENCE

Department of Animal Sciences and Industry

KANSAS STATE UNIVERSITY

Manhattan, Kansas

1988

Approved by:

Major Professor

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ACKNOWLEDGMENTS

I would like to express my gratitude to all those who have influenced and aided in my choice of career including my instructors and advisors for sharing their wealth of knowledge and ideas. Appreciation is extended to my graduate committee members: Dr. Frank Cunningham, Dr. Daniel Y.C. Fung, and Dr. Carol A.Z. Harbers for their suggestions and expertise.

Special appreciation is extended to my major professor, Dr. Frank Cunningham, for his project idea and his continual support and encouragement and his overall dedication to Food Science at Kansas State University.

Special thanks also goes to my parents, family, and friends for their patience and support of my educational endeavors.

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I. INTRODUCTION

The history of food law in the United States had its beginning over 300 years ago. Authorized by the Massachusetts Bay Colony in 1646, the decree determined how much a loaf of bread must weigh to be sold for a penny; and the weight was to be increased or decreased depending on the quality of the bread and the selling price of wheat. Official inspectors had the right to enter homes or small shops where bread was baked and sold, to weigh the loaves, and to seize any found light in weight (Schultz, 1981).

Since that time many events have contributed to the history of food law with the greatest changes occurring in the last 100 years. National attention was focused on the food industry in 1906 by Upton Sinclair. His book, The Jungle, stirred the sentiments of the American public by vividly describing unsanitary food processing and inhuman working conditions in Chicago meat packing plants. Within six months, public opinion generated enough pressure for Congress to pass the Meat Inspection Amendment as part of the 1906 Agricultural Appropriation Bill. This amendment established guidelines for maintaining sanitary conditions of processing and enabled the Department of Agriculture to inspect meat and meat products entering interstate

commerce. In 1967, this amendment was legally designated the Federal Meat Inspection Act.

On the same day the Meat Inspection Amendment was passed, the Food and Drugs Act of 1906 also became law, establishing Federal jurisdiction. Until that time, food laws were enacted and enforced by individual States. The Food and Drugs Act became necessary as the food industry developed from a local trade market among neighbors and communities to an import-export business among states and overseas countries. This general food act was to prevent the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein (Schultz, 1981). Dr. Harvey Wiley, Chief Chemist in the Bureau of Chemistry, was a major influence in persuading Congress to pass legislation to provide pure food and drugs. As early as 1889, Dr. Wiley was convinced that all food products made in this country should be required to be accurately labeled and sold under their true name. Throughout his professional life, he was dedicated to the progression and evolution of a general pure food and drug law (Anderson, 1958).

The 1906 Act set the stage for the current Federal Food, Drug, and Cosmetic Act approved in 1938. This new law sought to eliminate loopholes in the old act, but also

included regulation of cosmetics and therapeutic devices. Although the drug industry resisted this new regulation, many of the "snake oil remedy" companies were put out of business.

Over the next two decades, the Food, Drug, and Cosmetic Act was amended four times to keep pace with scientific and technological advances. The amendments addressed such matters as pesticides, food additives, color additives, and nonnutritive objects and substances in confectioneries. It was in the 1950's that the Delaney Committee investigated the effect of chemicals in foods. The Food Additives Amendment of 1958 and the Color Additives Amendment of 1960 include the now famous Delaney Clause which prohibits the use of substances found to be cancer-inducing in man or animals and are not allowed in food in any amount (Schultz, 1981).

Other food laws enacted over the years were not of the magnitude of the Food, Drug, and Cosmetic Act of 1938, but covered more specific products. A few include: The Impure Tea Act (1883), The Butter Act (1886), The Import Milk Act (1927), The Poultry Products Inspection Act (1957), and The Fair Packaging and Labeling Act (1966). The principal function of all food laws and regulations is consumer protection; to protect the consumer's health and to protect the consumer's pocketbook.

II. FOOD AND DRUG ADMINISTRATION

Also occurring during this time period between 1890 and 1938 was the development of the Food and Drug Administration (FDA). Originally called the Division of Chemistry of the Department of Agriculture in 1890 and the Bureau of Chemistry in 1901, its purpose from 1906 to 1927 was to examine samples of foods and drugs to determine whether there was adulteration or misbranding as established by the Food and Drug Act. In 1927, enforcement was transferred to the Food, Drug, and Insecticide Administration within the department. Reorganization in 1931 led to the group being renamed the Food and Drug Administration. This name has been retained over the years although the agency itself was transferred from the Department of Agriculture to the Federal Security Agency in 1940, then to the Department of Health, Education, and Welfare in 1953. It is now in the Department of Health and Human Services renamed in 1980 with the establishment of a separate Department of Education.

The Food and Drug Administration does not have direct authority or power to enforce food laws, however. It is the jurisdiction of the Secretary of Health and Human Services. This Secretary then delegates authority, through the

Assistant Secretary for Health, to the Commissioner of Food and Drugs. The Commissioner then delegates authority to the other officers in the Food and Drug Administration. Frank E. Young currently is serving as Commissioner of Food and Drugs.

The scheme of the federal government is shown on Figure 1. The FDA is part of the Department of Health and Human Services, whose Secretary is a member of the President's Cabinet. Other government agencies involved in the nation's food supply are shown in Figure 2 with the agencies' full titles shown in Figure 3. These regulatory agencies include: the United States Department of Agriculture (USDA) for regulation of meat, poultry, eggs, plants, grain, fruits, vegetables, and dairy products; the Bureau of Alcohol, Tobacco, and Firearms (BATF) which regulates alcoholic beverages except wine less than 7 percent alcohol; the Environmental Protection Agency (EPA) for regulation of pesticides, pesticide residues in food, and water quality standards; the Federal Trade Commission (FTC) which regulates all advertising of foods; and the National Marine Fisheries Service (NMFS) which regulates seafood quality and identification. State and local governments also work in accordance with the federal government to inspect restaurants, retail food establishments, dairies, and grain mills (Modeland, 1988).

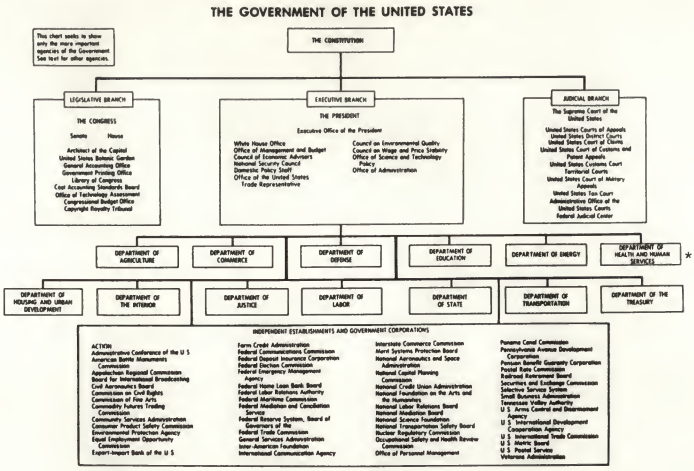

Figure 1. Diagram of the Federal Government. (Schultz, 1981).

* Department of Health and Human Services.

FEDERAL GOVERNMENT and WHOLESOME FOOD SUPPLY

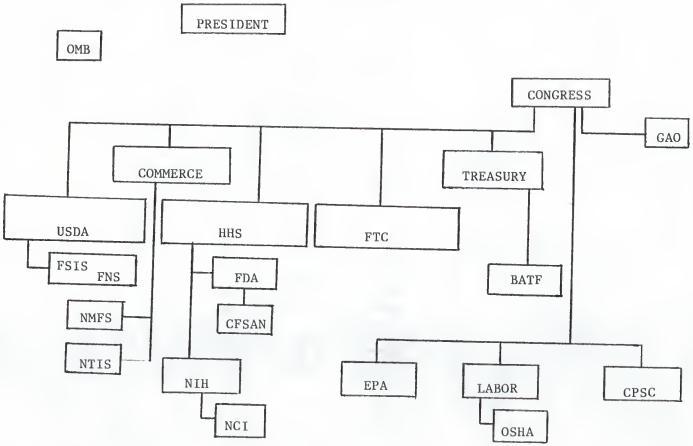

Figure 2. Government Agencies involved with the U.S. food supply (IFT, 1988)

Key for

FEDERAL GOVERNMENT AND WHOLESOME FOOD SUPPLY

BATF - Bureau of Alcohol, Tobacco and Firearms

CFSAN - Center for Food Safety and Applied Nutrition

CPSC - Consumer Product Safety Commission

EPA - Environmental Protection Agency

FDA - Food and Drug Administration

FNS - Food and Nutrition Service

FSIS - Food Safety Inspection Service

FTC - Federal Trade Commission

GAO - General Accounting Office

HHS - Health and Human Services

NCI - National Cancer Institute

NIH - National Institute of Health

NMFS - National Marine Fisheries Service

NTIS - National Technical Information Service

OMB - Office of Management and Budget

OSHA - Occupational Safety and Health Administration

USDA - United States Department of Agriculture

Figure 3. Key for Federal regulatory agencies of U.S. food supply.

These are businesses dealing predominantly with intrastate trade.

The principle function of FDA is to enforce the Federal Food, Drug, and Cosmetic Act of 1938, thereby carrying out the purpose of Congress to insure that foods are safe, pure, and wholesome and produced under sanitary conditions. Drugs, therapeutic devices, and cosmetics also are regulated by FDA with all of these products, including foods, to be honestly and informatively labeled and packaged. Enforcement of other food laws, in cooperation with other regulatory agencies, is also included as FDA's responsibility.

III. FAIR PACKAGING AND LABELING ACT

A major task of the FDA is enforcement of the Fair Packaging and Labeling Act of 1966. This law deals with the way in which the product is represented through its package or label and covers any consumer food commodity except meat and meat products, poultry, eggs, and alcoholic beverages. The Fair Packaging and Labeling Act was enacted to fulfill the goal that packaging and labeling "should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons" (Schultz, 1981). Under this Act, the FDA is authorized to take necessary action to prevent the deception of consumers. These activities include establishing and defining standards for characteristic sizes of packages, regulating qualifying size statements such as "giant size" or "economy size", and regulating the location on any package or label of any statement or implication that may affect the sale of that commodity (Schultz, 1981).

The current Fair Packaging and Labeling Act goes into much detail on such particulars as the prominence of information on the label and nutritional labeling established in 1973. The Act specifies that any word, statement, or other information required to appear on the

label must be located in a place and in such terms likely to be read by an ordinary individual under normal conditions of purchase and use. Type size of printing also is specified.

A "principal display panel" and an "information panel" have been designated to help consumers find the required information. The principal display panel is that part of the label most likely to be presented under customary conditions for retail sale. On most food packages, there are four sides of a label. Rectangular packages usually have one side considered to be the principal display panel. Cylindrical packages, such as cans and bottles, require 40% of the total area (height x circumference) of the container. Irregularly shaped packages also require 40% of the total area to be considered the principal display panel. This panel must contain the following information: 1) the manufacturer, 2) the name of the food product, 3) if a picture is used, it must be truthful, and 4) the net weight of the food in the container. Other information that may be on the front panel include the drained weight and the USDA seal if the food product contains meat or poultry (Schultz, 1981).

The information panel is immediately right of the principal display panel and is where ingredients must be listed in order of decreasing predominance. This is for

most foods excluding those with a standard of identity such as canned peas. Specific names are not needed for flavors, spices, and colors, except FD & C yellow #5 (tartrazine) and FD & C yellow #6 (Federal Register, 1987a). Below this list of ingredients is the name and address of the packer, distributor, or manufacturer.

The left side and back panels may provide a variety of information such as nutrition data, the Universal Product Code (UPC), and recipes. Nutrition labeling is voluntary for most foods. It becomes mandatory if the food contains any added vitamin, mineral, or protein, or if the food is labeled or advertised with any nutritional claim or information other than sodium content. Since July 1, 1986, sodium content is required to be included on any food that has a nutrition label (Lecos, 1986). Certain foods such as infant formulas or dietary supplements may be exempt but may have special labeling requirements (Schultz, 1981).

When nutrition labeling is used, it must conform to a standard format. The following items must be included and in this order: A) serving size, B) servings per container, C) calorie content per serving, D) protein content per serving (in grams), E) carbohydrate content per serving (in grams), F) fat content per serving (in grams), G) sodium content per serving (in milligrams) and H) percentage of the U.S. Recommended Daily Allowance (U.S. RDA) of the

following nutrients in this order: 1) protein, 2) vitamin A, 3) vitamin C, 4) thiamin, 5) riboflavin, 6) niacin, 7) calcium, and 8) iron. Other nutrients also may be listed (Schultz, 1981; Lecos, 1986).

The Universal Product Code (UPC) is a series of lines of varying width and a 10-digit number below these lines. The lines are read by a computer scanner that interprets the lines to determine the manufacturer, size, and product name of the item. The first five numbers identify the manufacturer and the last five numbers identify the size and contents. A zero (0) to the left of the lines signifies that the item is a food product (Cunningham, 1987).

The words, statements, and data on food packages and labels are intended to provide the consumer with information on which to base his or her purchase. The terminology and arrangement have been carefully developed to convey this information to the consumer in a reliable and educational manner. Since the Fair Packaging and Labeling Act was enacted, few debates have occurred over what may or may not be put on a package or label. Recently, however, the use of health claims on labeling has become a much discussed topic to those involved with the food industry.

IV. HEALTH CLAIMS IN FOOD LABELING

A. Introduction

"Calcium-rich", "high in fiber", "low in saturated fat", "a natural fluid replacement", these are just a few of the health claims that can be seen on food labels available in the supermarket today. But to the consumer, what do these claims mean, what are the bases for these claims, and how truthful are they?

Health claims can be defined as any statement or article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease (Labuza, 1987). The statements contend that a relationship exists between the consumption of a particular food and a specific disease (Anonymous, 1987c).

This health claims issue currently is under review by the Food and Drug Administration (FDA). The FDA is trying to answer these questions plus establish guidelines to regulate future nutritional findings. A proposed regulation regarding public health messages on food labels and labeling was issued by the FDA in the August 4, 1987 Federal Register (p. 28843 ff.) Comments on the proposal were accepted until November 2, 1987 with a formal ruling expected in September 1988.

B. Initial Health Claim

The use of health claims in labeling was initiated in October, 1984 by the Kellogg Co. for their All-Bran high-fiber cereal promoted to help prevent cancer (Anonymous, 1987b). This advertising campaign was endorsed by the National Cancer Institute (NCI) who had published a statement in 1979 entitled "Diet, Nutrition and Cancer." The 1979 statement recommended that daily dietary fiber consumption be increased and that high dietary fiber consumption had been linked to reduced risks of some forms of cancer. As shown in Figure 4, the Kellogg cereal label carries a message in the form of preventative health tips advising consumers to eat a well-balanced diet - including foods low in fat and high in fiber, which All-Bran represents, - plus fresh fruits and vegetables, and to maintain proper weight.

Fiber provides bulk or roughage in the diet. It is the indigestible component of food that aids in the passage of waste products through the intestines for elimination. Sources of fiber include plant foods such as cereal grain products, vegetables, fruits, seeds, and nuts. Table 1 shows examples of high-fiber foods and their fiber content. "Dietary fiber" is that part of food that is not digested in the gastrointestinal tract of the human body. This is contrast to crude fiber which is the component of food that

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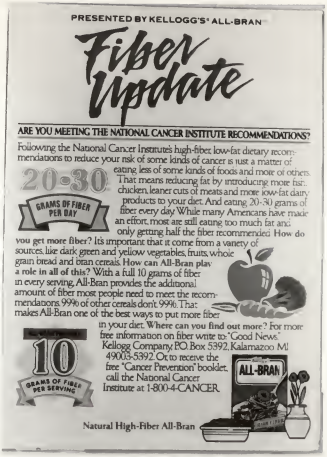

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Figure 4. Kellogg's All-Bran cereal label.

	Serving	Calories	Grams of Fiber*
Breads and Cereals			
All Bran-Extra Fiber™	1/2 cup	60	13.0
Fiber-One™	1/2 cup	60	12.0
All-Bran, Fruit & Almonds™	2/3 cup	100	10.0
100% Bran™	1/2 cup	75	8.4
All Bran™	1/3 cup	70	8.5
Bran Buds™	1/3 cup	75	7.9
Bran Chex™	2/3 cup	90	4.6
Corn bran™	2/3 cup	100	5.4
Cracklin' Oat Bran™	1/3 cup	110	4.3
Bran Flakes™	3/4 cup	90	4.0
Grapenuts™	1/4 cup	100	1.4
Air-popped popcorn	1 cup	25	2.5
Whole-wheat bread	1 slice	60	1.4
Whole-wheat spaghetti	1 cup	120	3.9
Legumes, cooked			
Kidney beans	1/2 cup	110	7.3
Lima beans	1/2 cup	130	4.5
Navy beans	1/2 cup	110	6.0
Vegetables, cooked			
Beans, green	1/2 cup	15	1.6
Broccoli	1/2 cup	20	2.2
Brussels sprouts	1/2 cup	30	2.3
Cabbage, red and white	1/2 cup	15	1.4
Carrots	1/2 cup	25	2.3
Cauliflower	1/2 cup	15	1.1
Corn	1/2 cup	70	2.9
Green peas	1/2 cup	55	3.6
Kale	1/2 cup	20	1.4
Parsnip	1/2 cup	50	2.7
Potato, with skin	1 medium	95	2.5

	Serving	Calories	Grams of Fiber
Fruits			
Apple	1 medium	80	3.5
Apricot, fresh	3 medium	50	1.8
Apricot, dried	5 halves	40	1.4
Banana	1 medium	105	2.4
Blueberries	1/2 cup	40	2.0
Cantaloupe	1/4 melon	50	1.0
Cherries	10	50	1.2
Dates, dried	3	70	1.9
Dried prunes	3	60	3.0
Grapefruit	1/2	40	1.6
Orange	1 medium	60	2.6
Peach	1 medium	35	1.9
Pineapple	1/2 cup	40	1.1
Raisins	1/4 cup	110	3.1
Strawberries	1 cup	45	3.0

Table 1. High-fiber foods. (Reprinted from NCI, 1986).

remains after treatment with acid and alkali in laboratory analysis. Although the lab analysis is a much more rigorous treatment than the digestive process in the body, food composition tables refer to crude fiber values (Clydesdale and Francis, 1980; Lecos, 1988).

The initial reaction from FDA regarding the Kellogg high-fiber label was that it was potentially misleading and, therefore, illegal. A regulatory letter was drafted by FDA noting the regulations violated by Kellogg and the procedures that would be followed if the company failed to cease its labeling actions. However, the letter was never issued. The Kellogg label had demonstrated a new media tool that could be used to educate consumers. As stated by Carol T. Crawford, director of the Bureau of Consumer Protection of the Federal Trade Commission (FTC), "The claims in the ad appear to be exactly the kind of adequately substantiated and responsible vehicles for providing beneficial information to the public that we believe is important for regulatory programs to encourage, not discourage." It was this speech that led to the suppression of the regulatory letter to Kellogg and ended any legal action by the FDA (Labuza, 1987). Instead, the assistant secretary for health, Dr. Edward Brandt, commended Kellogg for its efforts.

Following these proceedings, FDA was highly concerned about the future consequences of allowing health claims in labeling and the possibility that many food companies would abuse this new marketing tactic to increase sales. This was especially true since the health claims issue had the support of other government regulatory agencies, whereas the FDA had only the stringent policy of "no health claims permitted without a new drug application" established by the Food, Drug, and Cosmetics Act of 1938. Although no problems have occurred to any great extent, the health claims issue has generated much debate between consumer protection and consumer education within manufacturing ethics.

Health messages were included on other Kellogg brand high-fiber cereals and did contribute to a substantial increase in sales of Kellogg cereals; but more importantly, in less than one year, overall sales of all high-fiber, ready-to-eat cereals increased by 37 percent (Anonymous, 1987a). This figure was derived from a computerized purchase survey made by authors Alan S. Levy and Raymond C. Stokes (1987). Tables 2 and 3 show the change in percent of sales of this 64-week study. The authors noted that

> "The fact that sales of high-fiber cereals as a group increased ... suggested that the campaign was successful in attracting new consumers to try high-fiber cereals because of their fiber content rather than simply redistributing an existing demand in favor of Kellogg brands."

Cereal	Weeks 1-16 Baseline	Weeks 17-64, evaluation			
		Period 1 12 Weeks	Period 2 12 Weeks	Period 3 12 Weeks	Period 4 12 Weeks
Total	6.12	6.81	7.12	7.42	8.42
All Kellogg high fiber .	3.28	3.78	4.08	4.13	3.92
Kellogg's All-Bran . .	.99	1.31	1.46	1.47	1.29
Other Kellogg Brands .	2.29	2.47	2.62	2.66	2.63
Non-Kellogg high fiber .	2.84	3.03	3.04	3.29	4.50
Nabisco 100% Bran . .	.99	1.08	1.10	1.05	1.01
Other non-Kellogg . .	1.85	1.95	1.94	2.24	2.29
New products	--	--	--	--	1.20

Table 2. Percent of total ready-to-eat cereal unit sales of Kellogg and non-Kellogg high fiber cereals, before and after Kellogg's fiber-cancer prevention initiative (reprinted from Levy and Stokes, 1987).

Category	Weeks 1-16 Baseline	Weeks 17-64, evaluation			
		Period 1 12 Weeks	Period 2 12 Weeks	Period 3 12 Weeks	Period 4 12 Weeks
		Moderate fiber			
Total	28.86	29.04	29.41	30.25	29.28
Raisin bran type	14.94	15.20	15.50	15.77	15.71
Shredded wheat	4.85	4.45	4.67	5.32	4.86
High protein-high vitamin	7.09	7.02	6.81	6.74	6.71
Fruit & Fibre	1.98	2.37	2.33	2.42	2.00
		Low fiber			
Total	64.81	63.92	63.24	62.43	62.45
Wheat germ	.88	.89	.89	.80	.76
Granola/natural	7.22	6.23	6.19	5.89	6.19
Children's	31.91	31.31	31.33	30.83	31.79
Traditional	24.80	25.49	24.83	24.91	23.71

Table 3. Percent of total ready-to-eat cereal unit sales of moderate and low fiber cereal categories, before and after Kellogg's fiber-cancer prevention initiative (reprinted from Levy and Stokes, 1987).

In this study, classification of cereals was based on their dietary fiber content. Low fiber cereals have 2 g or less of dietary fiber per serving. Those cereals containing 2 to 4 g of dietary fiber are classified as moderate fiber and cereals considered to be high-fiber contain at least 4 g of total dietary fiber per serving. Kellogg's All-Bran cereal contains 10 g of dietary fiber per 1 oz. or 1/2 c. serving. It is recommended that the average adult consume 20 to 30 grams of dietary fiber daily (NCI, 1986).

According to the study, the successful educational impact of the Kellogg diet and health campaign showed consumers to be making an apparently conscious discrimination between high- and low-fiber cereals. The attraction of new consumers to high fiber also was marked successful, but clearest evidence of success would be increased sales for high-fiber products that were not advertised as such. All sales increases in high-fiber products had used some promotion of their fiber content. The overall conclusion of this study was that consumer purchases of cereals were influenced by the health messages, although other outcome measures, such as consumer knowledge and attitudes, would need to be evaluated (Levy and Stokes, 1987).

These increased sales results are consistent with industry objectives of labeling and advertising, but

undesirable effects could harm industry credibility. Addressing a seminar group discussing current issues in food labeling, FDA's L. Robert Lake warned the food industry that it risks losing consumer trust through the use of misleading statements on labels. He cautioned that too little attention is being paid to consumer confidence and that some industry labeling practices should consider the future consequences (Anonymous, 1988f). Past FDA surveys have shown consumers to have a high regard for the information that appears on food labels, so the food industry should take care to preserve that opinion or risk being a company with a poor public image.

In contrast to the reliability of the food industry and nutritional information, food safety and wholesomeness was viewed much differently by the public. In a poll conducted by the Food Marketing Institute, when consumers were asked what authority they relied on to ensure the foods they consumed were safe and wholesome, 25% responded the Federal Government, 15% consumer groups, and only 9% chose manufacturers. These results show that shoppers do not have much trust in industry on the issue of food safety (Anonymous, 1988a).

With this in mind, the FDA sought to establish guidelines to protect the consumer from false advertising while the food industry submitted proposals and guidelines

to maintain industry credibility. The Kellogg Co. submitted its own proposal to the FDA, pushing for regulatory guidelines instead of specific regulations. The proposal requested that FDA not consider a food a drug if it makes a health claim provided the claim followed the regulatory guidelines (Labuza, 1987). Other proposals for allowing health claims were submitted by such groups as the National Food Processors Association (NFPA), the Center for Science in the Public Interest (CSPI), and the Council for Responsible Nutrition (CRN).

C. FDA Proposal

After receiving these proposals, FDA developed its own guidelines to be used as criteria in evaluating health-related statements. It is this proposal that has been open to comment from industry, academia, consumer protection groups, and the public. The proposed criteria are as follows: 1) the information should be educational in nature and limited to a discussion of the relationship between nutrition and health. The information should not be misleading; 2) the information to support any claim must be based on and be consistent with widely accepted, well-substantiated, peer-reviewed scientific data, and generally based on recognized medical and nutritional principles. An individual should be able to use the information to develop

a total dietary pattern that may improve health; 3) the information must emphasize the importance of a total dietary pattern; 4) the information on food labeling must not over-emphasize or distort the role of a food in enhancing good health, and 5) the use of health related information constitutes a nutritional claim that must follow FDA's requirements for nutritional labeling. Products with health related information that comply with these criteria will not be misbranded and also will not invoke the new drug regulation of the Food, Drug and Cosmetics Act (Labuza, 1987).

In comments filed with FDA, NFPA President Charles J. Carey suggested that the wording of the FDA proposal be modified. Clarification of therapeutic, drug-like treatment, and therapy claims would not be permitted on traditional food labels without such products also being regulated as drugs under the Food, Drug and Cosmetic Act. NFPA felt these changes should be made to limit health messages on food labels and to create a firmer legal footing (Anonymous, 1988b).

Neither has the reaction to FDA's proposal by the individual states been positive. In a letter written to FDA Commissioner Dr. Frank Young by the Attorneys General of seven States, the FDA was urged to withdraw the agency's health claim proposal. The letter also asked for the

continuation of the former practice prohibiting all health claims on food labels. These seven States included Iowa, California, Minnesota, Missouri, New York, Texas, and Wisconsin. FDA's proposal would not be limited to the national level since the laws of many States reflect or rely on the FDA standard. The proposed rule would hamper States' enforcement efforts against those claims at the State level. Another argument against health messages was the lack of defined terminology. No pre-screening of health messages was included in the proposal, nor could the term "misleading" be defined clearly enough to prevent a seriously confused public. Even if pre-screening was included, the FDA would lack sufficient resources for enforcement. The Attorneys General also argued that consumers may get only partial information. The following example was cited "A company may promote milk as a source of calcium, but not disclose that whole milk is high in saturated fat and that calcium could be obtained from a lower fat milk product." Their general opinion was that the public should not be exposed to the potential hazards in allowing health claims, but that there are more efficient and effective ways to educate the consumer about health and nutrition (Anonymous, 1988g).

Food products with mixed attributes, such as whole milk being a good source of calcium but also high in

saturated fat, brings to question the issue of positive versus negative health claims. Dr. F. Edward Scarbrough, Deputy Director of the Office of Nutrition and Food Sciences in FDA's Center for Food Safety and Applied Nutrition said that it would be improbable to expect a prohibition against positive claims for foods even though they may contain another dietary component that is not healthful. The agency wants to avoid classifying foods as "good" or "bad" based on its mixed attributes (Anonymous, 1988d).

Other disagreements over the proposed ruling have been more procedural. The FDA has not conducted any formal consumer surveys or consultations regarding its proposal to allow health related messages on food labels (Anonymous, 1988d). In a speech, FDA Commissioner Frank E. Young noted that consumers consulted by FDA in drafting its policy, "believed that concerns about misleading claims were outweighed by the benefit of having more information on which to base their food choices." This datum was based on an FDA document called a "consumer prospective" on health messages, prepared by the Office of Consumer Affairs.

In the legal arena, the Public Citizen Litigation Group is threatening court action against the FDA (Anonymous, 1988e). Upon publication of the final regulation, the Public Citizen will decide whether or not

to challenge the legality of the health claim policy in an effort to represent the public's interest.

Since the health message on the Kellogg cereal label first appeared, the basis for the All-Bran fiber claim has been challenged. Hugh C. Cannon, FDA Associate Commissioner explained that "some epidemiological data support the statements being made. Other data, including animal and clinical studies, are less conclusive. In order for the Kellogg label to follow the 'truthful and not misleading' standard, the information should not imply that a food product be used as part of a drug-like treatment or a therapy-oriented approach to health care. Also, the information on food labeling must not overemphasize or distort the role of a food in enhancing good health. Other questions involve whether any studies have been made to determine the effects of too much fiber in the diet; too much fiber may be constipating (Anonymous, 1988c).

Besides the health claims for high fiber cereals, other food companies have started using nutritional information to promote their products' qualities. Antacid tablets provide an excellent source of calcium for reduced risk of osteoporosis, beverages can replace natural body fluids lost during exercise, and margarines low in saturated fat may reduce cholesterol and hence, lower the risk of heart disease (Figures 5, 6, and 7). It is this

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Figure 5. Tums Brand antacid tablets.

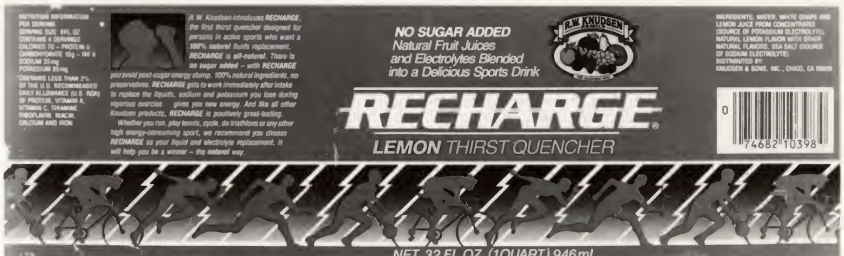

Figure 6. Recharge Brand beverage label.

Front

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Figure 7. Promise Brand margarine label.

range of products that FDA must regulate if health claims are to be used as a source of health and nutritional information to the consumer.

D. Conclusion

The health claims issue has raised more than the question of whether food companies can use health messages to attract consumer dollars. The issue has drawn attention to current marketing strategies, consumer rights to have access to nutrition information, and FDA's ability to enforce the current regulations. As stated previously, FDA's function is to enforce the food laws as they are written, and these laws were intended to protect the consumer. Nutritional information about food products cannot be denied to the public, so what must be decided is whether food companies can be trusted or regulated enough to ensure accurate information is being presented to consumers in the most beneficial manner. If health claims can be substantiated for the product and, at the same time, the consumer can be educated about the overall relationship between diet and health, then yes, health messages on labels should be allowed. Without close regulation, however, health claims again will become "snake oil remedies" with the consumer the target of unscrupulous marketing practices.

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Food Laws and the Consumer:
Health Claims in Labeling of Food Products

by

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B.S., Kansas State University, 1986

AN ABSTRACT OF A MASTER'S REPORT

submitted in partial fulfullment of the

requirements for the degree

MASTER OF SCIENCE

FOOD SCIENCE

Department of Animal Sciences and Industry

KANSAS STATE UNIVERSITY

Manhattan, Kansas

1988

ABSTRACT

The development of food laws has played an important role in providing a safe and nutritious food supply for the American public. Many laws and regulations have been enacted by Congress to cover specific food products, the manufacturing of them, and their presentation for sale to the consumer. The project Food Laws and the Consumer: Health Claims in Labeling of Food Products briefly reviews food law history and the development of the Food and Drug Administration. A closer look at the Fair Packaging and Labeling Act of 1966 is made, including a review of labeling requirements for food products. Finally, a summary of the recent health claims in labeling issue is discussed. Following the initial health claim message made by the Kellogg Co. in 1984 for its All-Bran high-fiber cereal, the FDA proposed guidelines for future use of health claims. This proposal has been open to comments from the food industry, trade associations, and consumer interest groups with a final FDA ruling expected in September, 1988. This project attempts to review some of the major issues that have arisen in support and opposition to the FDA proposal.