MAKING SMART CHOICES:
HEALTH CLAIMS, REGULATION, AND FOOD PACKAGING

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Facing high rates of obesity and chronic disease, American consumers are becoming increasingly conscious of the importance of their dietary choices, including the need to purchase "healthy" products. Food manufacturers cater to this demand by presenting health claims on the fronts of their packages. However, there is a public health concern that the proliferation of claims serving commercial interests may be misleading or confusing to consumers. Federal regulation must play a key role in any efforts to improve this health claim system, but the Food and Drug Administration has historically been reluctant to allow health claims or to guide their content. Behavioral models for consumer use of nutrition information indicate that front-of-pack labeling is a likely format for effectively encouraging healthier food purchases. Other countries have implemented national front-of-pack campaigns, and have experienced moderate success. However, in the United States many corporations and organizations administer proprietary front-of-pack health claim systems, each with its own nutritional criteria. Smart Choices, introduced in 2009, is one such program. Critical public health and media attention prompted the program's hiatus, and led the Food and Drug Administration to consider mandating a standardized, national system. This thesis recommends the implementation of a national food labeling program modeled after the UK's nutritional signposting system of labeling, which discloses both positive and negative nutritional information.

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1.0 INTRODUCTION

The influence of dietary choices on chronic disease prevention and management is well established, yet the prevalence of overweight and obesity continues to rise (World Health Organization & Food and Agriculture Organization, 2003). In the United States, 32% of adults are obese and 17% of children are overweight, with no indication of a decrease in incidence (Ogden et al., 2006). Obesity is an underlying cause in 300,000 deaths annually in the United States, accompanied by $147 billion in health care costs (Food and Drug Administration, 2009a). Public health agencies are devoting increasing resources to this situation, which has also become the subject of much public attention (Scott [Moderator] & Hamburg [Speaker], 2009).

As a result, American consumers are becoming more aware of the importance of selecting foods with beneficial nutritional value (Coulson, 2000). Although there are many determinants of product choice, one way that shoppers select healthier foods is by reading the package: 52% of consumers refer to food labels before purchasing; 85% for a first time purchase (Geiger, 1998; Morreale & Schwartz, 1995). By putting health claims on their packages, food manufacturers seek to appeal to these health-conscious shoppers by highlighting their products' nutritional value. However, there is growing concern that the public health impact of these claims may not always be positive (M. Nestle & Ludwig, 2010; Scott [Moderator] & Hamburg [Speaker], 2009).

Use of health claims in the United States has increased since the mid-1980s, and they appear on an increasing variety of foods (Calfee & Pappalardo, 1991). Cereal manufacturers are particularly prolific users of health claims. In their study of breakfast cereal marketing, the Rudd Center for Food Policy and Obesity (2009) found that family-targeted cereals display 2.4 health messages per box, including ingredient claims and "health URLs." The same report describes an even more troubling trend: cereals with lower nutrition scores actually feature more claims than healthier competitors (Harris, Schwartz, & Brownell, 2009). This example illustrates the reason for increasing public health concern regarding package health claims.

Through a review and synthesis of existing literature, this thesis examines health claims on food packaging from a public health perspective. It begins with a broad review of the environment in which health claims function, and narrows to the analysis of a single program. Chapter 2 presents the methodology employed for this research. Chapter 3 gives a brief overview of health claims and their originators, function, and formats. Chapter 4 describes the history of food health claims and their regulation in the United States, including current policy. Chapter 5 discusses consumer choice of food products, including factors that affect the search for information and proposed models for health claim use. Chapter 6 introduces front-of-pack programs, a variety of food health claim that is gaining prominence, and identifies examples and related research findings. Chapter 7 focuses on a specific front-of-pack program, and describes how developments taking place after its recent introduction prompted a reevaluation of health claim labeling in the United States. Chapter 8 concludes this thesis and makes recommendations for future health claim regulation.

2.0 METHODOLOGY

This thesis synthesizes information derived from a systematic search of three sources: peer-reviewed journals, federal agency records, and popular media.

2.1 SCHOLARLY LITERATURE REVIEW

In order to establish the historical background and examine the existing body of research, the author conducted a formal literature review. A search of online databases for pertinent terms provided the starting point for this research. Google Scholar was the primary database used, supplemented by PubMed and PITTCat^{+}, the University of Pittsburgh search tool. Searches used combinations of the following terms:

regulations	“Smart Choices”	food
packaging	consumer	purchasing
“health claims”	claims	“food information programs"
labeling	behavior	“front of pack”

The search terms entered into Google Scholar returned many thousands of results, patents excluded, listed in descending order of relevance. The author reviewed the search results, culled irrelevant material, and assessed the abstracts of promising articles. The University of Pittsburgh

library system provided copies of articles for which the full text was not accessible, and the interlibrary loan system supplied several otherwise unavailable articles. Citations found in the chosen articles provided many valuable sources; the majority of articles cited in the following pages were collected in this way. Recommendations from members of this thesis committee were also invaluable.

2.2 REGULATIONS, STATUTES, AND RECORDS

The author conducted much of the review of federal policies and regulations directly from the source documents, found through citations in the reviewed scholarly articles. The following sources were invaluable in locating these, sometimes obscure, resources:

- The United States Code as archived on the Cornell University Law School site was easily navigable (www.law.cornell.edu/uscode/).
- The LexisNexis Congressional database and the U. S. Government printing office provided access to the *Federal Register* (web.lexis-nexis.com/congcomp; www.gpoaccess.gov).
- The FDA Dockets Management database was used to locate full text of FTC/FDA Memoranda (www.fda.gov/RegulatoryInformation/Dockets/default.htm)

2.3 CURRENT EVENTS AND HEALTH CLAIM PROGRAMS

As a significant part of thesis deals with recent events and the public and media reactions, sources beyond scholarly journal articles were required. In order to examine the public positions

of the agencies and organizations involved, their official websites were located through Google and reviewed. For the media perspective, the author input the search term "Smart Choices" into the Google News engine approximately monthly from August 2009 to March 2010.

Much of the specific information about various front-of-pack labeling programs came from the official program websites or websites of the sponsoring organizations, all located via Google.

3.0 BACKGROUND

3.1 WHAT ARE HEALTH CLAIMS ON FOOD PACKAGING?

At the most basic level, health claims are simply claims about nutritional value that are designed to influence consumers' product choice. Unlike mandated nutrient disclosures, which do not directly refer to any health effects, health claims attempt to link specific product attributes to certain health outcomes. More generally, a health claim can be defined as "[an] easily readable label or claim that appears on the front of the package and describes the product's health outcome benefits, overall healthfulness, or role in a healthy lifestyle (e.g. "lower your cholesterol" or "heart healthy") (Harris et al., 2009, pg. 53).

Health claim labels differ from other advertising venues in the intended time of effect. Due to their placement directly on packaging, these health claims are intended to function in a point-of-purchase capacity—that is, they target the consumer in the store, at the time of purchase (Caswell & Padberg, 1992). This approach is expected to facilitate the consumer's decision-making process by reducing the need for interpretation of more detailed nutrition information (Smith, Stephen, Dombrow, & Macquarrie, 2002).

3.2 HEALTH CLAIMS AND THE FOOD INDUSTRY

Food retailers originated the use of health claims as a way to market their goods (Hutt, 1986). Before the advent of labeling regulation in the United States, these health claims were elaborate statements of the product's preventative and curative powers with no apparent basis in fact. Hutt provides the following example, a label submitted as evidence in United States v. Hygienic Health Food Co. (1911):

> Grant's Hygienic Crackers. No predigested stuff are they, but solid food for work or play. Just read what leading doctors say of Grant's Hygienic Crackers for Constipation, Indigestion, Dyspepsia and Sour Stomach. Ideal food for general family use. A daily regulator. A week's trial will convince you. Eaten daily in place of bread will keep the system in perfect order. Recommended & prescribed by leading physicians and dentists. (1986, p. 6)

While federal regulation has somewhat dampened their exuberance, health claims remain a favored tool of the food industry. By including claims on their packages, manufacturers hope to differentiate their products from others, resulting in increased market share (Caswell & Padberg, 1992).

3.3 TYPES OF HEALTH CLAIMS

Health claims can be classified as either general or specific. General claims are broad, "good for you" statements that do not refer to precise positive health effects related to the product. Specific claims do make an explicit link between their product and a particular aspect of health. These can be either disease risk-reduction claims, which allege a protective effect against a specific condition, or function claims, which propose to buoy the body's natural functions

(L'Abbe, Dumais, Chao, & Junkins, 2008). An ingredient claim, which can be general or specific, singles out a particular product attribute that bestows the benefit, as opposed to the product as a whole (Harris et al., 2009).

Most health claims appear on the fronts of packages, and consist of an eye catching graphic with a small amount of text. If details about the claim and the product are included, they are often on a less prominent part of the package. In addition to these traditional claims, manufacturers are experimenting with new formats. For example, package labels containing a website address have become popular among cereal manufacturers. These "health URLs" direct the consumer to a company website containing additional health claims and product promotions (Harris et al., 2009).

4.0 PACKAGE HEALTH CLAIM REGULATION IN THE UNITED STATES

4.1 HISTORY OF HEALTH CLAIMS AND THEIR REGULATION

4.1.1 Empowerment of the Food and Drug Administration

The effort to restrict the use of health claims or regulate their accuracy is by no means recent. Regulation in the United States began in earnest with the passing of the Federal Food and Drug Act of 1906. This act gave the U. S. Food and Drug Administration (FDA), still in its infancy, its first regulatory mandate (Swann, 1998). Among other things, Section 8 of the act prohibited label statements that were "false or misleading in any particular" and provided the agency with means to take measures against such claims (Hutt, 1986, pg.5). This legislation fulfilled its purpose by greatly reducing the incidence of completely spurious health claims (Hutt, 1986).

However, this system was soon complicated by the introduction of scientific evidence supporting the existence of vitamins, and touting their health benefits. The spread of this information to the public led to a surge in unsupported claims of vitamin content by manufacturers. As related in a 1929 FDA report,

> Some manufacturers have taken advantage of the general public interest in vitamins to exploit preparations as sources of vitamins when the facts do not warrant it. The administration has attempted to put a damper on unwarranted labeling of this character, seeking as far as possible to induce the manufacturers to make their own investigations and limit the statements on their labels to demonstrable facts. (Federal Food, Drug, and Cosmetic Law Administrative Reports, 1907-1949, as quoted by Hutt, 1986, p. 7)

Compounding this problem, the early 20th century also saw significant growth in weight loss-related health claims. The FDA struggled to rein in these extravagant claims made by "fraudulent remedies for obesity and leanness" (Hutt, 1986, pg. 8). However, it was soon clear that these developments had significantly altered the regulatory environment, and that existing legislation required modification in order to accommodate the changes. In 1938 the Federal Food, Drug, and Cosmetic Act (FDCA) was signed into law as a replacement for the Federal Food and Drugs Act of 1906 (Hutt, 1986). This act expanded upon previous FDA responsibilities and greatly enhanced the agency's powers. Officials were no longer required to establish the manufacturer's motive or prove a consumer effect before taking action. Under FDCA, even a true claim may be challenged if its presentation is misleading. The FDA fully availed itself of these powers, remaining committed to strict enforcement, and pursuing, often successfully, criminal prosecution (Hutt, 1986).

4.1.2 Diet and disease linked

Yet another challenge raised by scientific advances was on the horizon. In the 1950s, research began to suggest a link between certain dietary behaviors (e.g. animal fat consumption) and higher serum cholesterol levels, and consequently, increased risk of heart disease (Hutt, 1986). The notion that an individual's risk of heart disease was controllable through dietary modification opened the door for further food health claims, much as the discovery of vitamins had previously. The FDA, however, asserted that a causal link between diet and heart disease was not firmly established, and therefore any labels stating otherwise would be actionable (Hutt, 1986). This stance slowly softened over the next three decades as medical evidence strengthened

and received public support from the American Heart Association and the American Medical Association. Under pressure from the medical community, other government agencies, and public opinion, the FDA slowly began to consider health claims on general-purpose food labels as a potentially useful tool for consumers (Hutt, 1986). This gradual transition marked a critical shift from a regulatory philosophy of strict compliance to the inclusion of health advocacy role.

4.1.3 The move toward health claims and mandatory nutrition labeling

A key component of this new directive was the provision of comprehensible nutrition content information that could be utilized by consumers when choosing products. This was the objective of the nutrition labeling regulations put into place by the FDA in 1975, which required products featuring health claims to also display "affirmative label disclosure of basic nutrition information" (Hutt, 1986, pg. 35). Additionally, fortified foods were reclassified from "special dietary foods" to "general-purpose foods" and therefore became subject to these regulations. Mandatory disclosures, in a specified format, included fat and calorie content, while nutrients such as sodium and cholesterol remained voluntary (Hutt, 1986).

Despite these advances, health claims remained highly restricted. The FDA applied strict safety and efficacy testing requirements for any health claims made, strongly discouraging manufacturers from making them (Caswell & Padberg, 1992). The turning point came in October of 1984, when Kellogg chose to flout FDA guidelines in its promotion of All-Bran cereal as a protective measure against colon cancer. Kellogg had the full backing of the FTC and the National Cancer Institute, both of which pressured the FDA to reevaluate its policies. The FDA chose not to challenge the Kellogg campaign, setting the tone for a more permissive administration. Over the following years, the FDA did begin to embrace the inclusion of health

claims, and loosened its standards (Caswell & Padberg, 1992). This resulted in a new surge in health claim use, and the debate turned to the question of what types of claims were permissible, and how to make them more productive (Calfee & Pappalardo, 1991).

4.1.4 Nutrition and Labeling Act of 1990

Following the wave of regulation reforms in the 1970s-80s was the Nutrition Labeling and Education Act (NLEA), an extensive reform that is regarded as "one of the most important public policy initiatives related to nutritional information and food marketing" (Nayga, 1999, pg. 30). The NLEA entailed the design and implementation of a mandatory, uniform, and comprehensible food labeling system intended to aid consumers in choosing foods that support a healthy diet. This was a major investment of resources intended to improve the diets of Americans (Nayga, 2000).

Included in the overhaul was the establishment of official recommendations for serving sizes and daily nutrient intake, based on a 2,000 calorie per day diet (Nayga, 1999). The NLEA mandated the now familiar table of nutrition information, which provides the recommended serving size, number of servings per package, calories per serving, and calories from fat per serving. The amounts of six chosen nutrients are listed, and also appear as a percentage of recommended daily values per serving (Garretson & Burton, 2000).

NLEA also began the process of defining common health claims with explicit nutritional criteria. In order to label a product as "low in fat," for example, each 100 grams of food can contain no more than 3 grams of fat, with less than 30% of total calories derived from fat. Other claims are judged relative to recommended daily allowances (RDA); for example, "high in fiber" products must provide at least 20% of the RDA for fiber (Garretson & Burton, 2000).

4.1.5 The Federal Trade Commission

In order to present a consistent and unified message, marketers typically design labeling that complements their advertising campaign. However, in the food industry the irregular division of regulatory oversight between the FDA and the Federal Trade Commission (FTC) complicates this process. In the most generalized sense, the FDA oversees food labeling while the FTC regulates advertising, but the reality is much more convoluted (Caswell & Padberg, 1992).

This system originated in the period of heavy regulatory development at the beginning of the 20th century. Jurisdictions were not clearly defined when the agencies were developed and empowered, and the passage of the Federal Trade Commission Act of 1914 further muddied the boundaries. Section Five of this act outlawed "unfair methods of competition in commerce" and charged the FTC with enforcement (Hutt, 1986, pg. 6). The ambiguity of this statement was hotly debated for 24 years, after which the Wheeler-Lea Amendments of 1938 attempted to elaborate upon Section Five, adding that "unfair or *deceptive acts or practices* in commerce [italics added]" were also illegal (FTC Act 88 Stat. 2183, 2193, 1975). The FTC chose to interpret these statements as encompassing misleading health claims not only in advertising, but also on food packages. This translation was consistently upheld by the courts, which ruled that "although sections 15-18 of the FTC Act apply only to food advertising and not to food labeling, section 5 continues to apply fully to all food labeling" (Fresh Grown Preserve Corp. v. FTC, 125F.2d 917 2d Cir. 1942, as cited in Hutt, 1986, pg.10).

Traditionally, the FTC has discretionary power in its application of this mandate. In the case of claims based on contentious medical findings, unproven claims are potentially permissible if accompanied by a disclosure. If a claim is deemed deceptive and the FTC chooses to pursue action, a cease and desist order is filed, followed by an administrative hearing (Hutt,

1986). If this action is insufficient, the FTC, like the FDA, has proven willing to enforce its rulings through litigation. It may pursue a simple discontinuation of the offending labeling or advertising. However, if the misleading claims are judged to have wrought considerable damage, the manufacturer may be required to display a counteractive statement, either temporarily or permanently (Hutt, 1986).

Despite this readiness to prosecute, the FTC does advocate health claims that are substantiated by scientific research and endorsed by respected institutions (Geiger, 1998). In this regard, they were a step ahead of the FDA in their recognition of the distinction between "merely preventing deception and affirmatively increasing the informative value of advertising" (Beales, Craswell, & Salop, 1981, pg. 495).

4.1.6 Jurisdictional overlap

While the FTC wields some authority over food labeling, there is additional redundancy in the FDA's authority over food advertising. The FDA has long held to an expansive definition of labeling that includes all materials related to a product. It asserts, therefore, that health claims made in advertising should make the product subject to labeling regulations, even if no claims are made on the product itself (Hutt, 1986). Specifically, the Federal Food, Drug, and Cosmetic Act defines labeling as

> …written, printed, or graphic matter which accompanies a food … and by regulation this includes such matter accompanying an article while it is in interstate commerce or while held for sale after shipment or delivery in interstate commerce. Written, printed or graphic matter descriptive of a food … may at one time be used as advertising and at another time accompany the article and thereby become labeling. (Commissioner of Food and Drugs, 1971)

In an effort to manage this jurisdictional overlap, the FDA and FTC developed a "working agreement," introduced in 1954 and revised in 1971 (Calfee & Pappalardo, 1991). The memorandum states that

> (1) The Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods. … In the absence of express agreement between the two agencies to the contrary, the Commission will exercise sole jurisdiction over all matters regulating the truth or falsity of advertising of foods…
> (2) The Food and Drug Administration has primary responsibility for preventing misbranding of foods. … In the absence of express agreement to the contrary, the Food and Drug Administration will exercise sole jurisdiction over all matters regulating the labeling of foods… (Commissioner of Food and Drugs, 1971)

This division allows each agency to focus on one regulatory sector. For unusual situations in which collaboration is required, designated liaison officers coordinate the agencies' responses to avoid overlapping or conflicting actions (Commissioner of Food and Drugs, 1971).

4.2 REGULATION IN PUBLIC HEALTH AND THE FOOD MARKET

4.2.1 The need for regulation in the food market

The need for regulation of food labeling and health claims is not a universal assumption. As Calfee and Pappalardo point out, there is a First Amendment concern about "whether it is ever appropriate to prohibit sellers from including in ads simple, truthful information about expert opinion on food and health" (1991, pg. 35). There is also the view that traditional market forces could produce the desired consumer information without the interference of paternalistic agencies (Beales et al., 1981).

Economists and policy analysts, who make a strong case that the food information market will not self-regulate, have refuted the latter supposition. Caswell and Padberg (1992) argue that market forces will not act as expected in an unregulated labeling environment. This is because claims about nutritional content are not verifiable by the average consumer. The effect increases as foods become more complex, distancing the consumer from the basic ingredients, and further obfuscating any health qualities (Caswell & Padberg, 1992). This convolution results in the disassociation of foods from consumers—as products become more highly processed, they are more difficult for shoppers to evaluate.

Labeling practices reflect this continuum: simple products (e.g. fresh produce) are less extensively advertised and labeled because their value is more readily apparent. As the product becomes more complex, advertising and health claims increase because the consumer requires notification about the nutrient content (Caswell & Padberg, 1992). However, if consumers cannot distinguish reliable from unreliable claims, their choices cannot create market pressure for improvement. In fact, when health claims can improve a product's sales, and there is no way for consumers to verify the claims, an unregulated system would in essence give sellers an incentive to lie with impunity (Calfee & Pappalardo, 1991).

The advantages of regulation are not limited to consumers. Regulation also benefits manufacturers by giving their claims more credibility. In an unregulated environment, the proliferation of inaccurate health claims would significantly erode consumer trust in such claims, making them less effective (Caswell & Padberg, 1992). Additionally—assuming that the government has a responsibility to provide nutritional guidance to the public—it may be more cost effective to regulate commercial dissemination of this information, rather than creating an original promotional campaign (Calfee & Pappalardo, 1991).

4.2.1.1 A new model for health claim regulation: Third-party roles

Although the influence of package health claims on actual consumer purchasing behavior is not completely clear (Borgmeier & Westenhoefer, 2009; Grunert & Wills, 2007), the need for government oversight remains. Caswell and Padberg (1992) posit that food labels fulfill functions on several levels of the food market system beyond supplying consumers with point-of-purchase information. They define five of these "third-party" roles as crucial to the consideration of any regulatory debate.

Influence on product design

Regulated health claim labels are determined by the nutritive properties of their product—but the effect also occurs in the other direction. If health claims confer a competitive advantage, then they can also have an influence on future product design. Well-designed labeling criteria will influence manufacturers to reverse-engineer their products, in order to take advantage of as many claim qualifications as possible. This can include reformulations to achieve positive claims, or avoiding reportable ingredients in order to avoid negative labeling. The influence on product design seems to hold true even if manufacturers do not believe that consumers use the labels—as long as some agency is observing and publicizing the results.

Advertising franchise role

Although the FTC holds authority over non-package advertising, FDA labeling regulations can nonetheless guide advertising content. Because claims made in other media trigger mandatory nutritional disclosures on packaging, restrictions placed on label content implicitly limit the use of those claims in other media. In this way, labeling regulations set the tone for a product's entire marketing campaign.

Public Surveillance Assurance

Put simply, the presence of nutrition labeling and regulation reassures the public, even if the labels are not used in a point-of-purchase capacity. Caswell and Padberg describe this as "existence value:" a sense of security bestowed by the impression that someone, somewhere, is watching and taking care of things. In this way, regulation can decrease consumer skepticism—the simple existence of surveillance "signals to consumers that they can have confidence in the food supply's quality… and the reliability of food labels" (Caswell & Padberg, 1992, pg. 465).

Forum for consensus and defining public values

The presence of multiple and sometimes conflicting nutrition messages is a source of confusion for the public, contributing to consumer skepticism of such recommendations. In this environment, it is critical to convey a sense of assurance behind any dietary recommendations. Regulation can be a key to accomplishing this, as the very process of choosing what and how to regulate forces some level of national expert consensus. The choice of regulatory specifications then signals to consumers the issues about which they should be most concerned, providing a single, consistent nutrition message.

Nutrition education format

As product complexity increases and foods become less readily classifiable, nutrition education takes on an ever more crucial role. In light of this, the choices made in labeling regulation must deliberately complement national nutrition education initiatives. In the absence of this regulatory function, the impact of both labeling and education lessens. Conversely, if the emphasized qualities and proscribed labeling format reflect the educational message, the influence of each will increase.

Caswell and Padberg stress the importance of considering these third-party roles when contemplating any type of regulatory changes. They propose a comprehensive theory of food labeling that encompasses all of these functions, in addition the use of labeling in a point-of-purchase capacity, in order to foster changes in the broader food system (Caswell & Padberg, 1992). Recommendations made in Chapter 8 further explore this framework.

4.2.2 Potential costs of health claims and regulation

The most obvious cost of regulated health claims is the financial one: reaching and maintaining compliance with labeling laws is very costly to manufacturers, and enforcement of those regulations is a major expense for the government as well (Garretson & Burton, 2000; Nayga, 1999). These costs increase concurrently with the reach and specificity of the regulations. It is speculated, however, that long-term financial savings will be realized in terms of reduced spending on health campaigns and, ultimately, lower health care expenditures (Calfee & Pappalardo, 1991).

Calfee and Pappalardo (1991) hypothesize the existence of three additional categories of potential costs related to health claims on food packaging:

- Economic: This includes regulatory compliance costs passed on to consumers, as well as compromises in product qualities such as taste or convenience. Given time, competitive forces should minimize this effect.
- Adverse health effects: Persuading consumers to purchase healthier foods may have unintended negative consequences if they perceive this as a health measure that in any way replaces basic steps such as medical care, screenings, or physical activity. Additionally,

consumers may be likely to eat larger amounts of a "healthy" food than they might otherwise, or be less prudent with their other dietary components.

- Market spillover effects: There are opportunities for health claims to have a negative effect on the market for health information. First, health claims shown to be false would lessen the impact of true claims. Second, consumer reliance on food claims could take the place of more objective, scientific recommendations. Third, a health claim campaign focusing on a specific nutrient or quality may lead to the neglect of other nutritive factors.

Another possible hindrance to the operation of the health claim information market model is the potential for "free-riding." Free-riding occurs when smaller brands do not display health claims, but similar larger brands do. The consumer can apply the given information to the product lacking the claim, allowing that brand to benefit without the accompanying expense. This phenomenon lessens the market advantage bestowed by health claims, and may discourage larger brands from investing in them. However, the problem can be minimized by framing the claim as though it applies only to that specific brand (Calfee & Pappalardo, 1991).

4.2.3 Benefits of regulated health claims

While the above concerns are significant, the potential and realized benefits of efficiently regulated health claims are considerable.

Improvement of market function

Given the conditions that consumers are aware of desirable nutritional qualities, and have the intention and resources to locate and purchase products featuring those qualities, the inclusion of effectively regulated health claims should improve the market's ability to select for

healthier products (Caswell & Padberg, 1992). In fact, the current regulatory position that health claims should be encouraged reflects the view that "information in the hands of consumers facilitates rational purchase decisions; and, moreover, is an absolute necessity for efficient functioning of the economy" (44 Fed. Reg. 50218, 50222 (1979), as cited by Beales 1981, pg. 493). Essentially, claims incorporate health as a market driver, creating competitive forces that can lead to the development and sale of more nutritious products. This creates an economic incentive for manufacturers to generate and broadcast dietary information, leading them to invest heavily in nutrition research in the hopes that some of it may benefit them (Calfee & Pappalardo, 1991).

Efficient presentation of information to the consumer

Ultimately, the broad public health goal for package claims is the improvement of the population's diet. It is difficult, however, to evaluate the actual health benefits realized by food labeling regulation because the causal chain is so complex—health claims are only one of a multitude of factors that determine health status (Caswell & Padberg, 1992). However, it is expected that labels constitute a straightforward way for shoppers to obtain nutrition information, which they can then use to make healthier purchases (Calfee & Pappalardo, 1991; Feunekes, Gortemaker, Willems, Lion, & van den Kommer, 2008).

Calfee & Pappalardo (1991) provide an excellent illustration of this point. They explain that the severe limitations previously placed on health claims created a barrier for those wishing to choose more nourishing food items. Prior to 1984, restrictions resulted in two distinct "streams of information." The first, "ambient" stream was information received from public health sources about the components of a healthy diet; however, those sources did not mention specific foods that would fit the criteria. The second stream, in the form of commercial

marketing, provided information about specific products and bans—but manufacturers were legally unable to link their products with specifics from the ambient stream. As a result, consumers were left to deduce for themselves which foods might have the desired qualities. The use of health claims provides a bridge between the two streams of information, allowing consumers to utilize both.

4.2.4 Substantiation and pre-approval of health claims

The implementation of health claim regulations carries certain practical concerns. Foremost is the level and method of substantiation that is required of the claims. Levels of substantiation may vary according to the context of the claim, or may be fixed across all claims. Calfee and Pappalardo advocated a fluid guideline that would consider "both the probability the claim will be true and the benefits or costs that would ensue" (1991, pg. 41). However, some authorities support a fixed standard, applicable in every circumstance (Calfee & Pappalardo, 1991).

This then raises the issue of how to determine a universal level. Consensus can occur in three spheres: scientific consensus is the most straightforward, but by no means simple, method. It requires research-backed majority agreement among scientific authorities for any claims of nutrient effect. Scientific consensus is widely acknowledged as a key specification; the FTC, for example, ruled in 1971 that manufacturers must be able to provide scientific substantiation for any claim on demand (Hutt, 1986). A second level of substantiation, advice consensus, focuses on public practice and perception, valuing claims that are accessible to the consumer. A close examination of context and wording is necessary for a consensus of this nature. Finally, there is policy consensus, which questions whether the claim is an appropriate use of the agency's regulatory role (Calfee & Pappalardo, 1991).

There is also the question of whether manufacturers should be required to seek pre-approval from the FDA for the substance and wording of health claims. This approach is judged largely impractical, as it would result in significant delays for the seller, discouraging manufacturers from making health claims. Perhaps more significantly, the time lapse would hinder the industry's ability to respond to and promote new research findings. As one of the greatest strengths of health claims is the ability to notify unaware consumers of important dietary considerations, this delay could significantly affect their public health value (Calfee & Pappalardo, 1991).

A final point is concerned with the balance between positive and negative nutritive aspects in health claims. Some public health advocates would argue that products with significant negative qualities be required to announce those characteristics alongside their positive health claims (M. Nestle & Ludwig, 2010). Research supports the importance of negative attribute disclosure in healthy diet promotion, as discussed later in this thesis (Moorman, 1990). However, although this proposal is interesting and valid, it poses practical concerns—such a policy would almost certainly deter the majority of manufacturers from featuring health claims.

5.0 CONSUMER USE OF HEALTH CLAIMS

5.1 EXTERNAL FACTORS AFFECTING THE SELECTION PROCESS

When a consumer enters a typical American supermarket, they face more than 15,000 products from which to choose their household groceries (Caswell & Padberg, 1992). A reasoned selection of items from this dazzling array requires time, research, knowledge, and planning; yet studies show that as many as two of every three products purchased are chosen in the store (Food Institute Report, as cited by Caswell & Padberg, 1992). Health claims are only one of a kaleidoscope of factors that influence this selection process.

5.1.1 The shopping experience

The product attributes of most interest to consumers are cost, taste, nutrition, and convenience (Caswell & Padberg, 1992). Judging the relative value of a range of similar products based on these criteria is a daunting task, complicated by input from multiple sources of often conflicting and confusing information: prior experience, media advertising, word of mouth, medical and public health sources, and packaging (Caswell & Padberg, 1992). Additionally, the time constraints that affect many consumers significantly limit the nutrition information search process and to undermine consumers' ability to make sound, reasoned choices (Beatty & Smith, 1987; Nayga, 1999; Park, Iyer, & Smith, 1989). Finally, consumers are often subject to other

distracting environmental stimuli while shopping. Indeed, the difficulty of replicating these conditions in an experimental setting greatly complicates research in consumer point-of-purchase behavior (Feunekes et al., 2008).

In this environment, food package labels can be a valuable source of information, yet the extent to which package health claims influence consumer purchasing is unclear (Caswell & Padberg, 1992). According to FDA research, the proportion of consumers for whom labels play a role in a first-time purchase decreased significantly from 1992 to 2002, especially among those less than 35 years of age (Food and Drug Administration, 2009b). Caswell and Padberg (1992) speculate that consumers, faced with overwhelming input and limited time and interest, may simply opt out of the nutrition information search process in order to protect themselves from information overload. Given that possibility, it is important to keep in mind that reliance solely on labels to create and sustain dietary changes is ill advised.

5.1.2 Basic concepts of consumer label usage

Demographics

Demographic information can offer insight into patterns of labeling usage. Nayga (1999) identifies several demographic characteristics that influence the way that consumers interact with food labeling:

- Gender: Women are more likely to seek health information for food products and to consider it when making purchasing decisions. Other researchers, reaching the same conclusion, speculate that this may be because women place a greater value on nutrition than men (Blitstein & Evans, 2006).

- Age: Consumer perception of the personal utility of labeling is negatively correlated with their age—younger people are more likely to value and use nutrition information (Nayga, 1999). Other research suggests that older consumers have lower comprehension of the information than young people but greater confidence in their ability to interpret it (Moorman, 1990).
- Body mass index: Nayga's (1999) findings suggest that as consumers' body mass index increases, their perception of the utility of nutrition information on packages decreases. This is a particularly consequential finding, as it indicates that those who may be at higher risk are less likely to benefit from health claims. However, researchers have also found that other health measures (i.e. having high blood pressure, or being diagnosed with or at risk for heart disease and cancer) are associated with increased use of labeling and health claims (Szykman, Bloom, & Levy, 1997).
- Income: Higher income levels were found to be associated with increased perceptions of the usefulness of nutrition labeling (Nayga, 1999).
- Education: Findings about the relationship between education level and food label perception are mixed. Nayga (1999) found that higher levels of education are associated with reduced perceived utility of labels. This contradicts his own prior findings, which indicated that college educated meal planners are more inclined to use nutrition labels (1996). Moorman's research (1990) produced similarly complex results. Those findings indicate that while increased education is associated with greater comprehension, it also has a negative effect on the motivation to acquire nutrition information and the perceived ability to process it. Moorman puts forward two possible explanations: (a) consumers with higher education

levels believe that they have adequate knowledge and do not need additional information, or (b) they feel less able to process it because they are more aware of the issue's complexity.

Simplicity and ease of use of claims and information

In focus group research, consumers have expressed a preference for simple package health claims as an alternative to difficult-to-interpret nutrition information panels (P. Williams, 2005). This is especially true for individuals with low perceived nutritional knowledge, who tend to prefer more streamlined formats (Feunekes et al., 2008). However, this approach to labeling raises the issue of prioritization. Because the content is minimal, the author of a simple claim must decide which information is most crucial to their purpose.

Location of the claim

Mandated nutrition disclosures (e.g. tables, lists of ingredients) typically appear on the back or side panels of packaging. However, as noted above, this information may be inaccessible to consumers, who prefer short and simple claims, especially on the front of the box or package (Roe, Levy, & Derby, 1999; Svederberg, 2005; P. Williams, 2005). Such claims are now a significant source of nutrition information, and are a way for manufacturers to distinguish their products. Front-of-package (FOP) labeling programs are discussed in greater detail in Chapter 6 of this thesis.

General nutrition knowledge and self-efficacy

Consumer knowledge of basic nutrition information is linked with higher levels of self-efficacy—in this case, a consumer's belief that they are capable of improving their health through dietary choices. Self-efficacy, in turn, is positively linked with health claim utilization, as detailed in the following chapter (Moorman, 1990; Nayga, 1999; Szykman et al., 1997).

These findings suggest that general nutrition education programs will have a beneficial effect on health claim usage (Szykman et al., 1997).

Consumer trust and skepticism

Research widely suggests that distrust of claims and their sources is a significant barrier to consumers' effective use of health claims. In one study, the Food Standards Agency of the United Kingdom found that more than 50% of interviewees did not believe the health claims that they read on food labels (2004). Predictably, shoppers who are skeptical of health claims are far less likely to use them when making decisions (Szykman et al., 1997). Those who do express faith in health claims may presume that the claims have been evaluated and approved by a government agency, even if this is not the case (Mason & Scammon, 2000). It follows that effective health claim regulation by a federal agency should, over time, reduce consumer skepticism.

5.2 SELECTED MODELS OF CONSUMER LABEL USAGE

5.2.1 Transtheoretical Model—Stages of Change

The transtheoretical model was developed as a way to model deliberate behavioral change, such as a transition to improved dietary practices. The five stages sequentially map progressions of intent and behavior that culminate in successful change (see Figure 1). The initial stage, precontemplation, indicates that the consumer does not plan to change their behavior. When the consumer accepts that a healthy diet is a necessity, but has no immediate plan to change, they

have entered the contemplation stage. The preparation stage begins when the consumer formulates plans for change, followed by the action stage, in which the plans are implemented. Finally, the consumer enters the final, maintenance stage, during which the changes are sustained over time (Coulson, 2000).

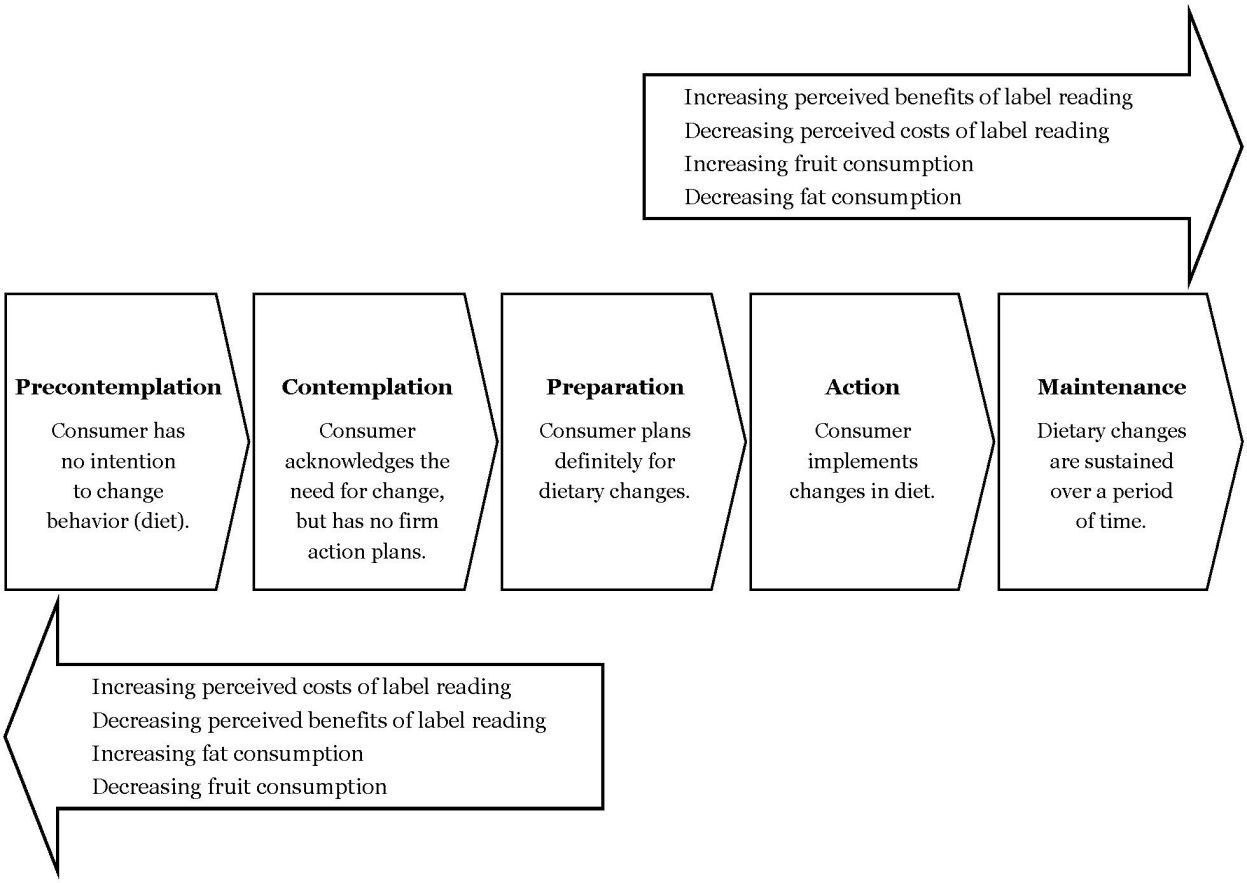

Figure 1: Coulson's application of the transtheoretical model (2000)

Coulson (2000) applied the stages of change model to the use of food labeling. He hypothesized that these stages correlate with the consumer's perceived costs and benefits of label utilization. A person in the action or maintenance stage would therefore perceive greater benefits in label usage, while a person in the pre-contemplation stage would anticipate more

potential costs. To test this theory, Coulson conducted an experiment that assessed participants' current stage of change through their self-described label reading habits. His study measured each participant's balance between perceived needs and costs with a 32-item Likert-style questionnaire. Sample pro and con questions are, respectively, "Reading labels allows me to compare similar food stuffs," and "Food labels are not clear" (pg. 664). Participants then used a 5-point Likert scale to describe the influence of 12 factors on their food choices. Finally, the study collected self-reported frequencies of fruit, vegetable, and fat consumption.

Coulson found that participants' stages of change, as measured by this experiment, significantly corresponded with perceptions of the utility of label information. Those in the maintenance stage reported many more perceived "pros" and fewer "cons." Additionally, later stages were associated with higher fruit and lower fat consumption. These results support the use of the stages of change model for understanding food label usage. Coulson suggests a practical application for this framework: Segmenting the audience by stages of change will give targeted nutrition education messages greater impact.

5.2.2 Theory of External Consumer Information Search

Usage of food labels can also be examined through the theory of external consumer information search. This theory describes the consumer's deliberate pursuit of product information prior to purchase as the result of multiple factors. Nayga (1999) applies this concept to the use of food labels by specifying 21 relevant influences, some of which have been described earlier in this thesis, categorized into three groups (see Figure 2). Any combination of these elements may work to determine the consumer's perception of label utility and the extent of their consideration.

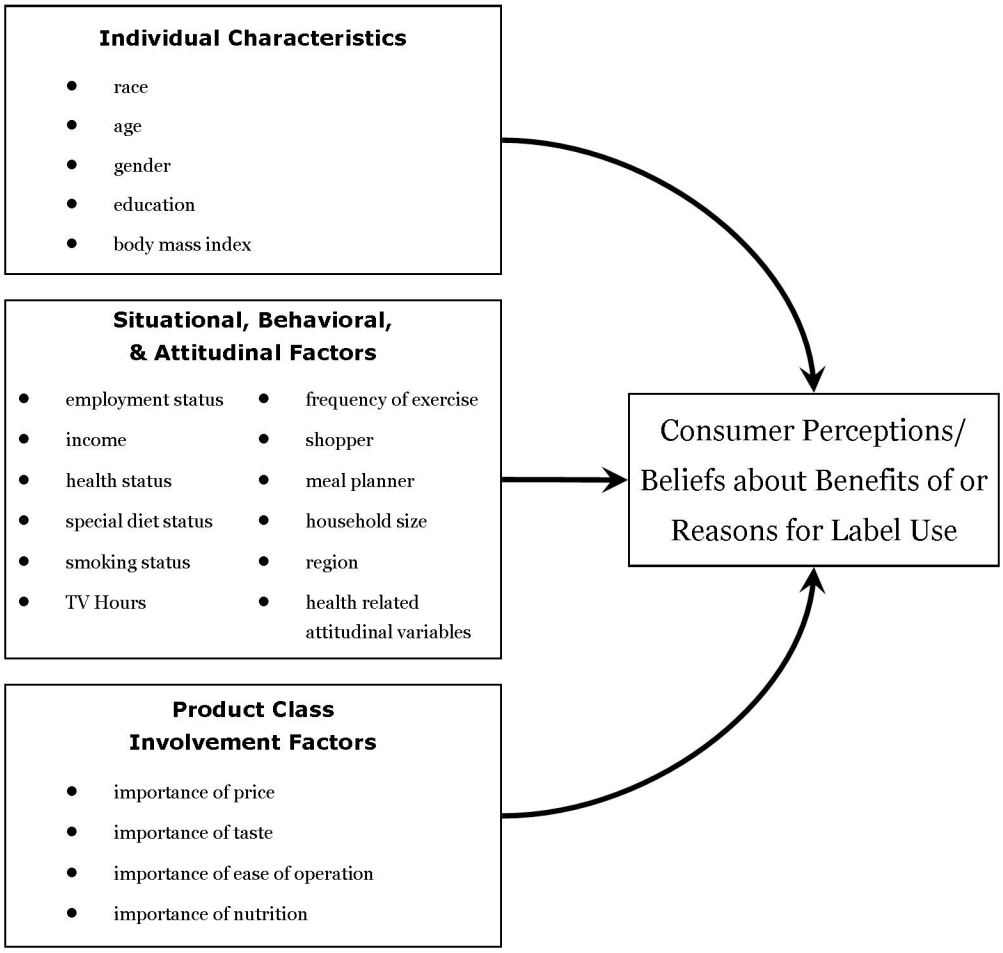

Figure 2: Nayga's conceptual framework for consumer perception of food labels (1999)

The first category, individual characteristics, contains many of the same demographic variables discussed earlier in this chapter. However, new concepts are introduced among the situational, behavioral, and attitudinal factors, including two familiar constructs from the health belief model (Mikhail, 1981). The first, perceived risk, is the consumer's self-evaluation of their susceptibility to potential health problems; perceived benefits are the consumer's assessment of the advantages resulting from health claim use. Higher values of either construct encourage increased label use. Nayga (1999) also acknowledges self-efficacy regarding dietary change and motivation to seek information as positively influential factors.

Nayga's framework may have valuable applications in nutrition education. By examining the roles that these factors play in the consumer information search, including their interactive effects, public health educators can design campaign messages that target the most influential factors or sets of factors. Further development of this model can also contribute to more effective nutrition label design. Any profitable public health use of food labeling is contingent upon promoting the perception that nutrition information is both applicable and beneficial to all consumers (Nayga, 1999).

5.2.3 The Consumer Utilization of Information Process

A different conception of consumers' use of health claims incorporates qualities of the claims themselves. Moorman's 1990 study proposes a framework modeling the role that consumer characteristics and stimulus (label) characteristics play in product choice. This model, depicted in Figure 3, clearly maps the influence of both sets of attributes on each stage of the decision making process.

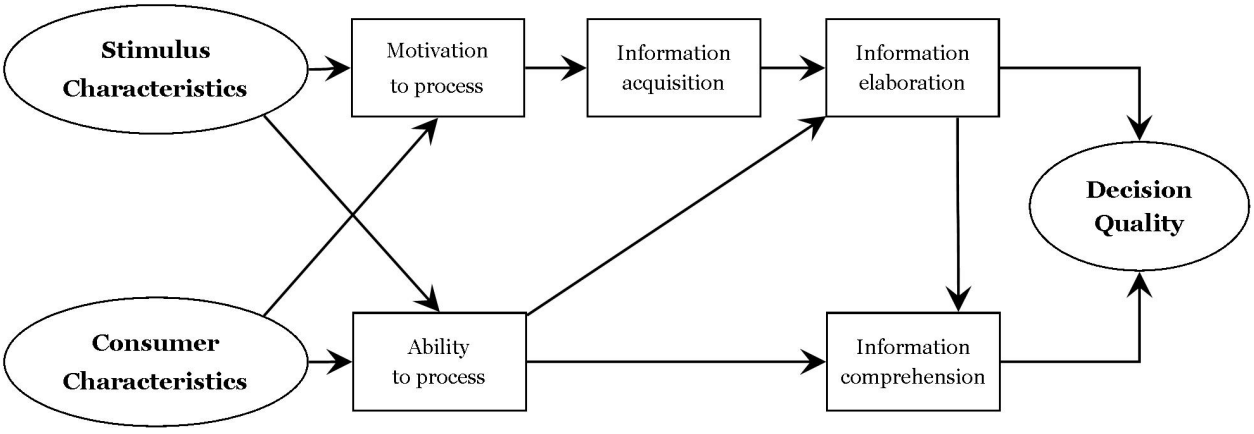

Figure 3: Moorman's Nutrition Information Utilization Process (1990)

Stimulus characteristics

Moorman (1990) identifies two stimulus characteristics to consider when presenting nutrition information. The first is consequence information, which describes the effects that specific product properties will have on the consumer. While most health claims focus on positive consequences, consumers give more attention to assertions of negative consequences resulting from consumption. This supports the policy proposal, discussed in Chapter 4 of this paper, that manufacturers be required to disclose any negative characteristics of their products alongside positive health claims.

In order to maximize the effect of negative consequence claims, a two-step approach is required. First, the consumer must be emotionally engaged by a sense of danger. This generates perceived susceptibility, activating the consumer for further information. Following this warning is a recommended course of action for the consumer to take in order to minimize the risk. This combined message increases the purchaser's motivation to process information.

The second noted stimulus characteristic is reference information, which is the framework of information used by the consumer to code the nutrition message. This may be information that the individual already possesses, or information that is contained within the claim. Moorman favors the use of reference information given within the context of the message, because this eliminates reliance on consumer knowledge, thereby increasing accessibility. Contextual information also allows the consumer to better evaluate an individual product without comparison to others. Moorman provides the example of nutrient levels given as percentages of recommended daily allowances (RDAs), in addition to the exact quantities. Comprehension of the message is not contingent upon existing knowledge of nutrient levels;

also, the information provides its own frame of reference for evaluation, and does not require comparison to other products.

Consumer characteristics

As in other models of label usage, Moorman (1990) accounts for the impact of consumer characteristics on the nutrition information utilization process. In addition to demographics, this framework describes four consumer traits: nutrient familiarity, acquisition, elaboration, and comprehension. Experimental research conducted by Moorman demonstrated that nutrient familiarity increased self-efficacy for label evaluation. However, the acquisition, elaboration, and comprehension steps did not benefit from familiarity, nor was the final decision quality improved. Moorman suggests that familiarity may result in a complacency that interferes with information utilization.

Other qualities that may assist in this process are consumers' motivation to acquire nutrition information and perceived ability to interpret that information. The final consumer characteristic highlighted in this framework is preventive orientation. An individual's approach to handling health concerns determines their orientation: a "preventive" orientation indicates that they are concerned with addressing potential problems before they are afflicted, while a "curative" orientation describes someone who seeks only to treat symptoms that they already experience. Moorman found that preventative-oriented consumers outperformed their curative counterparts in every stage of the information utilization process.

The value of this model for regulators and health promoters is the inclusion of stimulus characteristics as a manipulable variable. Models discussed elsewhere in this chapter suggest factors to consider when tailoring a nutrition message to the desired audience. Moorman's proposal retains consideration of those consumer characteristics, but supplements that approach

with more proactive strategies. This incorporation of stimulating elements allows communicators to craft claims that function well with less reliance on audience characteristics. This quality makes Moorman's model particularly well suited for application to nutrition labeling program planning.

6.0 FRONT-OF-PACK NUTRITION LABELING PROGRAMS

6.1 BACKGROUND

Front-of-pack (FOP) labeling programs[1] are coordinated health claim campaigns designed to provide an at-a-glance summary of products' nutritional quality. Like all health claims, the purpose of FOP labels is to influence the consumer to purchase the claim-bearing product. This goal is approached with a variety of motivations and methods, and with mixed success. However, given what is known about labeling usage, the potential benefits of an effective FOP program are tremendous.

FOP programs are often directed by government or public health agencies, although they may also be organized by private entities, such as a food manufacturing company or a chain of retail outlets. Whether public or private, the administrators set up an overseeing body, usually composed of a mixture of experts in pertinent fields. Using pre-determined standards, this panel establishes a clearly defined set or sets of nutritional criteria. Manufacturers typically pay a licensing fee to feature the logo on products meeting these standards. In the case of corporate programs, the application of the logo is limited to the products manufactured or sold by that company (Smith et al., 2002).

[1] The literature also refers to FOPs as food information programs (FIPs).

FOP systems address several barriers to label use. Their extreme simplicity lessens the amount of time required to process the label, and requires minimal nutritional literacy (Lando & Labiner-Wolfe, 2007). The visual format is also accessible to a range of demographic sectors, even across national borders. If endorsed by a known agency, established and consistent FOP campaigns may reduce consumer skepticism by increasing perceived reliability (Feunekes et al., 2008). As an additional benefit, FOP programs can influence manufacturers to reformulate foods in order to fit the criteria (Smith et al., 2002).

Experimental research suggests that FOP labels work. Fuenekes et al. (2008) found a correlation between simple front-of-pack claims and stated intentions to decrease consumption of less favorably labeled foods. Based on their results, the researchers recommend the use of simple FOP formats, leaving detailed nutrition information on the back of the package for those who seek it (Feunekes et al., 2008). Focus group research conducted by the FDA supports this conclusion. Participants in that study felt that a front-of-pack icon would facilitate their efforts to choose healthy foods (Lando & Labiner-Wolfe, 2007).

6.2 POSSIBLE FORMATS

6.2.1 Integrative: "seal of approval" systems

Integrative FOP labels consist of a single logo, or seal of approval. The seal typically contains a simple, central graphic accompanied by a minimum of text. Products that meet the applicable set of criteria are eligible to carry the seal; products that do not qualify may not use the program in any capacity (Smith et al., 2002).

Integrative systems excel in their simplicity; however, this approach does raise some public health concerns. Seal of approval formats create a false dichotomy of good and bad foods that does not allow consumers to distinguish gradations of relative healthiness (Smith et al., 2002). Because the logos do not contain additional information, they do not allow comparison among logo-bearing products or those without logos. Other researchers speculate that a "good for you" message encourages overconsumption of those products, or may become a justification for accompanying purchases of other, less healthy foods (Scott & Worsley, 1994).

Furthermore, integrative FOP labels have the potential for a "halo" effect, wherein positive impressions created by the seal generate the perception of other, non-existent benefits (Ford, Hastak, Mitra, & Ringold, 1996; Wansink, 2003). Similarly, the halo effect can result in the presence of negative nutrients (e.g. sodium, cholesterol) being overlooked (Murphy, Hoppock, & Rusk, 1998). In either case, consumers are deterred from looking beyond the logo to evaluate the nutrition information panel (P. Williams, 2005).

6.2.2 Nutrient signposting: "traffic light" systems

Nutrient signposting is an FOP system that indicates the quality of one or more nutritional measures relative to a pre-determined scale. A common way to indicate this rating on the FOP label is to use a red symbol for an unhealthy level, yellow for a moderate level, and green for a healthy level; thus nutrient signpost programs are commonly called traffic light systems. Alternatively, the levels can be represented with text (e.g. high, medium, low), numerical scores, or visually on a continuous scale (Stockley, 2007).

The key difference between this system and the seal of approval system is the identification of negative qualities. Manufacturers are understandably resistant to such

unfavorable disclosures; this is the likely reason that the traffic light system is much less common than seals of approval (Stockley, 2007).

6.3 EXISTING FOP PROGRAMS

FOP labeling programs exist on a national level in several countries. This section briefly describes four such not-for-profit programs, and research related to their implementation and impact.

6.3.1 Pick the Tick

Pick the Tick is an integrated FOP system developed and implemented by the Australian Heart Foundation in 1989 (Smith et al., 2002). The program was adopted and administered by the National Heart Foundation of New Zealand in 1991; in 1996 the two programs merged to create a larger Australasian program (Young & Swinburn, 2002).

Figure 4: Pick the Tick program logo (National Heart Foundation, 2009)

The Pick the Tick logo consists of a red circle with a white checkmark, or "tick," in the center; "National Heart Foundation Approved" is written around the logo's circumference (see Figure 4) (Young & Swinburn, 2002). Manufacturers with products meeting the program's criteria for certain nutrients (i.e. calcium, fat, saturated fat, sodium, sugar, fiber, and trans fatty acids)[2] may purchase licensing rights to feature the logo on their packages and related marketing materials. The price of participation is 0.5% of the initial product's estimated revenue, and 0.25% of turnover for each additional product (Smith et al., 2002). Pick the Tick is not-for-profit, as proceeds go towards administrative, testing, and promotional expenses (National Heart Foundation, 2009). All claimant products undergo independent analysis, and program administrators retain final approval of every logo depiction (Young & Swinburn, 2002).

This program's longevity provides an opportunity to evaluate the function of an established FOP program. Pick the Tick is generally considered a success; consumer support has remained strong over time, and the program has established credibility, increasing consumer trust as predicted earlier in this thesis. Negating concerns of misinterpretation, research shows that consumers are generally able to interpret the logo's meaning and significance correctly. Program awareness and logo recognition levels are well above 50% overall, while at least 60% of Australians use the logo at least occasionally while shopping (Smith et al., 2002). The logo itself has therefore become a powerful marketing tool, providing administrators with a persuasive tool in their negotiations with the food industry (P. Williams, McMahon, & Boustead, 2003).

The Pick the Tick program emphasizes and facilitates a relationship between administrators and manufacturers (Young & Swinburn, 2002). This collaboration has demonstrated fulfillment of Caswell and Padberg's (1992) primary third-party role of package

[2] Selected Pick the Tick nutritional criteria are located in the Appendix, Table 1.

health claims: influence on product design. Administrators actively encourage manufacturers to develop or adjust products with the program's criteria in mind; because of the logo's marketing value, the food industry is willing to comply. As a result, this FOP program has improved, to some extent, the nutritional quality of the Australasian food market. One study found that, over the course of one year, product reformulation attributable to Pick the Tick decreased the sodium content of 23 products by approximately 33 tons in New Zealand alone (Young & Swinburn, 2002).

6.3.2 The Green Keyhole

Sweden's version of the FOP system, the Green Keyhole program, was also introduced in 1989; however, it differs from Pick the Tick in several respects. The Green Keyhole is administered by a government agency, the Swedish National Food Administration, as opposed to a not-for-profit public health organization (Larsson, Lissner, & Wilhelmsen, 1999; Nordic Co-operation, 2009; Smith et al., 2002). The program is also unusual in that it does not charge manufacturers fees to feature the logo, nor does it directly certify products for inclusion in the program. The majority of participating manufacturers independently determine which of their products are eligible, and apply the symbol appropriately. Finally, the nutrition criteria include requirements for whole grain and vegetable or fruit content in addition to the standard micronutrient thresholds (National Food Administration, 2009)[3].

The program's logo is graphically simple: a white keyhole shape imposed on a green circle (see Figure 5) (National Food Administration, 2009). This symbol boasts widespread

[3] Selected Green Keyhole nutritional criteria are located in the Appendix, Table 2.

recognition and comprehension; six years after implementation, 53% of men and 76% of women studied were able to correctly interpret its meaning (Larsson et al., 1999; Smith et al., 2002). This is an increase over the results of a similar study completed at the program's three-year mark, demonstrating that an FOP system's influence continues to grow long after inception (Larsson et al., 1999). Perhaps surprisingly, heavier women reported higher rates of program comprehension. Larsson et al. (1999) speculate that these women may be more receptive to potential weight reduction strategies. This seems to contradict Nayga's (1999) finding of a negative correlation between BMI and label use, and raises questions about the direction of the causal link. Larsson et al.'s (1999) research yielded two additional key findings. First, there was no significant difference in comprehension ability between education levels, supporting the idea that the benefits of FOP labels are widely accessible. Second, the data suggests that familiarity with the Green Keyhole logo positively affects product choice, and may truly be altering consumption patterns.

Figure 5: The Green Keyhole program logo (National Food Administration, 2009)

The success and popularity of Green Keyhole have led to program expansion. In 2009, Green Keyhole was expanded to neighboring Denmark and Norway. The Swedish National

Food Administration is also developing a version of the program for use in both full service and fast food restaurants (National Food Administration, 2009).

6.3.3 Health Check

Canada's national FOP program is Health Check, introduced in 1999 by the not-for-profit Heart and Stroke Foundation (Heart and Stroke Foundation of Canada, 2009; Smith et al., 2002)[4]. Its logo consists of a red circle behind a white checkmark; "Health Check" appears around the circle with "Heart and Stroke Foundation" written below in French and English (see Figure 6). Health Check is a not-for-profit program, but does charge a licensing fee in order to cover administrative costs (Heart and Stroke Foundation of Canada, 2009). Manufacturers pay CAD$525 to have each product evaluated for eligibility; an annual fee is assessed thereafter. Fees amounts are determined by the market for the product, and range from CAD$250 to CAD$3,000 (Smith et al., 2002).

Figure 6: Health Check program logo (Heart and Stroke Foundation of Canada, 2009)

[4] Selected Health Check nutritional criteria are located in the Appendix, Table 3.

As with the previously discussed FOPs, a majority of surveyed consumers support the program and feel that it is useful (Smith et al., 2002). Additionally, a study completed three years into the program found a significant correlation between program awareness and use of the logo when shopping, as well as indications that consumers consciously use the logo to decrease dietary fat (Reid, Slovinec D'Angelo, Dombrow, Heshka, & Dean, 2004).

6.3.4 Traffic Light System

Amidst the popularity of seal of approval-type programs, the United Kingdom's Traffic Light System (TLS) is the sole well-established example of a nutrient signposting system. Implemented in 2006, TLS is a set of guidelines focusing on four nutritional quality measures: fat, saturated fat, sugar, and salt (Sacks, Rayner, & Swinburn, 2009)[5].

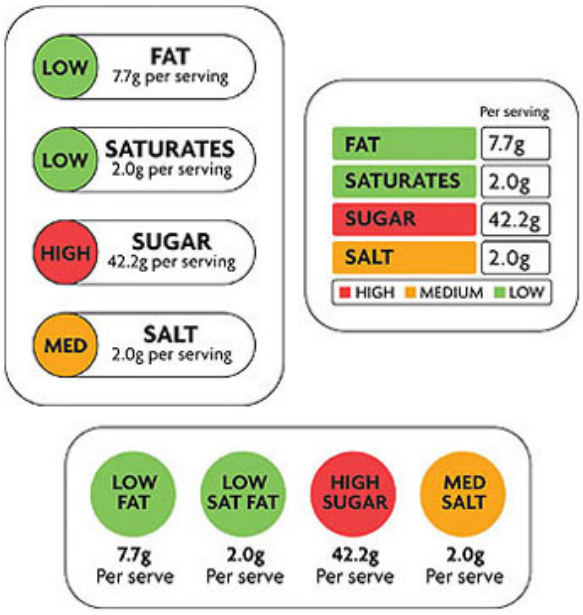

Figure 7: Examples of Traffic Light System logos (Food Standards Agency, 2007)

[5] TLS nutritional criteria are located in the Appendix, Table 4.

The Food Standards Industry developed and promotes the system, which is voluntary, but manufacturers choosing to adopt TLS may present the color ratings in their own format (see Figure 7). Labels typically feature the name of each nutrient on a background color corresponding to the nutrient level (green=low, yellow=medium, red=high). Caloric content per serving and percentages of daily recommendations may also be incorporated. The program is voluntary, and there is no fee to participate (Food Standards Agency, 2007).

Analysis of the program's impact has yielded generally positive results. A rigorous evaluation of the system conducted in 2008 reported label comprehension levels of 58% to 71%; however, it also discovered that the variety of formats inhibited comprehension levels (BMRB Social Research, Malam, Clegg, Kirwan, & McGinigal, 2009). Other researchers more recently found that consumers strongly preferred to reduce their intake of red light nutrients, particularly sodium and saturated fat ratings. This study concluded that TLS effectively informs consumers and has some impact on behavior (Balcombe, Fraser, & Falco, 2010).

6.3.5 Additional FOP programs

This thesis includes only a fraction of FOPs existing worldwide, selected based on longevity, scale of operations, and body of existing research. One such program of note is Healthy Choices. Introduced in 2009, Healthy Choices is the first large-scale attempt to create a standard, international FOP program (Choices International Foundation, 2010). While an interesting and promising concept, it is far too early for this program to provide reliable impact assessment data. In the United States, there is a single non-commercial FOP program of consequence: the Heart Check Mark program administered by the American Heart Association. Heart Check Mark has not achieved the recognition and prominence of those discussed above; it

also represents a relatively small number of products (Stockley, 2007). Therefore, it is also outside the scope of this thesis.

7.0 SMART CHOICES

7.1 OVERVIEW

In August 2009, a coalition funded by food manufacturers launched a new front-of-pack campaign in the United States. Smart Choices is a logo-based, not-for-profit FOP program designed by a multi-disciplinary administrative body. According to the program's website,

> The Smart Choices Program was developed based on the need for a single, trusted and reliable front-of-pack nutrition labeling program that could help guide consumers' food and beverage choices. The first of its kind, the Smart Choices Program was developed by a diverse group of scientists, academicians, health and nutrition specialists and food industry experts (Smart Choices Coalition, 2009)

The Smart Choices logo consists of a green checkmark within a green-bordered rectangle; text next to the checkmark reads "Smart Choices Program" and "Guiding Food Choices" (see Figure 8). When appearing on packaging, the calories per serving and number of servings per package appear with the logo (Smart Choices Coalition, 2009).

Figure 8: Two examples of Smart Choices logos (Smart Choices Coalition, 2009)

The program specifies nutritional criteria for 19 product categories, including soups, entrees, breakfast cereals, meats, sauces, bottled water, and chewing gum[6]. The standards for each category were "derived from the Dietary Guidelines for Americans, reports from the Institute of Medicine, and other sources of authoritative nutrition guidance…" (Smart Choices Coalition, 2009). Product qualification in Smart Choices is more complex than the previously discussed programs. Each category has specific thresholds for six "nutrients to limit" (total fat, saturated fat, trans fat, cholesterol, added sugars, and sodium). In addition, some categories require that products meet a minimum requirement in either a) one of seven "nutrients to encourage" (calcium, potassium, fiber, magnesium, vitamin A, vitamin C, or vitamin E) or b) one of four "food groups to encourage" (fruits, vegetables, whole grains, reduced fat milk products) (Smart Choices Coalition, 2009).

The Keystone Center, a not-for-profit, public policy group, coordinated the initial coalition organization. Program development took place over 21 months, funded by $1.47 million in food industry dollars—more than $680,000 of which was paid to the Keystone Center (Hughlett, 2008b; Ruiz, 2009). Initial contributors to the program included ConAgra, General Mills, Kellogg's, Kraft Foods, Pepsico, Tyson, and Unilever; retail giant Walmart also participated in the development process (Hughlett, 2008a; Smart Choices Coalition, 2009). The public health organizations NSF International and the American Society for Nutrition (ASN) were chosen to administer the program (Ruiz, 2009; Taylor & Mande, 2009).

Participating corporations each pay between $5,000 and $100,000 annually for program rights and operating expenses, in addition to per-product licensing fees (MacVean, 2009; Ruiz,

[6] Selected Smart Choices nutritional criteria are located in the Appendix, Table 5.

2009). They are also required to discontinue any existing brand-specific front-of-pack health claims (Hughlett, 2008b).

7.2 REACTION TO THE PROGRAM

Smart Choices caused contention long before its public introduction. Michael Jacobson, executive director of the Center for Science in the Public Interest, resigned his position in the coalition. He was concerned that consumers would not be able to discern negative nutritive qualities from the Smart Choices label (Hughlett, 2008b). Marion Nestle, a prominent food policy author, called the program an attempt on the part of manufacturers to preempt less favorable FDA requirements (M. Nestle, 2008). When Nestle later received an invitation to join the Smart Choices Board of Directors on behalf of the American Society of Nutrition (ASN), she publicly denounced ASN's involvement with the program as a financial and intellectual conflict of interest; she went on to criticize the commercial motivations of the program's industry backers (M. Nestle, 2009).

Criticism, focusing on Smart Choices' nutritional criteria, intensified after the program's debut. Almost immediately, FDA officials issued a letter to the program manager, reminding her that they would be monitoring Smart Choices closely, and cautioning

> FDA and FSIS would be concerned if any FOP labeling systems used criteria that were not stringent enough to protect consumers against misleading health claims; were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed food and refined grains instead of fruits, vegetables, and whole grains. (Taylor & Mande, 2009)

National media soon took notice. On September 5, 2009, the *New York Times* ran an article in which public health officials and nutrition experts denounced Smart Choices, citing lax qualification standards and the program's industry backing. This article also singled out a logo-bearing product that became a popular illustration of the program's shortcomings: Froot Loops breakfast cereal, which contains 41% sugar by weight. The Smart Choices board president is quoted as responding, "You're rushing around, you're trying to think about healthy eating for your kids and you have a choice between a doughnut and cereal. So Froot Loops is a better choice" (Neuman, 2009).

Increasing negative press led several institutions, including the American Diabetes Association and the American Dietetic Association, to actively disassociate themselves from Smart Choices (MacVean, 2009). On September 21, Congressional Representative Rosa DeLauro of Connecticut expressed concern over the program and publicly asked the FDA to investigate on grounds of mislabeling (DeLauro, 2009). Soon after, the Connecticut Attorney General announced his own inquiry into Smart Choices criteria selection, administrative processes, and funding sources (Connecticut Attorney General's Office, 2009).

A flurry of FDA action followed these events. In a response to Representative DeLauro, FDA Commissioner Margaret Hamburg assured that "[t]he agency is currently analyzing FOP labels that appear to be misleading," and that an alternative regulatory approach was in development (Hamburg, 2009). At the same time, a public letter of guidance to the food industry was issued, stressing the importance of non-misleading FOP labeling, and threatening "[I]f voluntary action by the food industry does not result in a common, credible approach to FOP and shelf labeling, we will consider using our regulatory tools toward that end" (Schneeman, 2009).

On October 20, FDA officials held a media call to address the situation and clarify the letters. Although the speaker did not mention any specific food brands, she did name Smart Choices as a potentially misleading FOP campaign. An FDA lawyer confirmed that "if there was a symbol that conveyed an overall healthy impression about a food but the food contained a level of a nutrient or was otherwise composed in a way that really wasn't consistent with that healthy message, that could be deemed misleading"—and therefore in violation of FDA regulation and subject to enforcement (Scott [Moderator] & Hamburg [Speaker], 2009).

On October 23, 2009, Smart Choices representatives announced that they would "voluntarily postpone active operations and not encourage wider use of the logo at this time by either new or currently enrolled companies" (Metcalfe, 2009). This statement also indicates their willingness to cooperate with the Connecticut Attorney General, and to collaborate with the FDA, USDA, and Institute of Medicine in the development of a uniform FOP program (Metcalfe, 2009). However, the program is not completely defunct; the author has seen the label on shelves as recently as March 2010.

7.3 REPERCUSSIONS IN THE REGULATORY SYSTEM

The reaction to Smart Choices has set in motion a new movement in health claim regulation for the United States (Food and Drug Administration, 2009a). In addition to the question of misleading labels, FDA officials cite concern that "the proliferation of divergent FOP approaches is likely to be confusing to consumers and ultimately counter-productive" (Hamburg, 2009). The agency is now working with the USDA to develop standards for the use of FOP labels, as well as uniform nutritional criteria for such programs (Food and Drug Administration, 2009a). At this

time, the agency has not decided if they will pursue a “single, uniform, government-mandated symbol” (Food and Drug Administration, 2009a).

8.0 DISCUSSION

8.1 RECOMMENDATIONS

Smart Choices has pushed US agencies to take a more active role in food labeling—a role beyond simple regulatory function. A single FOP system would bring US labeling policy in line with those of the countries described in the previous chapter, among others. Research and evaluation studies show that those early adopters of national FOP systems enjoy moderate to significant benefits, both in their population's food choices and in the nutritional quality of products offered for sale. A similar program developed and sponsored by the FDA would have the potential to improve dietary choices across the population.

There is support for this recommendation. In 2003, the Center for Science in the Public Interest asked the FDA to make the development of a government-backed FOP a top priority (Stockley, 2007). The FDA's own research describes study participants' views that "developing and branding an icon that signals more healthful products could help them to make better food choices" (Lando & Labiner-Wolfe, 2007, pg. 163). Participants went on to emphasize that such a program would have to be trustworthy, which is especially true in the wake of the publicity surrounding Smart Choices. Government development and backing would help to inspire that trust.

Comprehensive nutrition signposting is a better choice for FOP labels due to the impartial reporting of both positive and negative characteristics—making it less a "health claim" than a "health disclosure". It seems that the FDA is considering this option; they refer to the British system as a model in at least three instances (Food and Drug Administration, 2009a; Hamburg, 2009; Scott [Moderator] & Hamburg [Speaker], 2009). However, as noted in the previous chapter, the food industry views signposting systems as harmful to certain products, and likely to damage marketability (Stockley, 2007). Manufacturers are therefore likely to be highly resistant to this program format. When contemplating regulatory change, a complete lack of industry support is problematic, though not insurmountable.

Nonetheless, benefits realized by the nutrient signposting system are too important to ignore. Foremost, they provide consumers with a more complete nutritional profile, so that the presence of some positive content does not conceal significantly unhealthy characteristics (Stockley, 2007). Moorman's (1990) model of the nutrition information utilization process, introduced in Chapter 5, suggests that traffic light labels can also encourage consumers' receptiveness to nutrition messages, and improve their utilization of that information.

The signposting system's provision of negative content fulfills Moorman's first stimulus characteristic: consequence information. In step one, the label's warning activates the consumer's search for nutrition information. The presence of identical standards on competing products then supplies possible alternatives that will minimize risk. The second stimulus characteristic emphasized in this model is reference information, preferably given within the context of the message. The traffic light system presents nutrition information through a simple, three-part scale. Because a rating of "good", "moderate," or "bad" is comprehensible without

reference to existing knowledge, the consumer is able to quickly and independently evaluate the product (Moorman, 1990).

Beyond this point-of-purchase benefit, the signposting format is also consistent with Caswell and Padberg's advocacy of third party roles for food label regulation:

- *Influence on product design*: As demonstrated by the Pick the Tick program, manufacturers do respond to health claim systems by reformulating their products to achieve in-demand favorable ratings (Young & Swinburn, 2002). Because manufacturers would be highly motivated to avoid announcing poor nutritional content on the front of their packages, the addition of negative disclosure would significantly increase the pressure to market healthier products.
- *Advertising franchise role*: Under a nutrition signposting FOP system, health claims made in advertising will trigger mandatory use of the standardized label, including negative content. This will reduce the use of advertised health claims for unhealthy products.
- *Public surveillance assurance*: A national FOP system is the optimal way to exhibit governmental surveillance. The symbol's presence will reassure consumers that a trusted body is monitoring the products and claims. The inclusion of negative information will amplify this effect by demonstrating that the government is willing to place consumer welfare above commercial interests.
- *Forum for consensus and defining public values*: The process of choosing the key nutrients and defining their criteria will be a collaborative process between the FDA and public health nutritionists. This process will define a more consistent, official message for the public, and create greater consensus in the scientific community. The inclusion of negative nutrient

qualities in an FOP proposal will appeal to public health experts, and garner more support from that field.

- *Nutrition education format*: The use of a single format with standardized criteria facilitates the development of a complementary nutrition promotion initiative, with a curriculum informed by the FOP nutrient standards. Nutrition education would no longer need to devote time and space to addressing the interpretation of multiple FOP symbols. Together, the FOP and education programs would present a consistent message of nutrition recommendations to the public.

8.2 CONCLUSION

Health claims are one of a multitude of factors that affect consumers' food purchases, but unlike other influences, they are directly controllable through regulation. Therefore, health claims have the potential to become a powerful public health tool. In order to maximize efficacy, it is important to understand the role that health claims play in consumer decision-making. Behavioral models such as those discussed in Chapter 5 help to clarify this process, and identify barriers and access points for label usage.

Front-of-pack labeling is a popular approach to health claims that employs those access points. Many versions of these programs exist in the United States, causing confusion with their varying formats and nutritional criteria. To address this problem, other countries have instituted national FOP programs, which have generally been successful. Some US manufacturers have been resistant to this type of system, and instead created a coalition to develop their own FOP program, Smart Choices. Public health authorities perceived the program as a tailored

promotional campaign for over-processed foods of low nutritive quality. The overwhelmingly negative reaction to Smart Choices, amplified by the media, prompted a response from the FDA, and the program's partial suspension.

Smart Choices provides an example of the need for health claims that are beneficial to consumers, and not misleading in any way. This responsibility falls to the FDA, which oversees package labeling. The FDA's regulatory stance has undergone two major shifts: Originally resistant to the use of health claims, they began to loosen restrictions in the mid-1980s under pressure from both commercial and public health interests. Since that time, use of health claims has exploded, and Smart Choices provided the impetus for the current transition to a more structured regulatory environment. However, this is not a reversion to their original position, but rather the development of a new model for labeling in which the FDA plays an active role in determining claim content.

A national FOP system, in the nutritional signposting format, is one of the options under consideration by the FDA, and the option recommended in this thesis. Such a program would encounter resistance from manufacturers reluctant to provide an accurate front-of-pack representation of their products. However, the potential benefits for public health must override these considerations. The food industry will adjust, as they have after previous regulatory changes, and the American food system will realize far-reaching improvements.

APPENDIX A

SELECTED FOP LABELING PROGRAM NUTRITION CRITERIA

Table 1: Selected Pick the Tick Nutrition Criteria

Product Category	Breakfast cereal	Bread	Margarine & reduced fat spreads
Fat	5% or less*	5% or less*	Total saturated & trans unsaturated fats ≤ 28% of total fatty acids
Sodium	≤ 400 mg per 100 g	≤ 450 mg per 100 g	≤ 400 mg per 100 g
Sugar (added)	≤ 15 g	≤ 15 g	
Fiber	≥ 3 g per 100 g	≥ 3 g per 100 g	
* Products with a fat level between of 5-10% are accepted if saturated fatty acids are ≤ 20% of total fatty acids			

(Young & Swinburn, 2002)

Table 2: Selected Green Keyhole Nutrition Criteria

Product Category	Breakfast cereals and muesli	Prepared soups	Soft Bread	Spreadable fats and blends	Ready-prepared products (main meal, non-specific)
Required positive characteristics	≥ 50% whole grain, calculated on a dry matter basis	≥ 150 kcal per portion; ≥ 25 g per 100 g of vegetables or fruits, excluding peanuts & potatoes	≥ 25% whole grain, calculated on a dry matter basis		400-750 kcal per portion; ≥ 25 g per 100 g of vegetables or fruits, excluding peanuts & potatoes
Fat	≤ 7 g per 100 g	≤ 30% of calories	≤ 7 g per 100 g	≤ 41 g per 100 g; ≤ 33% of that as saturated fatty acids	≤ 30% of calories
Sugars	≤ 5 g per 100 g	≤ 3 g per 100 g	≤ 5 g per 100 g		≤ 3 g per 100 g
Sodium	≤ 0.5 g per 100 g	≤ 0.4 g per 100 g	≤ 0.5 g per 100 g	≤ 0.5 g per 100 g	≤ 0.4 g per 100 g
Fiber	≥ 5 g per 100 g		≥ 5 g per 100 g		

(National Food Administration, 2009)
http://www.slv.se/upload/nfa/documents/food_regulations/Nyckelh%c3%a5l_dec_2009_6%20eng.pdf

Table 3: Selected Health Check Nutrition Criteria[7]

Product Category	Breakfast cereals (55 g serving)	Soups (250mL serving)		Breads (50 g serving)		Margarines (10 g serving)	Dinners & entrees / mixed dishes (250 g serving)	
		Option1	Option 2	Option1	Option 2		Option 1	Option 2
Fat	≤ 3 g per serving	≤ 3 g per serving	≤ 3 g per serving	≤ 3 g per serving			≤ 10 g per serving	≤ 15 g per serving
Trans fat	≤ 5% of total fat	≤ 5% of total fat	≤ 5% of total fat	≤ 5% of total fat	≤ 5% of total fat	≤ 2% of total fat	≤ 5% of total fat	≤ 5% of total fat
Sugars (added)	≤ 11 g per serving							
Sodium	≤ 240 mg per serving	≤ 480 mg per serving	≤ 480 mg per serving	≤ 360 mg per serving	≤ 360 mg per serving	≤ 140 mg per serving	≤ 720 mg per serving	≤ 720 mg per serving
Fiber	≥ 4 g per serving	≥ 2 g per serving		≥ 2 g per serving	≥ 2 g per serving			
Protein							≥ 10 g per serving	≥ 10 g per serving
Additional criteria			≥ 5% of RDA for one of the following: Vitamin A Vitamin C iron calcium folate		total saturated and trans fat value ≤ 2g AND ≤ 15% of total calories	non-hydrogenated		total saturated and trans fat value ≤ 2g AND ≤ 15% of total calories

(Heart and Stroke Foundation of Canada, 2009)
http://www.healthcheck.org/sites/default/files/editor/Nutrient%20Criteria_Retail_December2009.pdf

[7] Health Check criteria have become more stringent; values listed here apply to products entering the program for the first time.

Table 4: Traffic Light System Nutrition Criteria

	Green (low)	**Amber** (medium)	**Red** (high)	
Fat	≤ 3 g/100 g	> 3.0 to ≤20.0 g/100 g	> 20.0 g/100 g	> 21.0 g/ portion
Saturated Fat	≤ 1.5 g/100 g	> 1.5 to ≤5.0 g/100 g	> 5.0 g/100 g	> 6.0 g/ portion
Sugars	≤ 5.0 g/100 g	> 5.0 to ≤12.5 g/100 g	> 12.5 g/100 g	> 15.0 g/ portion
Sodium	≤ 0.3 g/100 g	> 0.30 to ≤1.5 g/100 g	> 1.5 g/100 g	> 2.4 g/ portion

(Food Standards Agency, 2007)
http://www.food.gov.uk/multimedia/pdfs/frontofpackguidance2.pdf

Table 5: Selected Smart Choices Nutrition Criteria

Product Category		Breakfast cereals	Bread, grains, pasta, flours	Fats, oils, spreads, butter	Snack foods, sweets	Entrees, sandwiches, main dishes, meal replacements	Soups, meal sauces, mixed side dishes
Requirements for Inclusion		Category 1: all Category 2 or 3: ≥ 1	Category 1: all Category 2 or 3: ≥ 1	Category 1: all Category 2 or 3: no requirement	Category 1: all Category 2 or 3: ≥ 1	Category 1: all Category 2 or 3: ≥ 1	Category 1: all Category 2 or 3: ≥ 1
Calories		no limit	no limit	no limit	≤ 160	≤ 450	no limit
Category 1: Nutrients to Limit	**Total fat**	≤ 35% of calories	≤ 35% of calories	no limit	≤ 35% of calories or ≤ 3 g	≤ 35% of calories	≤ 35% of calories or ≤ 3 g
	Saturated fat	< 10% of calories	< 10% of calories	≤ 28% of calories	< 10% of calories or ≤ 1 g	< 10% of calories	< 10% of calories
	Trans fat	0 g	0 g	0 g	0 g	0 g	0 g
	Cholesterol	no limit	no limit	≤ 60 mg	≤ 60 mg	≤ 90 mg	≤ 60 mg
	Added sugars	≤ 12 g	≤ 25% of calories	≤ 25% of calories	≤ 25 of calories or ≤ 6 g	≤ 25% of calories	≤ 24% of calories or ≤ 6 g
	Sodium	≤ 290 mg	≤ 240 mg	≤ 140 mg	≤ 240 mg	≤ 600 mg	≤ 480 mg
Category 2: Nutrients to Encourage	**Calcium**	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Potassium	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Fiber	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Magnesium	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Vitamin A	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Vitamin C	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
	Vitamin E	≥ 10 % DV	≥ 10 % DV	no requirement	≥ 10 % DV	≥ 10 % DV	≥ 10 % DV
Category 3: Food Groups to Encourage	**Fruits**	½ serving	½ serving	no requirement	½ serving	1 serving	½ serving
	Vegetables	½ serving	½ serving	no requirement	½ serving	1 serving	½ serving
	Whole grains	½ serving	8 g /serving	no requirement	½ serving	16 g /serving	½ serving
	Reduced fat milk products	½ serving	½ serving	no requirement	½ serving	1 serving	½ serving

(Smart Choices Coalition, 2009)
http://www.smartchoicesprogram.com/pdf/Smart%20Choices%20Program%20Nutrition%20Criteria%20Matrix.pdf

BIBLIOGRAPHY

Balcombe, K., Fraser, I., & Falco, S. (2010). Traffic lights and food choice: A choice experiment examining the relationship between nutritional food labels and price. *Food Policy.* In press, corrected proof. doi: 10.1016/j.foodpol.2009.12.005

Beales, H., Craswell, R., & Salop, S. C. (1981). The efficient regulation of consumer information. *Journal of Law and Economics, 24* (3), Consumer Protection Regulation: A Conference Sponsored by the Center for the Study of the Economy and the State, 491-539. Retrieved from http://www.jstor.org/stable/725275

Beatty, S. E., & Smith, S. M. (1987). External search effort: An investigation across several product categories. *The Journal of Consumer Research, 14*(1), 83-95. Retrieved from http://www.jstor.org/stable/2489245

Blitstein, J. L., & Evans, W. D. (2006). Use of nutrition facts panels among adults who make household food choices. *Journal of Nutrition Education and Behavior, 38*(6), 360-364.

BMRB Social Research, Malam, S., Clegg, S., Kirwan, S., & McGinigal, S. (2009). *Comprehension and use of UK nutrition signpost labelling schemes* (Evaluation No. BMRB/SM/45106792) Project Management Panel. Retrieved from http://www.food.gov.uk/multimedia/pdfs/pmpreport.pdf

Borgmeier, I., & Westenhoefer, J. (2009). Impact of different food label formats on healthiness evaluation and food choice of consumers: A randomized-controlled study. *BMC Public Health, 9*(1), 184. Retrieved from http://www.biomedcentral.com/1471-2458/9/184

Calfee, J. E., & Pappalardo, J. K. (1991). Public policy issues in health claims for foods. *Journal of Public Policy & Marketing, 10*(1), 33-53. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=9602150571&site=ehost-live

Caswell, J. A., & Padberg, D. I. (1992). Toward a more comprehensive theory of food labels. *American Journal of Agricultural Economics, 74*(2), 460-468. Retrieved from http://www.jstor.org/stable/1242500

Choices International Foundation. (2010). *Healthy choices made easy.* Retrieved from http://choicesprogramme.org/en

Commissioner of Food and Drugs. (1971). Updated FTC-FDA liaison agreement-- advertising of over-the-counter drugs. *Trade Regulation Reports, 9851*(36 Fed. Reg. 18,359) Retrieved from http://www.fda.gov/ohrms/DOCKETS/DOCKETS/06p0394/06p-0394-cp00001-10-Tab-08-Trade-Reg-Rpts-vol1.pdf

Connecticut Attorney General's Office. (2009). *Attorney general investigates "Smart Choices" food labels that endorse mayonnaise and sugary cereals* [press release]. Retrieved from http://www.ct.gov/AG/cwp/view.asp?A=3673&Q=448878&pp=12&n=1

Coulson, N. S. (2000). An application of the stages of change model to consumer use of food labels. *British Food Journal, 102*(9), 661-668.

DeLauro, R. L. (2009). *DeLauro calls for FDA investigation into "Smart Choices" labeling* [press release]. Retrieved from http://delauro.house.gov/ text_release.cfm?id=2653

Feunekes, G. I. J., Gortemaker, I. A., Willems, A. A., Lion, R., & van den Kommer, M. (2008). Front-of-pack nutrition labelling: Testing effectiveness of different nutrition labelling formats front-of-pack in four European countries. *Appetite, 50*, 57-70.

Food and Drug Administration. (2009a). *Background information on point of purchase labeling*, 2009, from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm187320.htm

Food and Drug Administration. (2009b). Internet survey on barriers to food label use. *Federal Register, 74*(162), 42676-42677.

Food Standards Agency. (2004). *Consumer attitudes to food standards wave 4* (No. 257960). London: Food Standards Agency.

Food Standards Agency. (2007). *Front-of-pack traffic light signpost labelling technical guidance* (No. 2). Retrieved from http://www.food.gov.uk/multimedia/pdfs/frontofpackguidance2.pdf

Ford, G., Hastak, M., Mitra, A., & Ringold, D. J. (1996). Can consumers interpret nutrition information in the presence of a health claim? A laboratory investigation. *Journal of Public Policy and Marketing, 15*(1), 16-27.

FTC Act 88 Stat. 2183, 2193. (1975). *Unfair methods of competition unlawful; prevention by commission* (Title 15 U.S. Code 45 ed.) Retrieved from www.law.cornell.edu/uscode/html/uscode15/usc_sec_15_00000045----000-.html

Garretson, J. A., & Burton, S. (2000). Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease-related risks, and trust. *Journal of Public Policy & Marketing, 19*(2), 213-227. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=4446953&site=ehost-live

Geiger, C. J. (1998). *Health claims: History, current regulatory status, and consumer research* Retrieved from http://find.galegroup.com/itx/infomark.do?&contentSet=IAC-Documents&type=retrieve&tabID=T002&prodId=ITOF&docId=A53286599&source=gale&srcprod=ITOF&userGroupName=upitt_main&version=1.0

Grunert, K. G., & Wills, J. M. (2007). A review of European research on consumer response to nutrition information on food labels. *Journal of Public Health, 15*, 385-399. doi:10.1007/s10389-007-0101-9

Hamburg, M. A. (2009). *FDA response to representative DeLauro.* Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm187369.htm

Harris, J. L., Schwartz, M. B., & Brownell, K. D. (2009). *Cereal F.A.C.T.S. - evaluating the nutrition quality and marketing of children's cereals.* Rudd Center for Food Policy and Obesity. Retrieved from http://www.cerealfacts.org/media/Cereal_FACTS_Report.pdf

Heart and Stroke Foundation of Canada. (2009). *Heart & stroke health check... helping you eat well.* Retrieved January, 2010, from http://www.healthcheck.org

Hughlett, M. (2008a, October 24, 2008). Foodmakers come up with 'Smart Choice' label to denote healthier fare. *Chicago Tribune.* Retrieved from http://archives.chicagotribune.com/2008/oct/24/business/chi-smart-choice-food-label-oct24

Hughlett, M. (2008b, October 25, 2008). 'Good for you,' label will shout. *Chicago Tribune.* Retrieved from http://archives.chicagotribune.com/2008/oct/25/business/chi-sat_food-labeling_oct25

Hutt, P. B. (1986). Government regulation of health claims in food labeling and advertising. *Food, Drug, and Cosmetic Law Journal, 41*, 3-73.

L'Abbe, M. R., Dumais, L., Chao, E., & Junkins, B. (2008). Health claims on foods in Canada. *Journal of Nutrition, 138*(6), 1221S-1227.

Lando, A. M., & Labiner-Wolfe, J. (2007). Helping consumers make more healthful food choices: Consumer views on modifying food labels and providing point-of-purchase nutrition information at quick-service restaurants. *Journal of Nutrition Education and Behavior, 39*(3), 157-163. doi: 10.1016/j.jneb.2006.12.010

Larsson, I., Lissner, L., & Wilhelmsen, L. (1999). The 'Green Keyhole' revisited: Nutritional knowledge may influence food selection. *European Journal of Clinical Nutrition, 52*, 776-780.

MacVean, M. (2009, September 29). 'Smart Choices' food label: A sign of nutrition or marketing? *Los Angeles Times.* Retrieved from http://www.latimes.com/news/nationworld/nation/la-sci-smart29-2009sep29,0,4642882.story

Mason, M. J., & Scammon, D. L. (2000). Health claims and disclaimers: Extended boundaries and research opportunities in consumer interpretation. *Journal of Public Policy & Marketing, 19*(1), 144-150. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=3215151&site=ehost-live

Metcalfe, K. (2009). *Smart Choices program postpones active operations* [press release]. Smart Choices. Retrieved from http://www.smartchoicesprogram.com/pr_091023_operations.html

Mikhail, B. (1981). The health belief model: A review and critical evaluation of the model, research, and practice. *Advances in Nursing Science, 4*(1), 65-82.

Moorman, C. (1990). The effects of stimulus and consumer characteristics on the utilization of nutrition information. *The Journal of Consumer Research, 17*(3), 362-374. Retrieved from http://www.jstor.org/stable/2626801

Morreale, S. J., & Schwartz, N. E. (1995). Helping Americans eat right: Developing practical and actionable public nutrition education messages based on the ADA survey of American dietary habits. *Journal of the American Dietetic Association, 95*(3), 305-308. doi: 10.1016/S0002-8223(95)00078-X

Murphy, D., Hoppock, T., & Rusk, M. (1998). *Generic copy test of food health claims in advertising.* Bureaus of Economics and Consumer Protection, Federal Trade Commission.

National Food Administration. (2009). *The keyhole symbol.* Retrieved March, 2010, from http://www.slv.se/en-gb/Group1/Food-and-Nutrition/Keyhole-symbol/

National Heart Foundation. *Pick the Tick.* Retrieved December, 2009, from http://www.pickthetick.org.nz/

Nayga, R. M., Jr. (1999). Toward an understanding of consumers' perceptions of food labels. *International Food and Agribusiness Management Review, 2*(1), 29-45.

Nayga, R. M., Jr. (2000). Nutrition knowledge, gender, and food label use. *The Journal of Consumer Affairs, 34*(1), 97-112.

Nestle, M. (2008). *New food rating label: A step forward?*, 2009, from http://foodpolitics.com/2008/10/new-food-rating-label-a-step-forward/

Nestle, M. (2009). *Open letter to nutrition colleagues.*, 2009, from http://www.foodpolitics.com/2009/05/open-letter-to-nutrition-colleagues/

Nestle, M., & Ludwig, D. S. (2010). Front-of-package food labels: Public health or propaganda? *JAMA: The Journal of the American Medical Association, 303*(8), 771-772. doi:10.1001/jama.2010.179

Neuman, W. (2009, September 5). For your health, Froot Loops. *The New York Times.* Retrieved from http://www.nytimes.com/2009/09/05/business/05smart.html?_r=1

Nordic Co-operation. (2009). *Easier to choose healthy food in the Nordic countries.* Retrieved January, 2010, from http://www.norden.org/en/news-and-events/news/easier-to-choose-healthy-food-in-the-nordic-countries

Ogden, C. L., Carroll, M. D., Curtin, L. R., McDowell, M. A., Tabak, C. J., & Flegal, K. M. (2006). Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA: The Journal of the American Medical Association, 295*(13), 1549-1555. doi:10.1001/jama.295.13.1549

Park, C. W., Iyer, E. S., & Smith, D. C. (1989). The effects of situational factors on in-store grocery shopping behavior: The role of store environment and time available for shopping. *Journal of Consumer Research, 15*, 422-433.

Reid, R. D., Slovinec D'Angelo, M. E., Dombrow, C. A., Heshka, J. T., & Dean, T. R. (2004). The Heart and Stroke Foundation of Canada's Health Check food information program: Modelling program effects on consumer behaviour and dietary practices. *Canadian Journal of Public Health, 95*(2), 146-150.

Roe, B., Levy, A. S., & Derby, B. M. (1999). The impact of health claims on consumer search and product evaluation outcomes: Results from FDA experimental data. *Journal of Public*

Policy & Marketing, 18(1), 89-105. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=1932040&site=ehost-live

Ruiz, R. (2009, September 17). Smart Choices foods: Dumb as they look? *Forbes.Com, 2009.* Retrieved from http://www.forbes.com/2009/09/17/smart-choices-labels-lifestyle-health-foods.html

Sacks, G., Rayner, M., & Swinburn, B. (2009). Impact of front-of-pack 'traffic-light' nutrition labelling on consumer food purchases in the UK. *Health Promotion International, 24*(4), 344-352. doi:10.1093/heapro/dap032

Schneeman, B. O. (2009). In Food industry (Ed.), *Guidance for industry: Letter regarding point of purchase food labeling.* Retrieved from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm

Scott [Moderator], M., & Hamburg [Speaker], M. (2009). In Taylor M., Schneeman B. and Mande J. (Eds.), *FDA position on front-of-package labeling* [media call transcript]. Food and Drug Administration. Retrieved from www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM187809.pdf

Scott, V., & Worsley, A. F. (1994). Ticks, claims, tables and food groups: A comparison for nutrition labelling. *Health Promotion International, 9*(1), 27-37.

Smart Choices Coalition. (2009). *Smart Choices program.* Retrieved 09/27, 2009, from http://www.smartchoicesprogram.com/

Smith, S. C., Stephen, A. M., Dombrow, C., & Macquarrie, D. (2002). Food information programs: A review of the literature. *Canadian Journal of Dietetic Practice and Research, 63*(2), 55-60.

Stockley, L. (2007). *Review of 'front of pack' nutrition schemes.* European Heart Network. Retrieved from http://www.ehnheart.org/files/FOP%20Report%202007-104826A.pdf

Svederberg, E. (2005). *Consumers' views regarding health claims on two food packages* (No. 0347-8467). Lund, Sweden: Lund University. Retrieved from http://www.qualitative-research.net/index.php/fqs/article/view/886

Swann, J. P. (1998). *FDA's origin*, 2010, from http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm

Szykman, L., Bloom, P., & Levy, A. (1997). A proposed model of the use of package claims and nutrition labels. *Journal of Public Policy and Marketing, 16*(2), 228-241.

Taylor, M. R., & Mande, J. R. (2009). In Sarah Krol, General Manager, Smart Choices Program (Ed.), *Letter to the smart choices program.* Food and Drug Administration. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm180146.htm

Wansink, B. (2003). How do front and back package labels influence beliefs about health claims? *Journal of Consumer Affairs, 37*(2), 305-316. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=aph&AN=11736103&site=ehost-live

Williams, P. (2005). Consumer understanding and use of health claims for foods. *Nutrition Reviews, 63*(7), 256-265.

Williams, P., McMahon, A., & Boustead, R. (2003). A case study of sodium reduction in breakfast cereals and the impact of the Pick the Tick food information program in Australia. *Health Promotion International, 18*(1), 51-56. doi:10.1093/heapro/18.1.51

World Health Organization, & Food and Agriculture Organization. (2003). *Diet, nutrition, and the prevention of chronic diseases* (WHO Technical Report Series No. 916). Geneva: Retrieved from https://www.who.int/dietphysicalactivity/publications/trs916/en/gsfao_introduction.pdf

Young, L., & Swinburn, B. (2002). Impact of the 'Pick the Tick' food information programme on the salt content of food in New Zealand. *Health Promotion International, 17*(1), 13-19.