QUALIFIED HEALTH CLAIMS: COMMUNICATING SCIENTIFIC CERTAINTY ABOUT FUNCTIONAL FOOD RELATIONSHIPS

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ABSTRACT OF THE DISSERTATION

Qualified Health Claims: Communicating Scientific Certainty about Functional Food Relationships

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The US Food and Drug Administration (FDA) regulates and authors qualified health claims (QHCs) for voluntary use by companies on food and dietary supplement labels. QHCs communicate the scientific certainty about diet-disease relationships that are not supported by significant scientific agreement among qualified experts. These claims emerged from a federal lawsuit that ruled QHCs a First Amendment issue.

Several lawsuits about the description of evidence (i.e. disclaimer) in QHCs led to case law and technical regulatory documents. The FDA must write more than one clear and succinct QHC for the same diet-disease relationship, and the disclaimer may not contradict the diet-disease relationship. However, research indicates consumers are confused by QHCs and are rarely used.

To catalogue their description of scientific certainty, a content analysis parsed the 53 currently-enforced QHCs. Thirty-six formats to communicate scientific evidence were found. Most demonstrate a reading level above 9th grade, describe the quality of evidence ("very weak") and/or reference its consistency, while a quarter quantify the evidence ("two studies").

A 2012 lawsuit over green tea QHCs prompted an investigation of seven QHCs pertaining to a green tea-cancer relationship designed to test stakeholder's assumptions and arguments from the lawsuit and to understand the potential benefit of QHCs to companies. An online experiment was used to assess and to directly compare consumer comprehension of the scientific support implied by each of the claims and resulting intentions to purchase green tea.

Overall, consumers understood the level of evidence for the green tea-cancer relationship. Consumers who had made health-related dietary changes and considered health claims important reported greater purchase intentions after reading a green tea-cancer QHC. Consumers who read a claim written by the green tea company perceived greater evidence for the green tea-cancer relationship, were more confident in the relationship, and reported greater purchase intentions than others. The currently enforced QHC resulted in lower scores for perceived level of evidence for and confidence in the green tea-cancer relationship, and purchase intentions for green tea when compared with QHCs written by the green tea company and higher scores when compared to other FDA QHCs. The current QHC appears to be a compromise between claims written by the green tea company and other QHCs written by FDA.

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CHAPTER ONE
Introduction

The US Food and Drug Administration (FDA) regulates qualified health claims on food and dietary supplement labels. Qualified health claims (QHCs) communicate the quality and strength of scientific evidence behind the claim of a diet-disease relationship (Government Accountability Office, 2011). An example of a QHC is: "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim" (Food and Drug Administration, 2011e).

The significance of QHCs is that there is limited evidence for the diet-disease relationships, considerable potential to impact the public's health, and great potential for financial gain for companies. Proponents of QHCs suggest that they hold potential to mutually benefit both the public and the manufacturers of foods and dietary supplements (Grocery Manufacturers Association, 2003) through a kind of "virtuous cycle" (Figure 1) (Berhaupt-Glickstein & Hallman, 2015).

Qualified health claims on food supplement labels could help to inform consumers about diet-disease relationships and guide their dietary decisions toward healthier products (Ippolito & Mathios, 1990; Lepkowska-White & Parsons, 2001). The added value of products that bear QHCs is also attractive for the food and dietary supplement industry (Lahteenmaki, 2012) because it could increase the product's appeal to consumers, leading to greater purchases and financial gain (Grocery Manufacturers Association, 2003). This, in turn, could incentivize companies and researchers to explore novel diet-disease relationships (Grocery Manufacturers Association, 2003; Ippolito, 1999). The increase of evidence for diet-disease relationships and nutrition information in

the public arena could generate greater awareness and potentially lead to improved dietary habits (Taylor, 1995). Healthier diets could reduce the incidence of nutrition-related non-communicable disease, and help to address the FDA's mission to promote public health. However, the potential value and utility of QHCs is contingent upon the abilities and actions of the stakeholders involved. For QHC's to be effective, companies must use them on their products and consumers must be able to understand them in ways that help them make informed choices.

Stakeholders

US Food and Drug Administration

Companies petition the FDA to use a QHC on their product(s). The agency requires the petitioner to define the dietary substance(s), diseases, or health-related conditions, provide a summary of the scientific data about the diet-disease relationship and copies of their literature search, as well as any data about adverse effects, and one or more model claims (Food and Drug Administration, 2011d; Kavanaugh, Trumbo, & Ellwood, 2007).

Once the petition is submitted, the FDA reviews the evidence for the diet-disease relationship. If the agency determines there is, at least, some scientific support for the claimed relationship, they are required by law to allow a QHC in the marketplace (Pearson, Shaw, American Preventive Medical Association, & Citizens for Health, 1999).

Since there are different levels of evidence for diet-disease relationships described in QHCs, the FDA catalogues them through an evidence grading system (Food and Drug Administration, 2003). Qualified health claims may be assigned a grade of B, C, or D to represent the level of scientific support for the claimed relationship (Food and Drug

Administration, 2011a). A B-grade represents “promising but not definitive” evidence, a C-grade means there is a “low” level and a D-grade indicates a “very low” level of evidence (Food and Drug Administration, 2003).

Once the level of evidence is determined, the FDA considers the model claims submitted by petitioners. The agency may adopt, adapt, or rewrite a model claim so as to ensure it accurately characterizes the scientific support for the claimed relationship. Qualified health claims do not include their evidence grade but rather a description of evidence that the FDA approves for use on food supplement labels (Food and Drug Administration, 2003). The challenge for FDA is to write QHCs that are scientifically accurate, legally compliant, and easily understood by the public.

These activities require substantial resources from FDA. As of 2010, the agency had spent nearly $13 million on qualified health claim activities (Government Accountability Office, 2011). These resources have been allocated towards 89 professionals who, among other functions, have developed multiple guidance documents for industry, conducted consumer research about label claim comprehension, and completed exhaustive reviews of literature for petitioned diet-disease relationships (Government Accountability Office, 2011).

Food and Dietary Supplement Industry

The petition process also requires extensive resources on the part of companies who manufacture and market functional foods and dietary supplements (Nocella & Kennedy, 2012). It is unclear whether the potential for profit is worth the effort required to use a new QHC. A prime example is the QHC about the relationship between walnuts and heart disease. The claim reads, “Scientific evidence suggests but does not prove that

eating 1.5 ounces per day of most nuts [such as name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]"(Food and Drug Administration, 2011e). The California Walnut Commission (CWC) who represents walnut growers and handlers, has reported that few walnut packages include the QHC because the description of evidence is overly complicated (Alster, 2004). Instead, the CWC companies use nutrient content claims to promote walnuts as a source of omega-3 fatty acids (California Walnuts, 2005).

Research also suggests that QHCs may not hold value for manufacturers and marketers because they are seldom used (Fitzgerald Bone & Russo France, 2009; Government Accountability Office, 2011; Hooker, 2007). An analysis of green tea products revealed that QHCs were not included on any eligible items (Hooker, 2007). A national survey of food product labels similarly found that less than 1% displayed a QHC (Government Accountability Office, 2011) and an analysis of 1,200 products revealed that fewer than 5% used a QHC (Fitzgerald Bone & Russo France, 2009).

There are several reasons that food manufacturers may be reluctant to use QHCs. Anecdotal evidence from industry experts suggest that QHCs offer limited utility to marketers because the disclaimers that are an essential part of the QHC are negative and do not highlight the health benefits of the products on which they appear (Fitzgerald Bone & Russo France, 2009) which limits the value of both the claim and the product. Further, the resources required to work with FDA to receive approval for a new QHC are considerable. Yet, after the QHC is approved, the claims are not proprietary. They can be used on any product containing the dietary component that also meets the technical specifications enforced by the FDA. Consequently, QHCs do not provide a competitive

edge for specific companies or their specific products, but rather apply to all of the applicable products in the category. For example the QHC associated with consumption of unsaturated fatty acids from canola oil and reduced risk of coronary heart disease can be attached to the label of a variety of products containing canola oil, made by many companies.

However, there is evidence to suggest that QHCs do hold value for companies. Some have suggested that since consumers learn about nutrition and health from television, the Internet and magazines (Academy of Nutrition and Dietetics, 2011), the benefit of QHCs may be their advertisement in the media (Fitzgerald Bone & Russo France, 2009). Trade group members of the Grocery Manufacturers Association find QHCs useful to market their products (Emord & Schwitters, 2012; Grocery Manufacturers Association, 2003). Further, over the past five years, the number of QHCs allowed on food supplement labels has tripled from 12 to 53 (Berhaupt-Glickstein & Hallman, 2015; Government Accountability Office, 2011). Even more important is that companies are willing to (and do) take FDA to court to ensure their ability to use favorable QHCs on products (Alliance for Natural Health U.S., 2010; Alliance for Natural Health U.S., 2011; Fleminger, 2012; Pearson et al., 1999; Pearson & Shaw, 1998; Pearson, 2001; Whitaker, 2003). The mere occurrence of these federal lawsuits suggests that the ability to make QHCs on products is valuable and, theoretically, influential of food purchase decisions.

Consumers

Research has found that QHCs are difficult for consumers to understand. The "degree of scientific support" communicated in QHCs (Government Accountability

Office, 2011) is often misinterpreted as an indicator of the healthfulness and quality of a product (Food and Drug Administration, 2009b; Food and Drug Administration, 2011c; Hooker & Teratanavat, 2008; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008). Moreover, research suggests that if an individual is already knowledgeable about a diet-disease relationship, the claim is less important (Food and Drug Administration, 2011b).

Several studies have explored consumer understanding of scientific evidence in QHCs in different formats including a graphic with and without the inclusion of an evidence grade (Fitzgerald Bone, Kees, France, & Kozup, 2012; Food and Drug Administration, 2009a; Hooker & Teratanavat, 2008; Kim, Kang, Kwon, & Kim, 2010; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008; Roe, Levy, & Derby, 1999) as well as text-only claims also with and without a grade (Fitzgerald Bone et al., 2012; Food and Drug Administration, 2009a; Food and Drug Administration, 2011b; Hooker & Teratanavat, 2008; Kim et al., 2010; Reinhardt-Kapsak et al., 2008; Roe et al., 1999).

Overall, the research showed that consumers are unable to distinguish between the levels of evidence (Derby & Levy, 2005; Food and Drug Administration, 2009a; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008). While two scales showed promise in aiding consumer understanding of different levels of evidence, (France & Fitzgerald Bone, 2009; Kim et al., 2010) those scales may not be realistic given the FDA's scientific and legal framework.

Overall, the QHC system is not working for stakeholders. Consumers are unable to make informed decisions because they do not understand QHCs. As a result, the food

and dietary supplement industry refrain from using QHCs on products. However, the law requires that FDA continue to implement this ostensibly ineffective program that requires extensive resources.

Unintended outcomes

An unintended consequence of the current QHC system is that the food and dietary supplement industry elect to use other types of claims (Fitzgerald Bone & Russo France, 2009; Government Accountability Office, 2011) that are more acceptable to consumers and scrutinized less by the FDA (Taylor, 2010). The problem is that consumers cannot distinguish among these different types of claims and because of this, consumers are arguably misled and unable to make informed dietary decisions (Government Accountability Office, 2011).

Companies use “nutrition-related claims to market products even when the scientific substantiation that consumers will actually benefit is weak or non-existent” (Taylor, 2010). Structure/function claims (S/F) and the nutrient content claims (NC) are used in place of QHCs. Since these claims do not link a nutrient with a disease and because of this, the FDA does not require a review of evidence before they are used on food supplement product labels. S/F claims describe the role of a food component intended to affect the normal (not diseased or unhealthy) structure or function in humans (Table 1) and NC claims describe the level of a dietary component (i.e. "contains 100 calories"; “low fat”) to imply comparative nutrient content with similar products (Food and Drug Administration, 2009b) (Table 1).

Theoretically, the algorithm for the food and dietary supplement industry is to maximize the promotion of the health benefits of their products while using the least

amount of resources. Since QHCs require scientific proof prior to their use, they are infrequently used. Rather, S/F or NC claims are used in place of them because the FDA enforces them less rigorously due to limited resources (Taylor, 2010).

While a fundamental argument for permitting QHCs was that they could increase public awareness of novel or emerging relationships about health-promoting compounds (Pearson et al., 1999), the current claim language, prescribed by FDA, confuses consumers (Derby & Levy, 2005; Hooker & Teratanavat, 2008; Nocella & Kennedy, 2012; Reinhardt-Kapsak et al., 2008). This suggests that such claims do not meet the key criteria of being "truthful and not misleading". And stakeholders recognize these limitations

An alliance of consumer health advocates urged Congress to take action in 2007 (Center for Science in the Public Interest, 2007). In response, Representatives Henry Waxman and Rosa DeLauro and Senators Edward Kennedy and Richard Durbin called for the FDA to suspend related activities until the QHC regulations were reviewed (Starling, 2008). Two years later the FDA revised the guidance document for industry indicating research was underway to explore "various possible ranking systems that could be used to describe the strength of the evidence for a health claim" (Food and Drug Administration, 2011c). Moreover, in 2011 the Government Accountability Office released a report of their performance audit that examined the agency's oversight of QHCs, the industry's use of them, and consumers' understanding of those claims (Government Accountability Office, 2011).

The current use of QHCs does not adequately meet the needs of either manufacturers or consumers. Both the nature of the QHC approval process and the

complexity of the wording of the resulting claims has failed to facilitate their use by manufacturers and subsequently, the use of products with health benefits by consumers. As it stands, QHCs do not appear to significantly benefit the public's health, and are a potential resource burden for the public and private sectors.

The purpose of this investigation was to comprehensively examine QHC policies, and to assess the comprehension and utility of current QHCs. In doing so, the study was designed to generate baseline data useful for future testing of alternative ways to communicate science within legal bounds, leading to the improvement of QHCs such that they that might be of greater utility to consumers. The main research questions for this study were:

1) What is the current state of qualified health claims?
    a. What is the legal context for qualified health claims?
    b. What are the scientific and regulatory requirements for qualified health claims?
2) How do currently enforced qualified health claims communicate scientific certainty to consumers, using an evidence continuum?
3) Using green tea qualified health claims as a case study, what characterizes existing green tea consumers?
    a. How have qualified health claims about green tea and cancer changed in response to court rulings about language requirements?
    b. Have the revised green tea claims improved consumer understanding of the scientific content?

c. Do qualified health claims change consumer perceptions of health benefits and behavioral intentions for green tea?

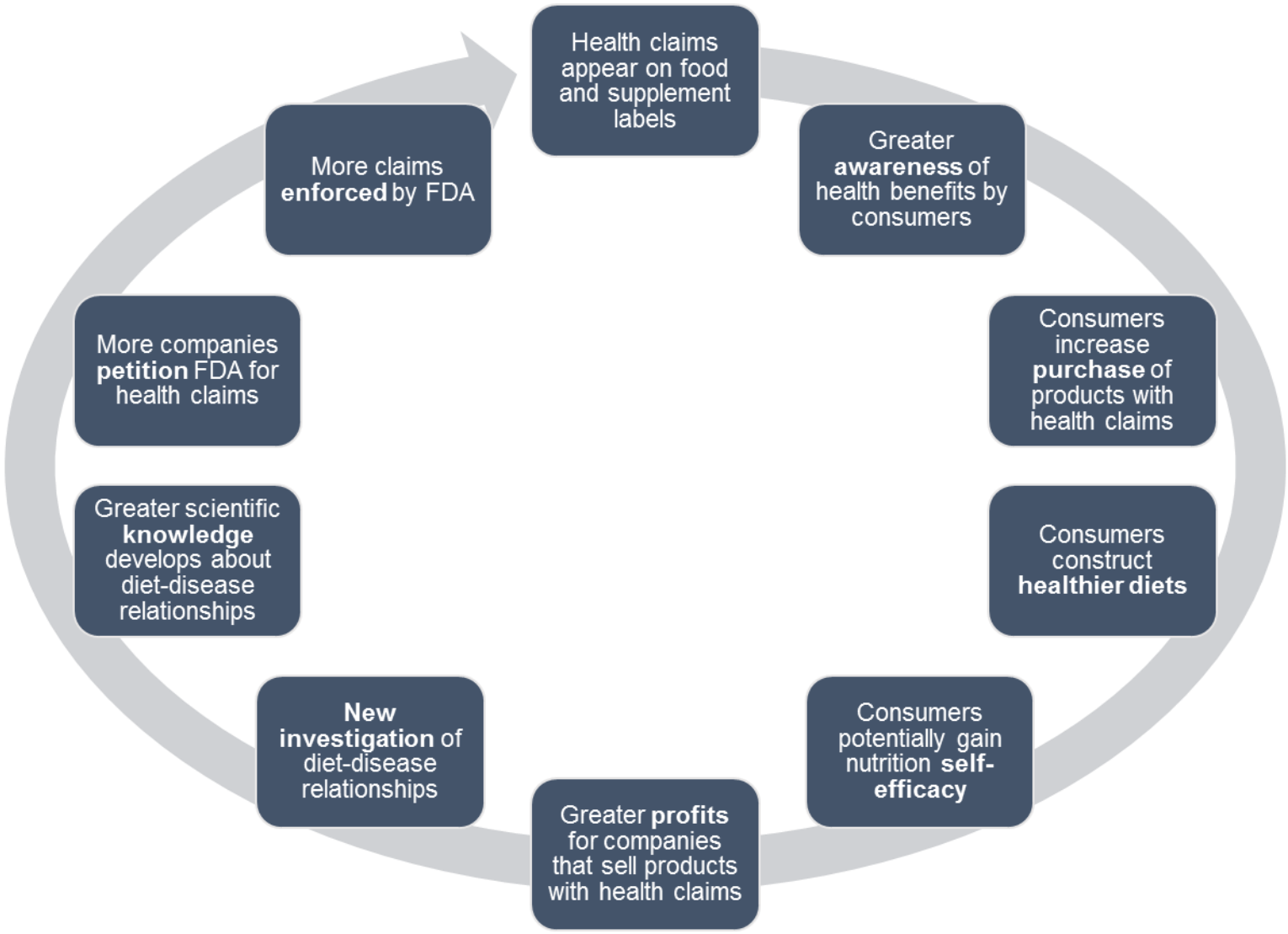
Chapter 2 identifies the state of qualified health claims in the US. This comprehensive review includes FDA regulatory documents for the food and dietary supplement industry and consumers, a literature review of consumer research, and an examination of the federal lawsuits between the food and dietary supplement industry and the FDA concerning qualified health claims. **Chapter 3** continues with a thematic content analysis of the 53 qualified health claims currently enforced by the FDA for use by the industry. The aim of this chapter was to understand the FDA's approaches or strategies to communicate scientific evidence to consumers in existing QHCs. **Chapter 4** reports the results of an experimental survey and is the first of three chapters dedicated to the qualified health claim case study about green tea. The aim of this first step is to understand and characterize the existing green tea consumer. **Chapter 5** continues with the experimental survey data in which participants were exposed to one of seven qualified health claims about the green tea-cancer relationship and responded to a battery of questions that aimed to test assumptions and points of disagreement about the green tea QHCs. **Chapter 6** uses the same survey data but focuses on behavioral intentions in relation to the qualified health claim presented. This final piece of the green tea case study aims to create a parsimonious linear regression model for purchase intentions of green tea in response to the qualified health claim. Finally, **Chapter 7** summarizes the findings, offering future research direction and policy relevant recommendations for stakeholders.

Table 1. Nutrition Label Claims for Food and Dietary Supplement Products that are regulated by the US Food and Drug Administration

Claim	FDA Preapproval	Definition	Example
Health Claim	Yes	Describes a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition.	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.
Qualified Health Claim	Yes	Describes a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition, and require a scientific certainty qualifier	Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.
Structure-Function Claim	No	Describes the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans.	Calcium builds strong bones
Nutrient Content Claim	No	A claim on a food product that directly or by implication characterizes the level of a nutrient in the food.	Only 200 mg of sodium
Dietary guidance statement*	No	Describes general dietary patterns that promote health. Make reference to a category of foods and not to a specific substance.	Carrots are good for your health

*Permissible on conventional food labels; not dietary supplements
Reference: http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm#main

Figure 1. Virtuous cycle of health claims



CHAPTER TWO
The Evolution of Language Complexity in Qualified Health Claims

1. Introduction

The market for foods with health benefits and dietary supplements continues to expand in the United States (US) (Neiner, 2012), European Union (EU) (Sanaullah Khan, Grigor, Winger, & Win, 2013), and Japan (Leatherhead Food Research, 2011). Front-of-pack nutrition claims are a primary vehicle used to inform American consumers about the health benefits of foods and supplements (Lytton, 2010). Manufacturers and marketers of these products value the ability to make health claims. Such marketing strategies (Koponen, Sandell, Salminen, & Lenoir-Wijnkoop, 2012) can increase the perceived value of specific products, making them more competitive (Freimuth, Hammond, & Stein, 1988; Levy & Stokes, 1987) and profitable (Institute of Medicine of the National Academies, 2010; Institute of Medicine of the National Academies, 2011; Pearson, Shaw, American Preventive Medical Association, & Citizens for Health, 1999; Sanaullah Khan et al., 2013) in the marketplace.

The public also appears to appreciate health claims associated with foods and dietary supplements. The majority of Americans believe that certain foods provide particular health benefits that can play a significant role in improving and maintaining overall health (International Food Information Council, 2011). Therefore, American consumers actively seek nutrition, food, and health information (Academy of Nutrition and Dietetics, 2011), and nearly 30% indicate that they usually or always purchase products with labels that claim to improve a specific health condition (Sloan, 2012).

However, because health claims may serve as incentives to consumers to purchase products, manufacturers and marketers of foods and supplements may wish to associate their products with health benefits even when the evidence is tenuous. As a result, the food and dietary supplement industry have advocated for strengthened commercial speech rights both in the US and internationally to enable them to more freely associate their products with specific health benefits.

Yet, most consumers do not have the ability to assess the veracity of these claims and must rely on governmental regulatory efforts to police claims that are inaccurate or misleading. Government agencies in the US, EU, Japan, South Korea, Australia and New Zealand, have focused substantial efforts on regulating and enforcing accurate and truthful health claims. This has resulted in conflicts between these governments and the food and dietary supplement industry.

It is important to note that FDA makes distinctions among what it considers to be regulated health claims, structure/function claims, nutrient content claims and dietary guidance statements. Under FDA guidelines, health claims ‘‘describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition.’’ For example, a health claim may state, ‘‘diets high in calcium may reduce the risk of osteoporosis.’’ A statement that does not include both a descriptor of a food substance and a disease or health-related condition does not meet the definition of a health claim and therefore is not regulated as such. For example, structure/function claims describe the role of a nutrient intended to affect normal structure or function in humans; for example, ‘‘calcium builds strong bones’’. These claims are not pre-approved by FDA, but must be both truthful and not misleading.

Nutrient content claims describe the level of a nutrient in a product either in absolute terms or under regulatory requirements that govern the consistent use of terms (e.g. ‘‘high’’, ‘‘healthy’’, ‘‘lite’’) and other words and phrases that state or imply comparative nutrient content. Label statements such as ‘‘a good source of calcium’’ fall under the guidelines that govern claims about nutrient content. Finally, dietary guidance statements describe the health effects of a broad category of foods; for example: ‘‘Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.’’ Since neither nutrient content claims nor structure/function claims explicitly link a nutrient to a disease or health-related condition, they are not subject to regulation as a health claim (Food and Drug Administration, 2003a).

In sum, health claims are permissible on food and dietary supplement packaging and describe a relationship between a dietary component and the reduced risk for a disease. Emerging evidence (not always supportive or definitive) of the links between diet and health has created a dynamic and complex science communication environment. In the US, there has been much legal activity between the Food and Drug Administration (FDA) and predominantly, the dietary supplement industry. Specifically, there has been litigation concerning the health benefits linked to certain foods and supplements, the strength of the evidence supporting those claims, and the language used to describe those associations.

Key court rulings (Pearson et al., 1999) have led to a four-tier system where health claims are assigned to one of four levels of evidence (Food and Drug Administration, 2003b). Dependent upon the strength of evidence for an association between the consumption of a food or dietary supplement and a specific health outcome,

claims are assigned a grade of A, B, C, or D. An A claim has strong supportive evidence for the diet–disease relationship, and may be expressed as a straightforward declarative statement. For example: ‘‘Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors’’ (National Archives and Records Administration, 2012). In contrast, claims assigned B–D represent evidence that is emerging, uncertain, or inconclusive. Therefore, B–D claims must be qualified with a disclaimer that describes the evidence for a relationship so as to prevent consumer confusion.

This requirement has facilitated the enforcement of complicated health claim statements. An example of their complexity is a claim about the relationship between tomatoes and the reduced risk of gastric cancer, “Four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, the FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer” (Food and Drug Administration, 2011c).

A series of lawsuits in the US have had substantial impacts on how qualified health claims have been formulated, regulated, and enforced. Research has shown that consumers are confused by QHCs (Derby & Levy, 2005; Food and Drug Administration, 2009; Hooker & Teratanavat, 2008; Nocella & Kennedy, 2012; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008)(Derby and Levy, 2005; FDA, 2005; Hooker and Teratanavat, 2008; Reinhardt-Kapsak et al., 2008; Nocella and Kennedy, 2012) and that the food and dietary supplement industry seldom include them on products (Fitzgerald Bone & Russo France, 2009).

To create an environment that protects the consumer, promotes healthful products, and encourages research into emerging diet–disease relationships, a collaborative and reciprocal relationship must exist between government and industry (Sanaullah Khan et al., 2013). When this relationship fails, litigation is often the result (see Table 1). Devised by federal courts, the elaborate health claims system aims to protect consumers and commercial speech. However, consumer research indicates this system is ineffective. Therefore, the purpose of this paper is to provide an overview of the litigation surrounding health claims in the US and an analysis of the challenging task of effective science communication within a dynamic food litigation and policy environment. Through this we identify the impact of the evidence review system and subsequent language used to describe the balance of the scientific evidence underlying claims of health benefits on foods and dietary supplements.

While the current analysis focuses on health claim regulations in the US, the debate concerning levels of scientific evidence and consumer understanding of food and health relationships is ubiquitous (Grunert, Scholderer, & Rogeaux, 2011). Japan and Korea have adopted evidence-rating schemes for health claims within their food system (Kim, Kang, Kwon, & Kim, 2010; Yamada, Sato-Mito, Nagata, & Umegaki, 2008) and the EU, Australia, and New Zealand have made considerable regulatory changes for use of health claims designed to protect consumers (Food Standards Australia New Zealand: Te Mana Kounga Kai – Ahitereiria me Aotearoa, 2012; Lugard, 2012; Starling, 2008).

2. Background of health claims and qualified health claims

2.1. Health claims on food products

Products regulated by the FDA are categorized by their intended use as dictated by the 1938 Federal Food Drug and Cosmetic Act (FDCA) (Bass, 2011). A food is defined as an article ‘‘used for food or drink for man or other animals, chewing gum, and articles used for components of any such article’’. A drug is a substance ‘‘intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease’’ (FFDCA 21 U.S.C. §321(g)(1)(B), 1938). In this 1938 framework, health-related claims pertaining to disease or health conditions could only be applied to drugs. If a food package specified a relationship between a dietary ingredient and a health-related condition, the intended use of the product would change to a drug. A shift to drug status would subject a product to FDA review of evidence prior to market release.

The FDCA regulatory framework was challenged in 1984 when the Kellogg Cereal Company partnered with the National Cancer Institute (NCI) in a campaign that publicized the role of a low fat, high-fiber diet in reducing the risk of colon cancer. Promoted on their high fiber breakfast cereal All Bran (Institute of Medicine of the National Academies, 2010), the campaign included food labels, television commercials, and print advertisements. Kellogg never consulted FDA about their marketing content and NCI never communicated with FDA about the campaign despite both agencies being housed under the Department of Health and Human Services (DHHS) (Nestle, 2002).

Since it was a multimedia campaign, the FDA, and the Federal Trade Commission (FTC) which regulates television and print advertisements (Diaz, 2011), were required to determine the legal status. Although the FTC ruled the campaign non-deceptive and legal, the 1938 FDCA prohibited marketing diet–disease relationships on food labels. However,

the DHHS approved the Kellogg campaign and discouraged (Nestle, 2002) FDA from taking legal action (Consumers Union, 1986).

The Kellogg-NCI partnership proved successful for Kellogg. Within the first six months of the campaign, Kellogg's All-Bran cereal experienced a 0.47 (0.99–1.46%) share point growth within the cereal market (Freimuth et al., 1988; Levy & Stokes, 1987). Other food manufacturers launched similar campaigns for high fiber foods (e.g. prunes, breads) (Freimuth et al., 1988). Soon after, non-fiber containing products marketed health benefits, such as drinking Florida Grapefruit Juice as a way to prevent hypertension (Freimuth et al., 1988).

The subsequent proliferation of unregulated health claims and potentially misleading information caused concern among consumer groups (Consumers Union, 1986). Congress responded by amending the 1938 FDCA with the Nutrition Labeling and Education Act (NLEA) of 1990, which provided greater oversight and regulation of health claims. The NLEA applied the definitive criterion of significant scientific agreement (SSA) for health claims.

2.2. Scientific agreement of health claims on dietary supplements

Other amendments to the FDCA further contributed to the health claim story (Fig. 1). Until the mid-1990s, health claims were exclusive to food products. Dietary supplement manufacturers witnessed the advantage of using health claims and were instrumental in Congress passing the Dietary Supplement Health and Education Act (DSHEA) of 1994. The DSHEA further amended the 1938 FDCA by regulating dietary supplements as food products and allowing them to employ health claims (Bass, 2011).

Dietary supplement petitioners had less success in receiving approval for the use of health claims than did petitioners for food products (Emord, 2000). Shortly after the passage of DSHEA, the FDA rejected four claims petitioned by supplement manufacturers: (1) Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer, (2) Consumption of fiber may reduce the risk of colorectal cancer, (3) Consumption of omega-3-fatty acids may reduce the risk of coronary heart disease, and (4) A dose of 0.8 milligrams of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than is a lower amount in foods in common form (Pearson et al., 1999).

An assemblage of dietary supplement marketers and distributors, and consumer organizations opposed the rejections and filed a lawsuit against the FDA challenging the legitimacy of the petition outcomes (Pearson et al., 1999). The FDA argued that the evidence was limited for health benefits associated with dietary components and demonstrated greater support for foods containing those same ingredients (Pearson et al., 1999). However, the US Court of Appeals, DC Circuit ruled in favor of the plaintiffs, stating that the SSA standard was overly restrictive and interfered with commercial speech under the First Amendment (Pearson et al., 1999). The court asserted, ‘‘the mere absence of significant affirmative evidence in support of a particular claim…does not translate into negative evidence ‘against’ it’’ (McColl & Bump, 2005). The FDA could not reject health claims judged to be misleading unless it was determined that a disclaimer would not eliminate deception.

3. The QHC system: qualifying scientific agreement in health claims

The 1999 Pearson vs. Shalala court decision was the catalyst for qualified health claims (QHCs), which are ‘‘claims that characterize the quality and strength of the scientific evidence if the claim is not based on significant scientific agreement’’ (Schneeman, 2012). In addition, a four-tier ranking system (A–D) was created to rate the evidence for diet–disease relationships based on ‘‘quantity, consistency, and relevance to disease risk reduction in the general population or target subgroup’’ (FDA, 2003). Whereas a health claim meets SSA standards and demonstrates an ‘‘A’’ level of evidence, QHCs are ranked as having a ‘‘B’’, ‘‘C’’, or ‘‘D’’ level of evidence and require a scientific certainty disclaimer (Fitzgerald Bone & Russo France, 2009).

The attempts by the FDA to improve the qualifying language in QHCs as required by the courts also contributed to further legal activity and led to a more specific regulatory framework (Table 1). The current state of QHCs can be attributed to five influential lawsuits that occurred between 2001 and 2012. The court rulings defined the language and evidence requirements for QHCs, which contributed to their complexity. In turn, this limited consumer ability to comprehend QHCs (Derby & Levy, 2005; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008) while also limiting their use in the marketplace (Fitzgerald Bone & Russo France, 2009).

4. Case law and qualified health claims

4.1. Pearson vs. Shalala I, 1999 US Court of Appeals, District of Columbia Circuit

The 1999 Pearson court offered three disclaimers for the contested diet–disease relationships, ‘‘The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods.’’ ‘‘The

evidence in support of this claim is inconclusive.'' ''The FDA does not approve this claim.'' (Pearson et al., 1999).

The FDA revisited the rejected health claims and ultimately denied QHC status for dietary fiber and colorectal cancer. The agency maintained the evidence suggested a relationship between a reduced risk of colorectal cancer and ''diets high in fiber-containing grain products, fruits, and vegetables and low in total fat'', not an isolated, supplemental form of dietary fiber (Food and Drug Administration, 2000a).

The FDA did grant QHC status for the relationship between omega-3 fatty acids and heart disease. However, the agency modified the court-suggested disclaimers to distinguish between relationships that exhibit preliminary evidence and others that demonstrate robust evidence (Pearson et al., 1999), "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids".

4.2. Pearson vs. Shalala II, 2001 US District Court, District of Columbia

The folic acid health claim was found ''inherently misleading'' because it suggested supplements were more effective than foods in delivering folic acid (Food and Drug Administration, 2000b), which was not supported by the ''weight of the evidence.'' Manufacturers of folic acid supplements filed a separate lawsuit against the FDA claiming a violation of the First Amendment, and requested an injunction (Pearson, 2001). The court granted the motion, which required FDA to allow a QHC for folic acid and to ''draft one or more appropriately short, succinct, and accurate disclaimers.'' The court reasserted two generic disclaimers from Pearson I and offered a folic acid-specific

disclaimer, ‘‘Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects’’ (Pearson, 2001).

The agency prescribed a different folic acid-specific disclaimer to accompany the claim, “FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects” (Food and Drug Administration, 2011c).

4.3. Whitaker vs. Thompson, 2002 US District Court, District of Columbia

The FDA also reevaluated and denied QHC status for the relationship between antioxidant vitamins and cancer. This resulted in a subsequent lawsuit known as Whitaker vs. Thompson (Whitaker, 2003). The agency argued that the weight of the evidence against the relationship was greater than the weight of supportive evidence. The court disagreed with the FDA’s logic and ruled that claims could only be prohibited if there was little qualitative evidence in support of the proposed diet–disease relationship (Whitaker, 2003). The court ordered FDA to draft one or more alternative scientific certainty disclaimers from which companies could choose (Whitaker, 2003). This ruling introduced multiple QHC statements for a single relationship. While the decision was valuable for the food and dietary supplement industry and for protecting commercial speech, the result was three QHC statements for the relationship between antioxidant vitamins and the reduced risk of cancer. The court assumed that multiple QHC statements for the same diet–disease relationship that used different approaches to describe evidence would hold the same meaning for consumers. In accordance with the ruling, three QHCs were crafted with slightly different language to describe the evidence, “Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of

certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive." "FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive" (Food and Drug Administration, 2011c).

4.4. Alliance for Natural Health, US vs. Sebelius I, 2010 US District Court, District of Columbia

Manufacturers of selenium supplements petitioned for claims for 10 relationships about selenium and site-specific cancers. The agency denied seven of the 10 relationships. The three relationships considered enforceable were about supplemental selenium and cancer of the bladder, thyroid, or prostate. However, petitioners were displeased with the language prescribed by FDA about prostate cancer. Known as Alliance I, selenium manufacturers filed a lawsuit claiming the agency had replaced their proposed disclaimer with language that contradicted the relationship. The petitioned claim read, "Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive" (Alliance for Natural Health U.S., 2010). While the FDA-prescribed QHC read,

> "Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer" (Alliance for Natural Health US, 2010).

The court agreed that FDA had not justified their ‘‘complete substitution’’ of the proposed QHC, particularly because the objection related to the wording, not the evidence about the relationship (Fleminger, 2012). The court required FDA draft short, succinct, and accurate disclaimers (Pearson, 2001) and consider ‘‘whether inclusion of appropriate disclaimers would negate the potentially misleading nature of manufacturers’ claims’’ (Alliance for Natural Health U.S., 2010). The court also required that FDA summarize the strength of the evidence in QHC statements, as it would be ‘far less restrictive than negation of the plaintiffs’ claim’ (Alliance for Natural Health U.S., 2010). This resulted in 10 QHC statements enforced by FDA about the anticarcinogenic effects of selenium and site-specific cancers (i.e. bladder, prostate, thyroid, colorectal) (Food and Drug Administration, 2011c).

4.5. Alliance for Natural Health, US vs. Sebelius II, 2011 US District Court, District of Columbia

In a similar case, the same plaintiffs filed legal action against FDA asserting that the agency had replaced petitioned claim language for the relationships between vitamin C and gastric cancer, and vitamin E and bladder cancer. The proposed claims read, “Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive.” “Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive” (Alliance for Natural Health U.S., 2011).

The agency contended that the QHCs were rephrased to accurately summarize the evidence (Alliance for Natural Health U.S., 2010) and read,

> “One small study suggests that vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based

> on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer.
>
> "One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer" (Food and Drug Administration, 2011c).

The court ruled the agency had ''…completely eviscerated plaintiffs' claim[s], with no explanation as to why a less restrictive approach would not be effective'' (Alliance for Natural Health U.S., 2011). The FDA was again required to draft one or more precise disclaimers for the vitamin C-gastric cancer and vitamin E-bladder cancer claims. While FDA continues to enforce the two contested QHCs, in 2012 the agency also began enforcing four additional QHCs, "Vitamin E may reduce the risk of bladder cancer although the FDA has concluded that there is very little scientific evidence for this claim". "Vitamin E may reduce the risk of bladder cancer. FDA has concluded that there is very little scientific evidence for this claim". "Vitamin C may reduce the risk of gastric cancer although the FDA has concluded that there is very little scientific evidence for this claim". "Vitamin C may reduce the risk of gastric cancer. FDA has concluded that there is very little scientific evidence for this claim" (Food and Drug Administration, 2012a).

The language challenged in Alliance I and II reflected QHCs about green tea and prostate cancer and breast cancer. In 2004, a manufacturer petitioned for claims about green tea and the reduced risk of breast and prostate cancers (Food and Drug Administration, 2005a). Allowable on dietary supplements and foods, the agency began enforcing QHCs for the two diet-disease relationships,

> "Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer".

> "One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer" (Fleminger, 2012).

However, the petitioner was unsatisfied with the language and sent a letter to FDA requesting the claims be adjusted to, "Green tea may reduce the risk of breast and prostate cancers. There is credible evidence supporting this claim although the evidence is limited" (Fleminger, 2012).

The agency never responded since: (1) the letter failed to follow FDA guidelines, (2) the content focused on QHC language, not the review of evidence and, (3) the QHC statements were scientifically accurate (Fleminger, 2012). Therefore the 2005 green tea QHCs continued to be enforced.

4.6. Fleminger, Inc. vs. US Department of Health and Human Services, 2012 US District Court, D Connecticut

In 2011, the FDA noticed the similarity in the language contested in the Alliance lawsuits and that of the green tea QHCs. The agency revised the QHCs (Food and Drug Administration, 2011b) by combining and simplifying them into one claim in 2011, "Drinking green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce that risk because there is very little scientific evidence for the claim" (Food and Drug Administration, 2011b).

However the manufacturer filed legal action against the FDA (Fleminger, 2012) asserting the new disclaimer negated the claim (i.e. ''FDA does not agree…''). The FDA reasoned that the disclaimer prevented consumers from assuming the claim reflected the agency's stance that green tea reduces the risk of breast or prostate cancer (Fleminger,

2012). The court again required FDA to draft a disclaimer that did not contradict the claim (Fleminger, 2012).

The 2005 QHCs are no longer enforced since the language reflected a disputed claim from a previous lawsuit (Alliance for Natural Health U.S., 2011) and the 2011 QHC is not enforced because the disclaimer negated the diet–disease claim (Fleminger, 2012). As of 2012, two new QHCs supersede the earlier versions, "Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim". "Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim" (Food and Drug Administration, 2011c).

4.7. Case law summary

The court rulings shaped two main aspects of QHC regulations by specifying: (1) evaluative parameters of scientific evidence for diet–disease relationships petitioned for QHC status and (2) requirements to describe the evidence in the disclaimer portion of QHCs. The seminal case, Pearson I, required the FDA to allow claims with disclaimers about diet–disease relationships that demonstrated emerging scientific evidence so long as they did not mislead consumers (Pearson et al., 1999). This opened the door, allowing manufacturers to make ''qualified'' health claims for diet–disease relationships where the supporting scientific evidence for those claims has not yet reached the level of significant scientific agreement.

The 2002 Whitaker case expanded the possibilities for manufacturers to include QHCs on products, stipulating that FDA could only reject a claim when there was no evidence for a diet–disease relationship or when the supportive evidence was

qualitatively weaker than the unsupportive evidence (Whitaker, 2003). For diet–disease relationships that meet this criterion, the FDA prescribes QHCs that may be created de novo or adapted from petitioned claims from manufacturers.

Several of the key court cases have involved disputes concerning the specific language prescribed by FDA for QHCs. The outcomes of these cases have shaped QHC language by requiring FDA to write clear and short claims (Alliance for Natural Health U.S., 2011; Pearson, 2001), with disclaimers (i.e. description of evidence) that do not contradict the claim (i.e. diet–disease relationship) (Fleminger, 2012), while also providing multiple QHC statements for diet–disease relationships (Whitaker, 2003) so that manufacturers may select that most appropriate for their product. The agency is also required to consider petitioned claims and may not entirely rewrite them (Alliance for Natural Health U.S., 2010).

Significantly, while these latter court decisions have created case law, the effect has largely been restricted to the specific claims litigated (such as green tea), and how FDA is likely to construct QHC language in the future. It has not led FDA to revise all of the previously enforced QHCs. As a result, these cases have not resulted in a coherent system for describing the scientific evidence behind the diet–disease relationships in QHCs. Instead, the currently enforced QHCs describe emerging scientific evidence in a variety of inconsistent ways.

5. The illogic of QHC language

Since the establishment of QHCs in 1999, acceptable language to describe the balance of evidence for a claim has been at the center of intense legal debate. In part, this is because QHCs hold the potential to increase the sales of products that carry them

(Freimuth et al., 1988; Levy & Stokes, 1987; Nielsen, 2012; Nocella & Kennedy, 2012). Court cases have focused on different aspects of claims including: the regulatory system and pace of petition review, the application of SSA, the legitimacy of dietary supplements to use health claims or QHCs, and the prescribed language that describes the evidence regarding diet–disease relationships.

It is clear that the court activity has contributed to the inconsistent language observed in FDA-enforced QHC statements, which are ever evolving. There are four stakeholder groups with varied and intertwining interests. First is the courts, which make a fine distinction between protecting commercial and consumer interests related to speech. The courts are responsible for protecting commercial speech rights under the First Amendment as well as for safeguarding the public from inherently misleading information.

The interests of the food and dietary supplement industry relate to financial gain (Pearson et al., 1999). Profit is linked to their pursuit of language that, in the strongest way possible, establishes the link between a product and a positive health outcome. Closely related is the FDA which is responsible for regulating and enforcing claims to ensure there is truthful information on food and dietary supplement packaging and to prevent consumers from being misled (Food and Drug Administration, 2012b).

As a result of these competing interests, significant differences of opinion exist between the courts, the FDA, and the industry about what can and cannot be said in QHC statements. The succession of court cases challenging the implementation of QHCs by the FDA has resulted in rulings that have affected claim language. This has led to a series of enforced QHCs with complex and inconsistent language. While case law has upheld

the First Amendment and commercial speech, and the FDA-enforced QHCs intend to accurately communicate evidence, it does not appear consumers have benefitted from these protective intentions.

While American consumers do not have a role in the language used in QHCs, they are stakeholders through their interest in foods and dietary supplements with associated health benefits (International Food Information Council, 2011; Neiner, 2012; Nielsen, 2012). Since American consumers have a varied ability to understand and act on scientific information (Crowell & Schunn, 2013) it seems understanding the evidence on product packages would be cognitively challenging.

Indeed, consumer research has shown that study participants do not understand QHCs as indicators of the ‘‘quality and strength of the scientific evidence’’ (Schneeman, 2012) about diet–disease relationships. Research completed by the FDA tested different formats to communicate the information found in QHCs (Food and Drug Administration, 2005b).

Focusing on the disclaimer portion, respondents were less likely to understand the strength of science underlying a claim when only words were used to describe the evidence. An alternative format tested a disclaimer that included the grade of evidence (B–D) for a claim. This format allowed participants to understand there was an order of scientific strength for claims. However, the majority of respondents misinterpreted B claims to have greater scientific certainty than A graded claims since they do not require disclaimers. Further study participants misjudged the evidence grade as an indication of products’ health benefits and overall healthfulness (Food and Drug Administration, 2005b).

Similarly, other consumer research found that when presented with a QHC describing the evidence, respondents were unable to distinguish between the four levels of evidence (Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008). Some were unaware that inconclusive information was allowed on product packaging (Hooker & Teratanavat, 2008). A visual aid that indicated evidence grades improved communication of a hierarchy however participants extrapolated the grade as an indication of product quality rather than the underlying scientific evidence (Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008). The visual aid suggested to participants that the FDA approved the message and as a result felt they could trust it more (Hooker & Teratanavat, 2008).

Much of the consumers' understanding of health claims and QHCs stem from prior knowledge. The claim language is more important for understanding a relationship if consumers are unaware of a dietary ingredient (Food and Drug Administration, 2011a). Substance-specific health claims (e.g. potassium) were found more helpful than food-specific (e.g. banana) health claims if a diet–disease relationship was less recognized (Lin, 2008). This suggests that for emerging diet–disease relationships with theoretically lesser-known ingredients, more detailed information in the claim is important for comprehension.

It also seems that the food and dietary supplement industry are not benefitting from QHCs. A content analysis of QHC-eligible products demonstrated limited use of QHCs among foods and dietary supplements. Five percent of the 1200-catalogued (n = 55) products employed QHCs (Fitzgerald Bone & Russo France, 2009).

6. Conclusion and implications

In the struggle to protect consumers and commercial speech, QHC statements seem to inadvertently mislead consumers (Emord & Schwitters, 2012), which is a likely cause for their limited use on foods and dietary supplements. Consequently, consumers have a limited ability to learn about emerging diet–disease relationships on products. It appears the health claims regulatory system is ineffective since QHCs are used on a limited basis (Fitzgerald Bone & Russo France, 2009) and subsequently consumers have limited exposure to information about emerging relationships between diet and health. Still, petitions for QHCs about emerging diet–disease relationships continue to be submitted to the FDA. Most recently, a petition was submitted for the consumption of psyllium husk as a way to reduce the risk of type 2 diabetes (Murphy, 2013) and the FDA began enforcing two QHCs about the relationship between whole grains and the reduced risk of type 2 diabetes (Watson, 2012). The food and dietary supplement industry clearly values QHC status for diet–disease relationships. The announcement of newly enforced QHCs and newly acknowledged diet–disease relationship by the FDA has previously generated significant media coverage for a health benefit of a product (Johnson, 2007). This is a plausible reason for the continued business interest of QHCs and their associated language.

This suggests the issue of health claims spans beyond the FDA regulatory jurisdiction of food and supplement labels. Health claim history has spotlighted the conflicts in authority between federal agencies. In the 1984 Kellogg-NCI case, the FTC ruled the campaign legal while FDA refrained from taking legal action (Consumers Union, 1986). The fragmented regulations between the FDA and FTC have since been

recognized and the two agencies have begun to cooperate and collaborate regulatory efforts (Villafranco, Pippins, & Wolff, 2011).

Nonetheless, inconsistent language in QHC statements remains a major issue. While four Congress members urged FDA to implement a moratorium on QHCs until regulations were reviewed and revised (Starling, 2008), few changes have been made. Discussion and action is needed among stakeholders to ensure QHC language is lawful, consistent, and aligned with consumer needs. To achieve this, a coordinated effort between regulatory agencies (i.e. FDA, FTC), the food and dietary supplement industry, and academic researchers is essential to reassess the QHC system and guarantee informed laws and regulations.

Most important, while several district and appellate courts have dictated language requirements for QHCs, the court rulings have not been based on consumer research. As pointed out in the judicial opinion concerning green tea, the general public does not understand internal-to-FDA terms such as ‘‘credible evidence’’ (Fleminger, 2012). Therefore, QHCs should not include internally used terminology (Fleminger, 2012). The notion of public misunderstanding of scientific terminology can be generalized to other QHCs since many demonstrate similar language. This concern is supported by research that suggests a similar disconnect exists between the QHC language required by the courts and consumer understanding (Derby & Levy, 2005; Food and Drug Administration, 2009; Hooker & Teratanavat, 2008; Nocella & Kennedy, 2012; Reinhardt-Kapsak et al., 2008).

In accordance with the court rulings, FDA has attempted to use different strategies to more effectively communicate the balance of evidence supporting diet–

disease relationships. Depending upon the amount and strength of evidence for a relationship, QHCs are assigned a letter grade (B–D), however this information is not available to the public. Rather, the level of evidence or grade is arguably discerned through the language used to describe the evidence in QHCs. Considering consumer research this aspect might need reconsidering, as should the FDA's communication approach in claims.

In Pearson I, the court required FDA to consider disclaimers prior to banning a health claim (Pearson et al., 1999). If research has demonstrated that enforced disclaimers are ineffective for consumer understanding, how much evidence is needed to conclude that a claim is misleading? Further, what does the ‘‘average consumer’’ (Grunert et al., 2011) understand about science, evidence, and perhaps probability (Nocella & Kennedy, 2012)? Health claims regulations in the EU require that claims be understood by the average consumer or someone who is ‘‘reasonably well informed’’ (Grunert et al., 2011). It is not clear who the average consumer is in the US or how well-informed he or she is. Court rulings about QHCs in the US and the global debate about health claims largely revolve around the average consumer and how much they can understand about the health benefits communicated on products (Grunert et al., 2011). Although different legal systems exist that dictate health claim regulations, there is a steady international discussion about the amount of evidence needed to substantiate a claim or potentially mislead consumers. In Japan, qualified FOSHU require a disclaimer and use modal verbs that indicate probability (Lalor & Wall, 2011; Yamada et al., 2008). Similarly, the Korean Food and Drug Administration employs a rating system for health claims of functional foods (Kim et al., 2010).

The different types of QHC statements derived from court cases is an aspect of US policy that may provide regulators in other countries insight to improve consumer understanding of health and science (Nocella & Kennedy, 2012). Qualified health claims are relevant to other countries because they demonstrate language and communication strategies that may or may not help consumers make informed decisions.

7. Future research

To ensure a successful health claims system in the US and to provide evidence for international regulatory authorities, consumer research must determine how to communicate emerging evidence to the average consumer (Gray, 2012) and perhaps, whether she can understand scientific evidence at all. The available research about consumer understanding of QHCs was completed prior to 2008, before three significant court rulings that affected disclaimer language. Since then, 26 QHC statements have been enforced or revised so it is critical to determine consumer understanding of the evidence presented in QHCs in pre-2008 and post-2008 QHC statements.

Another area of study would be to explore consumer perceptions of evidence in QHC statements that are about the same diet–disease relationship and have the same level of evidence. As demonstrated in the legal history, the courts emphasized that FDA ‘‘draft one or more appropriately short, succinct, and accurate disclaimers’’ from which companies could choose (Pearson, 2001). This promoted language diversity in QHC statements for a single diet–disease relationship. For example, there are three QHC statements for the relationship between vitamin E and gastric cancer, vitamin E and colon cancer, and vitamin E and bladder cancer. While this was an important decision to protect commercial speech, the diversity of linguistic options was arguably counterproductive for

the consumer. It is not known how consumers understand different evidence descriptors that attempt to communicate the same level of evidence.

Other areas in need of investigation include alternative strategies to communicate emerging scientific evidence to consumers. Short claims are not as cognitively demanding as long claims (Kiesel, McCluskkey, & Villas-Boas, 2011). Perhaps researchers could test shorter statements that describe evidence on consumer ability to understand evidence. Adopted from the World Cancer Research Fund, the World Health Organization employs a four-tier evidence hierarchy to demarcate activities to reduce the risk of diet-related chronic diseases (World Health Organization, 2003). This scale has been tested with Korean consumers (Kim et al., 2010) and been suggested as a promising alternative to the current system (Emord & Schwitters, 2012).

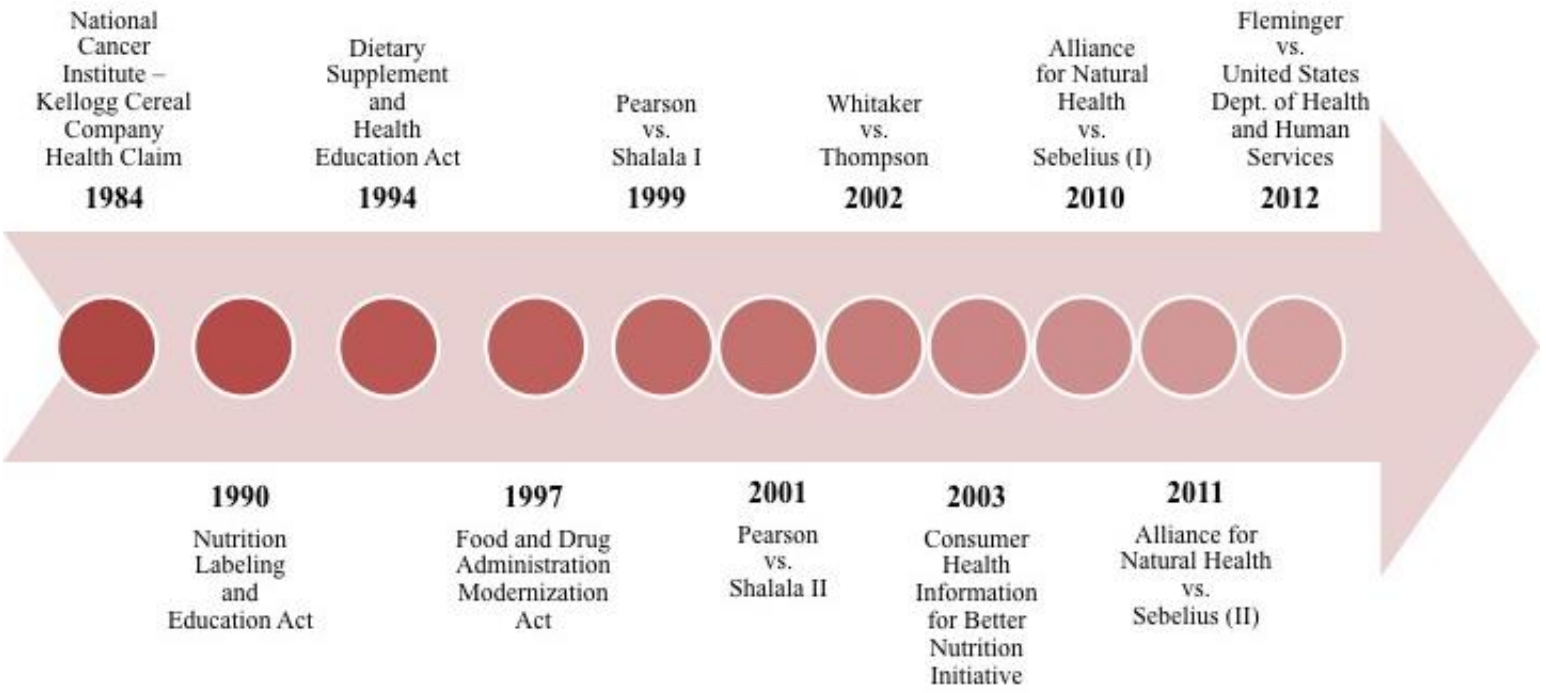


Figure 1. Significant Events related to Qualified Health Claims

Table 1. Case Law and FDA Requirements related to Qualified Health Claims

Case Law	Diet-Disease Relationship(s)	FDA Requirements
Pearson v. Shalala I, 1999 164 F.3d 650.	• Fiber – Colorectal Cancer • Antioxidant Vitamins – Cancer • 0.8mg Folic Acid – Neural Tube Defects • Omega 3 Fatty Acids – Heart Disease	• Must allow health claims with scientific certainty disclaimer *unless* proven misleading to consumers
Pearson v. Shalala II, 2001 130 F.Supp.2d 105.	• 0.8mg Folic Acid – Neural Tube Defects	• Must "draft one or more appropriately short, succinct, and accurate disclaimers"
Whitaker v. Thompson, 2002 248 F.Supp.2d 1.	• Antioxidant Vitamins - Cancer	• A claim can be banned when: o There is no evidence in support of the claim o Evidence in support of claim is qualitatively weaker than evidence against claim, and FDA demonstrates with empirical evidence that the public would be deceived with a disclaimer • Must provide more than one QHC option from which manufacturers may choose
Alliance for Natural Health, US v. Sebelius I, 2010 714 F.Supp.2d 48.	• Selenium – Cancer	• Cannot entirely replace a petitioner's claim with different and contradictory language • Court suggested…"the portion of the proposed claim to 'more accurately reflect the strength of the scientific evidence at issue.'"
Alliance for Natural Health, US v. Sebelius	• Vitamin C – Cancer • Vitamin E – Cancer	• Disclaimers must be precise • Literal = "purpose of drafting one or more precise disclaimers"

II, 2011 786 F.Supp.2d 1.		
Fleminger, Inc. v. US Dept. of Health and Human Services, 2012 854 F.Supp.2d 192.	• Green tea – Breast or Prostate Cancer	• Disclaimer language must not negate a claim

CHAPTER THREE
Communicating Scientific Evidence in Qualified Health Claims

Qualified health claims (QHCs) are regulated by the US Food and Drug Administration (FDA) and are permitted on the labels of food and dietary supplements to describe the relationship between the consumption of a dietary component and the reduced risk for a particular disease. The key characteristic of QHCs is they are intended to characterize the quality and strength of scientific evidence for the claimed relationship so that consumers can make better-informed decisions (FDA, 2003a; Schneeman, 2012).

Labeling products with information about their dietary components and associated health benefits has long been shown to increase sales (Freimuth et al., 1988; Levy and Stokes, 1987). As a result, proponents of QHCs suggest that they hold significant potential to mutually benefit both the public and the manufacturers of foods and dietary supplements (GMA, 2003) through a kind of "virtuous cycle" (Figure 1).

By marketing the health benefits of products, QHCs can inform the public about diet-disease relationships, encourage consumers to purchase more healthful foods, and promote sales of the products that bear them. Boosts in product sales attributable to marketing health benefits through QHCs should incentivize researchers and sponsoring industries to study other diet-disease relationships (GMA, 2003). Such research should increase the body of scientific evidence about new diet-disease relationships, and make more products with demonstrable health benefits available to the public. The QHCs associated with these products would then expose consumers to more diet and health-related information (GMA, 2003; Ippolito, 1999). Greater understanding of these health benefits would ideally improve consumer willingness to purchase (Lepkowska-White &

Parsons, 2001; Roe et al., 1999) and consume products bearing such claims (Ippolito and Mathios, 1990), helping them "construct healthier diets" (Taylor, 1995). This could improve a person's sense of health and well-being as well as their self-efficacy to make healthy decisions, and possibly reduce the risk for some chronic diseases, thus completing the cycle.

Yet, the cycle is not inherently virtuous. Because health claims sell products, there is an incentive for marketers to claim health benefits for their products without regard to the level of scientific evidence underlying those claims. This may result in marketers claiming health benefits of products that mislead consumers since they lack "a high level of scientific support" (Murphy, 2005). Similarly, without a clear description of what is known about the diet-disease relationship encompassed by the product, consumers may overestimate (or underestimate) the level of scientific evidence supporting a health claim. Therefore, the FDA plays an important role in helping consumers make informed choices by assessing health claims, and prescribing clear language that describes the relationship between consuming the dietary component in the product and the health outcome that form the basis of these claims.

However, ensuring the clarity of these claims to reduce consumer misunderstanding is a challenging task. The courts have decided that unless there is no evidence for a claimed diet-disease relationship or the evidence supporting the claim is qualitatively weaker than the evidence that does not support it, FDA must enforce a claim (Whitaker v. Thompson, 2003). Moreover, because a "well-drafted disclaimer could remedy any supposed weakness" in a claim (Pearson v. Shalala, 1999), the FDA is burdened to craft disclaimers that are both scientifically accurate and clearly written to protect consumers

from deceptive marketing. The result is that enforced QHCs must indicate both that there is some evidence for the diet-disease relationship in question, while simultaneously communicating that there is a "low level of scientific certainty" for that relationship (Murphy, 2005).

In theory, this framework allows consumers to make better-informed decisions about the potential health value of products bearing those claims. However, research has demonstrated that QHCs unintentionally mislead and confuse consumers (Derby & Levy, 2005; FDA, 2009a; FDA, 2009b; Hooker & Teratanavat, 2008; Nocella & Kennedy, 2012; Reinhardt-Kapsak et al., 2008). This review helps to explain why that may be the case.

Background of QHCs

Qualified health claims resulted from the landmark court case, Pearson v. Shalala, which ruled that commercial entities have a right to market their products by making labeling claims about relevant diet-disease relationships, even when these relationships are supported only by partial evidence (Pearson v. Shalala, 1999). Prior to the Pearson decision, only health claims that met rigid scientific standards (i.e. Significant Scientific Agreement [SSA]) were allowed on food and dietary supplement labels in the US. The Pearson case allowed health claims that do not meet the SSA criterion, so long as they include disclaimers to prevent consumers from being misled (Pearson v. Shalala, 1999).

As a result of the Pearson decision, the FDA was required to regulate and enforce a new system of qualified health claims for diet-disease relationships where the scientific evidence was emerging, incomplete, or inconsistent. This led to a four-tier regulatory system in which the FDA assesses the available scientific evidence supporting the diet-

disease relationship and creates enforced claim statements for use by marketers that characterizes this evidence (FDA, 2011a). Under this new system, the FDA also assigned a letter grade (A-D) with respect to the level of scientific evidence; however, these grades are not included in the enforced claim statements.

"A" claims (i.e. health claims) demonstrate "a high level of comfort among qualified scientists" and do not require "qualifying" language (FDA, 2003b). Manufacturers have the autonomy to craft claims, so long as they are "truthful and not misleading" (FDA, 2013a). The remaining three tiers are qualified health claims and are assigned a B, C, or D grade, depending on the scientific support for the diet-disease relationship (FDA, 2011a). A "B" grade demonstrates "promising but not definitive" evidence, a "C" grade means there is 'low scientific support by qualified scientists,' and QHCs assigned a "D" grade have a very "low consistency with conclusions from authoritative bodies or ranked very low by qualified scientists" (FDA, 2003b).

The FDA considers three main parameters when determining a grade of evidence: quantity, consistency, and relevance (FDA, 2003b). Quantity refers to the number of studies, sample size, and generalizability of results. Consistency denotes "whether studies with both similar and different designs report similar findings." Relevance is an assessment of "magnitude of the risk-reduction effect in the target population…" (FDA, 2003b).

In theory, QHCs are constructed and enforced by the FDA to reflect its evaluation of the quantity and consistency of the scientific evidence and the magnitude of risk reduction in the target population. The FDA prescribes the language in QHCs for diet-disease relationships and manufacturers must implement them exactly as written (Bone &

France, 2009; FDA, 2003b). However, FDA is required to make multiple QHCs available for a single diet-disease relationship so manufacturers may choose that which is most appropriate for their product (Whitaker v. Thompson, 2003).

Current Status of QHCs

At the time of this analysis, the FDA enforced 53 QHCs (see Table 2). Although the structure and organization of QHC regulations was designed to systematically grade and communicate the level of scientific evidence for diet-disease relationships, the "letter grade" system does not appear to be functional. Claims are not formally assigned B, C, or D grades in FDA enforcement documents or in any other way that is transparent to the public.

In its 2009 Final Guidance for Industry, the FDA abandoned references to including formal letter grades as part of QHCs (FDA, 2011b). The original grading system was likely dropped because research showed that consumers frequently misunderstood the letter grades. The inclusion of a letter grade did help consumers understand there is a ranking system. With the introduction of the FDA Health Claims Report Card (Figure 2), which served as a visual aid, consumers were provided a frame of reference about the hierarchy of evidence, which also improved their awareness of a four-tier system (Bone & France, 2009; Hooker & Teratanavat, 2008; FDA, 2009a; FDA, 2009b; Reinhardt-Kapsak et al., 2008). However, studies showed that consumers mistakenly interpreted the grade as indication of other product attributes (FDA, 2009b; Reinhardt-Kapsak et al., 2008). Consequently, these perceptions lowered purchase intentions of products exhibiting a C or D grade (Reinhardt-Kapsak et al., 2008).

Without the inclusion of a letter grade, consumers must depend on the specific language of the enforced QHC to communicate the level of scientific evidence. Yet, the substantial variability in the language used to "qualify" the level of evidence in the 53 QHCs does not readily give an indication to consumers that there is an underlying classification system.

In part, this variability in language is a necessary function of appropriately describing the quantity, consistency, and relevance of the scientific evidence, which itself varies depending on the diet-disease relationship that the QHC attempts to summarize. However, much of the variability is also attributable to a series of legal disputes between the FDA and the food and dietary supplement industry (Alliance for Natural Health U.S. v. Sebelius, 2010; Alliance for Natural Health U.S. v. Sebelius, 2011; Fleminger, Inc. v. US Department of Health and Human Services, 2012; Pearson v. Shalala, 1999; Whitaker v. Thompson, 2003). These court rulings required the FDA to discontinue enforcement of some QHCs and replace them with new QHCs, leading to inconsistencies in language and perhaps to increased consumer confusion (Berhaupt-Glickstein et al., 2014).

Of particular note are the variations in the construction and language of existing claims. Words and the length of a claim statement influence consumers in different ways. For example, some consumers understand the word "inconclusive" as an honest and believable summary of evidence, while others view it as an extremely negative assessment. Interpretations of the word "may" (which is a key word in every QHC) is perceived by some as hedging, or an indication of weak evidence (Reinhardt-Kapsak et al., 2008). Also, short claims (~ nine words) appear to generate positive thoughts about a product's health benefits and to increase overall appeal whereas long claims do not (~26

words) (Wansink et al., 2004). In part, longer QHCs may increase cognitive exertion, which may then influence perceptions of evidence.

It is clear however, that manufacturers continue to value QHCs, as evidenced by recent petitions by manufacturers to the FDA to evaluate new claims about the relationships between: omega-3 fatty acids and blood pressure (2014), psyllium husk and type 2 diabetes (2012), whole grains and type 2 diabetes (2012), and infant formula and atopic dermatitis (2011) (FDA, 2009c; FDA, 2011c). Their continued interest suggests that the ability to make QHCs enhances the ability to sell products containing those dietary ingredients (Emord & Schwitters, 2012).

Focus and Objectives of the Study

While a fundamental argument for permitting QHCs was that they could increase public awareness of novel or emerging diet-disease relationships (Pearson v. Shalala, 1999), the current claims confuse consumers (Derby & Levy, 2005; Hooker & Teratanavat, 2008; Nocella & Kennedy, 2012; Reinhardt-Kapsak et al. 2008). This suggests that such claims do not meet the key criteria of being "truthful and not misleading."

The purpose of this study is to examine the differences in language and construction of currently enforced QHCs so as to contribute to the improvement of ranking systems that might be of greater utility to consumers. Further, it is essential to understand the current ranking system as a basis for testing alternative communication strategies. Through a content analysis, we classify the format, constructs, and language patterns found in QHCs, with a particular focus on language characteristics used to convey the level of scientific evidence for the diet-disease relationships.

Methodology

A thematic analysis categorized the 53 QHCs (See Table 2). The QHC format was examined through deductive analysis, as were the evaluative parameters of evidence for diet-disease relationships set by the FDA (i.e. Quantity, Consistency, & Relevance), and evidence grade (i.e. B, C, D) (FDA, 2003b). Inductive analysis catalogued characteristics that emerged as the investigation progressed (Elo & Kyngas, 2007).

First, QHCs were parsed to distinguish key constructs the FDA considers in the review of scientific evidence for diet-disease relationships (FDA, 2003b). The three FDA evaluative parameters are: the quantity of evidence, the consistency of evidence, and the relevance to the general population or a subgroup. The adjectives used by FDA to describe these constructs within the QHCs were also catalogued.

Next, the position of evidence was noted. Previous research has identified two formats for presenting evidence in QHCs (FDA, 2013b; Reinhardt-Kapsak et al. 2008). The position of evidence may be (1) "embedded" in a statement, or may be positioned as (2) "point-counterpoint" (Table 1). Embedded QHCs follow a format in which the evidence is stated first, followed by the diet-disease relationship (FDA, 2013b; Reinhardt-Kapsak et al. 2008). Alternatively, point-counterpoint QHCs first identify the diet-disease relationship and then describe the available scientific evidence for the relationship (FDA, 2013b; Reinhardt-Kapsak et al. 2008).

As the analysis progressed, three subcategories to characterize the evidence were identified. Termed, description of evidence, there were: quantitative descriptions (e.g. "two studies"), qualitative descriptions (e.g. "very limited evidence"), or mixed model

descriptions meaning the evidence was described both quantitatively and qualitatively (e.g. “one weak study”) (Table 1).

Other aspects of the QHC statements were recorded such as the inclusion of an FDA summary statement (Table 1), product eligibility (Table 2), and reading difficulty (Table 2). Flesch-Kincaid (F-K) grades serve as a predictor of readability and roughly correspond with the grades in the US educational system. The two-step formula used for reading level was (CMS, 2012b):

(1) Flesch Kincaid (F-K) Grade = (.39 x ASL) + (11.8 x ASW) – 15.59

where: ASL = average sentence length (words ÷ sentences)

ASW = average number of syllables per word (syllables ÷ words)

(2) Centers for Medicaid and Medicare reading level

where: F-K grades combined into one of three categories:

Easy (F-K 4^{th}, 5^{th}, 6^{th} grades)

Average (F-K 7^{th}, 8^{th}, 9^{th} grades)

Difficult (≥ F-K 10^{th} grade) (CMS, 2012b)

Finally, each QHC was assigned to one of the three levels of evidence (B, C, D) based on the criteria set forth in the FDA Guidance for Industry (2003c), along with the descriptions of the evidence in the enforced QHCs. Since there can be multiple QHCs for one diet-disease relationship, the relationships were graded (n=34) and that grade was assigned to each of the associated QHCs. For example, the evidence for the relationship between the consumption of dietary supplements containing selenium and the reduced

risk of colon or rectal cancers was assigned a C grade. Therefore, the four corresponding QHCs were also assigned a C grade.

Two researchers graded the QHCs, independently. They agreed about grade assignment for 94% of the diet-disease relationships and their associated QHCs. Disagreements were resolved through consensus.

Results

FDA Evaluative Parameters: Quantity, Consistency, & Relevance

The majority of QHCs (n=39, 74%) indicate the quantity of evidence for a diet-disease relationship. The evidence is quantified either by stating the number of studies involved (e.g. "three studies suggest") or by less precise descriptions (e.g. "some studies"). Seventy-seven percent (n=41) of the QHCs describe the consistency of evidence (e.g. "scientific evidence suggests but does not prove"). However, there is often overlap between the constructs of quantity and consistency of evidence described within the QHCs. For example, the phrase "some evidence suggests" indicates that more than one study was likely conducted to evaluate the diet-disease relationship, and that there is some inconsistency among those studies. Four QHCs were identified that exclusively reference the consistency of evidence (e.g. "supportive but not conclusive research").

The FDA's criterion of relevance is problematic because it is a combination of the "magnitude of the risk-reduction effect" and its applicability to "the general US population or a subgroup of the US general population" (FDA, 2003b). Significantly, no QHC contains a description of the potential magnitude of the risk-reduction effect. However, 16 (30%) QHCs specify a target population (e.g. women, infants [0 - 3 years]).

The remaining 35 do not and are implicitly understood as relevant to the general population.

By definition, QHCs represent health claims that do not meet the standard of significant scientific agreement. Therefore, the qualifying language describing the available scientific evidence about the diet-disease relationships is used to indicate where there are weaknesses, inconsistencies, or deficiencies in that evidence. The qualifiers in currently enforced claims include terms such as: unlikely, uncertain, very limited and preliminary, [a] weaker and more limited [study], inconsistent, and inconclusive.

Position of Evidence: Point-counterpoint vs. Embedded Format

Diet-disease relationships may be presented before the evidence for a claim (i.e. point-counterpoint), or presented after the evidence (i.e. embedded) (FDA, 2013b). Just over half (n=28, 53%) of the statements represent embedded diet-disease relationships with the remaining 25 (47%) QHCs organized in a point-counterpoint format (Table 2).

Description of Evidence: Quantitative, Qualitative, Mixed Model

Nearly three-quarters (n=40, 75%) of QHCs were classified as qualitative, meaning a description of evidence is included but the statement does not detail the specific number of studies completed (Table 2). Two QHCs (4%) specifically quantify the evidence by providing the number of supportive and unsupportive studies, and 11 (21%) were categorized as mixed model, using a combination of both quantitative and qualitative language to describe the evidence for the claim.

FDA Summary Statement

Most QHCs (n = 45, 85%) include a summary statement. Each of these summary statements also identifies FDA as its source. For example, “FDA concludes that there is

little scientific evidence supporting this claim." A range of verbs was identified in the summary statements: The FDA…does not endorse, concludes or has concluded, does not agree, has evaluated, or has determined that … (Table 2).

Product Eligibility

The 1999 Pearson court ruling applied only to dietary supplements (Pearson v. Shalala, 1999). Four years later, the FDA expanded the QHC system and began permitting QHCs to appear on the labels of food products (FDA, 2011a). The majority of QHCs (n=38, 72%) are permitted on dietary supplements labels, while just over a quarter (n=18, 34%) may be used on food labels (FDA, 2011c). Three QHCs are permitted on both supplements and food products (Table 2).

Reading Level

There is a wide range of F-K grades in the 53 QHCs (range = 5.37 – 30.30) with 21 claims demonstrating a F-K grade above high school (i.e. >12^{th} grade). The average F-K score for all QHCs is 12^{th} grade (m = 12.63, sd = 4.97 mdn = 11.89). The highest F-K grade was 30.30, for the QHC concerning 100% Whey-Protein Partially Hydrolyzed infant formula and atopic dermatitis. Using the CMS (2012b) classification system, 41 (77%) of the 53 QHCs are rated as difficult (i.e. ≥ 10^{th} grades), nine (17%) as average (i.e. 7^{th}-9^{th} grades), and only three (< 1%) as easy (4^{th}-6^{th} grades).

The F-K grade and CMS reading difficulty range are imperfect measures but together are intended to serve a proxy for reading difficulty (CMS, 2012b). While the claims are structured to indicate that a particular dietary component may reduce the risk of a particular disease, and may be understood by consumers as such, the reading level difficulty associated with many QHCs may impair consumer understanding of the details

of these relationships. For example, while some claims include familiar dietary components such as vitamin C, others necessarily include the complex names of relatively obscure dietary components such as phosphatidylserine and chromium picolinate. Similarly, some QHCs are comparatively short (e.g. calcium supplements and colon cancer), while others resemble a small paragraph (e.g. atopic dermatitis and infant formula) (FDA, 2011c). The F-K/CMS formula characterizes these differences.

Evidence Grade

After analyzing the language in the QHCs, the FDA Guidance for Industry document, and enforcement letters were used to decipher evidence grades for each QHC (FDA, 2003c; FDA, 2011c). The guidance document includes a loose framework of evidence descriptors for each grade. While enforcement letters do not include a specific letter grade, they often contain an indication of a particular level of evidence. For example, "FDA ranks the evidence for tomatoes and gastric cancer as the lowest level for a qualified health claim" (FDA, 2005). This suggests that under the 4-level system such a claim would be assigned a D grade. Based on this analysis, three (6%) of the QHCs were assigned a B grade, 12 (22%) were judged to have a C grade of evidence, and the remaining 38 (72%), were ascribed a D grade (Table 2).

Results by Level of Evidence

FDA Evaluative Parameters: Quantity, Consistency, & Relevance

All B QHCs (n=3) describe the consistency of evidence, but do not quantify it. Since there are no references to target groups, B claims are assumed to apply to the general population. Eleven (92%) of the 12 C QHCs detail the quantity of evidence and all indicate the consistency of evidence. Thirty-two (84%) D claims mention quantity and 33

(87%) indicate the consistency of evidence of the available research. Two C claims apply to infants and children up to 3 years old and the remainder presumably applies to the general population. Fewer than half (n=14, 37%) of D QHCs specify a target group.

Since diet-disease relationships designated with QHC status demonstrate emerging, inconsistent, or incomplete evidence, the language qualifying the evidence reflects this. There is a logical association between the qualifying language and evidence grade; as the grade decreases, the evidence description in QHCs appears more detailed. B QHCs express the consistency of evidence as "supportive but not conclusive", or state that the evidence "suggests but does not prove" that a dietary component may reduce the risk of a disease. B QHCs do not quantify the evidence. C graded claims describe evidence as "inconclusive", "limited", or "inconsistent"; whereas D QHCs characterize evidence as "very little", "preliminary", "weak and limited", or "inconclusive".

Position of Evidence: Point-counterpoint vs. Embedded

All three B claims use an embedded format, meaning it first states the evidence and then the diet-disease relationship. Eight (67%) C claims and 19 (50%) D claims also use an embedded format. The remaining four (33%) C claims and 19 (50%) D claims make use of a point-counterpoint presentation, stating the diet-disease relationship first, followed by a statement regarding the totality of available evidence.

Description of Evidence: Quantitative, Qualitative, Mixed Model

Additional analysis of evidence presentation in QHCs revealed that B and C claims are altogether qualitative, meaning they describe, but do not quantify, the scientific evidence for diet-disease relationships. In contrast, some D claims describe

evidence qualitatively (n=25, 66%), quantitatively (n=2, <1%), or through a mixed model approach (n=12, 32%) of quantitative and qualitative language.

FDA Summary Statement

None of the B claims include an FDA summary statement, while the majority of C (n = 9, 75%) and D QHCs (n = 36, 95%) do include such statement. Given their greater amount of supporting evidence, it is possible that FDA purposefully refrains from including a summary statement in B QHCs.

Product Eligibility

The three diet-disease relationships assigned a B grade are permissible on dietary supplements with one also applicable for food products (e.g. omega 3-fatty acids and coronary heart disease). Of the 12 C claims, eight (67%) are applicable to dietary supplements and the remaining four QHCs are allowed on foods. More than three-quarters (n=29, 76%) of D claims are allowed on dietary supplements and 11 (29%) may be used on food products. Two (5%) are eligible for use on both foods and dietary supplements and relate to green tea and the reduced risk of breast or prostate cancer.

Reading Level

Although a proxy for reading difficulty, the average reading level for QHCs is above the 12th grade or "difficult". Evidence grades did not particularly correspond with levels of reading difficulty. The average reading level for both B and C claims was grade 16 (sd = 4.24, sd = 5.08, respectively). D claims averaged an 11th grade (sd = 4.53) reading level. Thus, greater levels of scientific evidence did not necessarily translate into QHCs that are easier to read.

Discussion

The present study demonstrates the range of communication strategies and outlines the nuanced nature of QHCs. Among the 53 QHCs currently enforced, there are distinct combinations used to present evidence to the consumer. Given all combinations, shoppers may view one of 36 different formats (i.e. FDA evaluative parameters [3] X Position of evidence [2] X Description of evidence [3] X FDA summary statement [2]). This lack of consistency may make it more difficult for consumers to decipher QHCs. Thus, it is reasonable that consumers are confused by QHCs since some claims specify the number of studies while others do not, some claims lead with the health benefit and then follow with the supporting evidence (or vice versa), and a small portion of claims identify a target group by a condition or disease.

When confronted with two similar food products, consumers may improve their choice certainty by "avoiding complicated and confusing food labels" (Shiu et al., 2011) and gravitating towards products with shorter and more attainable nutrition information (Wansink et al., 2004). Unfortunately, QHCs represent complicated messages for consumers to understand and use during their shopping experience (Bone & France, 2009; FDA, 2011c; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al. 2008).

Research shows that American consumers strategize in the supermarket by avoiding unhealthy foods (FMI, 2013) and are motivated to purchase products to achieve health goals for specific health conditions (Reinhardt-Kapsak et al., 2011). Since many consumers believe that food plays "a great role" in maintaining and improving overall health (IFIC & AND, 2011), marketing health benefits on food and dietary supplements appears a worthy approach to public health. Yet, while QHCs are designed to communicate the health benefits of certain products, consumers often have difficulty

understanding and using the information in these claims. Consequently, few products bear them (Bone & France, 2009).

The variety of claim language identified in our study may be explained by a couple of known factors. A federal court ruling required the FDA prescribe more than one QHC for the same diet-disease relationship so that manufacturers could choose the most appropriate claim for their product (Whitaker v. Thompson, 2003). Another reason is the emerging evidence for diet-disease relationships in QHCs. There are gaps in the available research, which "may sometimes limit the information that can be included in the claims" such as a dose requirement associated with a reduced risk of a disease (FDA, 2011b). Accordingly, a consumer may understand the level of scientific evidence for a diet-disease relationship but not know how much of a dietary component to consume to achieve the health benefit. As currently enforced, therefore, QHCs may not provide enough information for consumers to make health-related decisions and take action.

Knowledge of the FDA's criteria set forth in its Interim Guidance for Industry (2003c), along with variations in the adjectives used to characterize the level of scientific evidence (e.g. supportive but not conclusive vs. limited vs. very limited and preliminary) makes it possible to distinguish among B, C, and D graded QHCs. However, this is only made practical by using a formal content analysis applied to the entire set of 53 QHCs, permitting comparisons of patterns of language, form, and content among them. It also depends on knowing that there is an underlying 4-tier classification system. Without this prior knowledge, the inconsistent patterns in language, form, and content, especially within the C and D-level claims, would make it extraordinarily difficult to recognize its existence.

Consumers are especially unlikely to comprehend that such a system exists. The first, and most obvious reason is that none of the QHCs include a letter grade. However, research demonstrates that consumers have difficulty interpreting such grades and this explains why they are justifiably not part of the statements (FDA, 2009a; Hooker & Teratanavat, 2008). Still, while it may make sense to exclude the actual letter grade, the text of the each QHC makes no mention of a classification system, or of the 4-level scale of evidence.

The way that consumers are likely to encounter QHCs also inhibits their ability to identify a classification system. As already indicated, research shows that few QHCs are used in the marketplace; less than five percent of food packages eligible for a QHC actually use one (Bone & France, 2009; GAO, 2011). Moreover, consumers are most likely to see a single QHC printed on an individual product rather than coming across them in any coherent grouping. Because consumers are unlikely to observe multiple QHCs at any one time, they would not be in a position to make comparisons that might provide clues as to the existence of a multi-level classification system.

Because consumers are unlikely to realize that a classification system exists for QHCs, they have no particular frame of reference within which to place any particular claim. As an example, the FDA summary statement accompanying a C grade QHC reads, "FDA has determined that this evidence is limited and not conclusive." Without a prior frame of reference, it is plausible for a consumer to conclude that the level of evidence supporting the diet-disease relationship is extremely low. In contrast, an FDA summary statement found in a D grade QHC is characterized by, "FDA has concluded that there is very little scientific evidence for this claim." Only by comparing the C and

D grade QHCs, would a consumer be able to judge that the "limited and not conclusive" evidence in the C grade claim potentially represents stronger evidence than "very little scientific evidence" represented in the D grade claim.

The difficult reading level identified in these claims provides further support as to why consumers are confused by QHCs. Federal recommendations for materials intended for public use suggest that writers use a "reader centered" approach (CMS, 2012a) and create materials that meet a 4th, 5th, or 6th grade reading level (i.e. easy) (CMS, 2012b). A "reader centered" approach requires writers to acknowledge their differences from the reader and to design text that is appropriate for the layperson, not the expert (CMS, 2012a).

The 2010 Plain Writing Act also identified the need for Federal agencies to improve their communication with the public (Plain Writing Act of 2010, Pub. L. No. 111–274, 124 STAT. 2861). While the law does not specify food (and dietary supplement) labels, it does recognize the limitations of existing federal regulations.

The sum of the current analysis determined there are 36 formats to present evidence in 53 QHCs and suggests that these claims do not represent "reader centered" text. Further, the average reading level is greater than that of a high school senior (Table 2). There are three distinguishing factors between the FDA staff and consumers: the awareness of the QHC's purpose, the familiarity with the evidence and diet-disease relationships, and the level of interest and investment (CMS, 2012b). These principles must be considered when crafting language, including nutritional information, for the public.

Indeed, consumers are familiar with several diet-disease relationships that have FDA-enforced QHCs. Reinhardt-Kapsak et al., (2011) found that nearly 80% of US consumers surveyed were familiar with the relationship between consuming omega-3 fatty acids or B vitamins as an approach to reduce the risk of cardiovascular disease. Nearly a quarter of consumers were aware of the relationship between monounsaturated fats in olive oil and the reduced risk of heart disease (Reinhardt-Kapsak et al., 2011). Further, almost half of those respondents reported that they already consumed products that contained those dietary ingredients (Reinhardt-Kapsak et al. 2011).

The degree to which consumers appear to be familiar with existing diet-disease relationships appears unrelated to the level of the strength of evidence assigned by the FDA. Claims given an "A" grade and are supported by the highest level of evidence appear to be as well-known as relationships that have been denied any claim status (A, B, C, D). Recent research has demonstrated that more than half of consumers were aware of the role of soy protein or plant sterols in reducing the risk of heart disease (IFIC & AND, 2011; Reinhardt-Kapsak et al. 2011), both of which "A" claims that meet significant scientific agreement. Yet, in the same study, nearly half of consumers were familiar with relationships that do not have adequate evidence even for a D grade QHC. While the relationships between lycopene and prostate cancer, and lutein and eye health, were denied QHC status in 2005 (FDA, 2009c), many consumers were familiar with these dietary components and their purported health benefits (IFIC & AND, 2011).

Likely, this is because information about emerging diet-disease relationships is ubiquitous, appearing in the news, on the Internet, and on social media (Johnson, 2007) and are "useful advertising tools" (Emord & Schwitters, 2012). Therefore, consumers

may be aware of a diet-disease relationship before they ever encounter the QHC on a particular product. As a result, the essential role of a QHC may not be to introduce consumers to new diet-disease relationships, but rather to temper their expectations regarding the strength of the scientific evidence behind that diet-disease relationship. Unfortunately, the critical aspect of communicating evidence for the diet-disease relationships in QHCs has been proven unsuccessful.

Limitations

The reading level ratings (i.e. F-K grade and CMS ranking) should be interpreted with caution since they predict reading difficulty. We addressed this limitation by collapsing F-K grades into one of three rank levels (i.e. easy, moderate, and difficult) (CMS, 2012b). Sentence length affects the F-K score. For example, there are two QHCs for the relationship between vitamin E and colorectal cancer that use virtually identical language. The difference is that the first QHC is composed of one sentence, while the second is composed of two. Yet, the difference in F-K score is about five grade levels (>12th grade vs. 8th grade) (Table 2). Finally, the F-K score is limited since it does not account for a reader's search for meaning, their attitudes, interests, knowledge, and past experiences that influence comprehension (CMS, 2012b). The F-K score and ranking (e.g. difficult) serve as proxy measurements.

A reviewer suggested that replacing the dietary components in claims with a standard of "nutrient" and specific health condition/disease with "disease" would improve the F-K/CMS reading level. To address this concern the readability calculations were rerun for the 53 QHCs. On average, the substitution of "nutrient" and "disease" improved the reading level by one or two grades (m=13, sd=4.86, mdn=12 vs. m=11,

sd=4.34, mdn=11). Nevertheless, when converted into the CMS range, the average reading level remained in the difficult range.

Conclusion

While consumers acquire health and nutrition information from numerous sources (e.g. health professionals, the media), nearly half of American shoppers use food labels, which act as a quintessential medium for nutrition information transfer (IFIC & AND, 2011). Qualified health claims present a tremendous opportunity for consumers to learn about new or emerging diet-disease relationships and to gain awareness of the health benefits in familiar products, so they may change their purchase and consumption behaviors. Yet, if consumers cannot properly distinguish among the claims, they may be unable to make appropriately informed decisions about the likelihood that a food will have the claimed health benefit.

The current study contributes to the existing body of research by identifying the variability of scientific evidence presented in QHCs enforced at the time of study. The absence of a system to communicate science would be a first step to ameliorating the regulatory and enforcement policy. Further, it is likely more difficult for consumers to understand science-based information without a sufficient educational background (Norman & Skinner, 2006), therefore, a more consistent format, which is more congruent with consumer ability to understand science-based information is necessary for QHCs to be useful to the consumer. A frame of reference might improve consumer understanding of the different levels of supportive evidence for diet-disease relationships.

Qualified health claims are ineffective, and are complicated by their two communication objectives. Their inefficacy may be attributed to the current

implementation, which is not parallel with consumer needs and has limited their use by manufacturers (Bone & France, 2009) and consequently, the use of products that bear or are eligible to bear these claims. Therefore, researchers should continue to investigate new strategies to systematically communicate the science to consumers in claims to inform regulations for QHCs.

Figure 1. Virtuous cycle of health claims

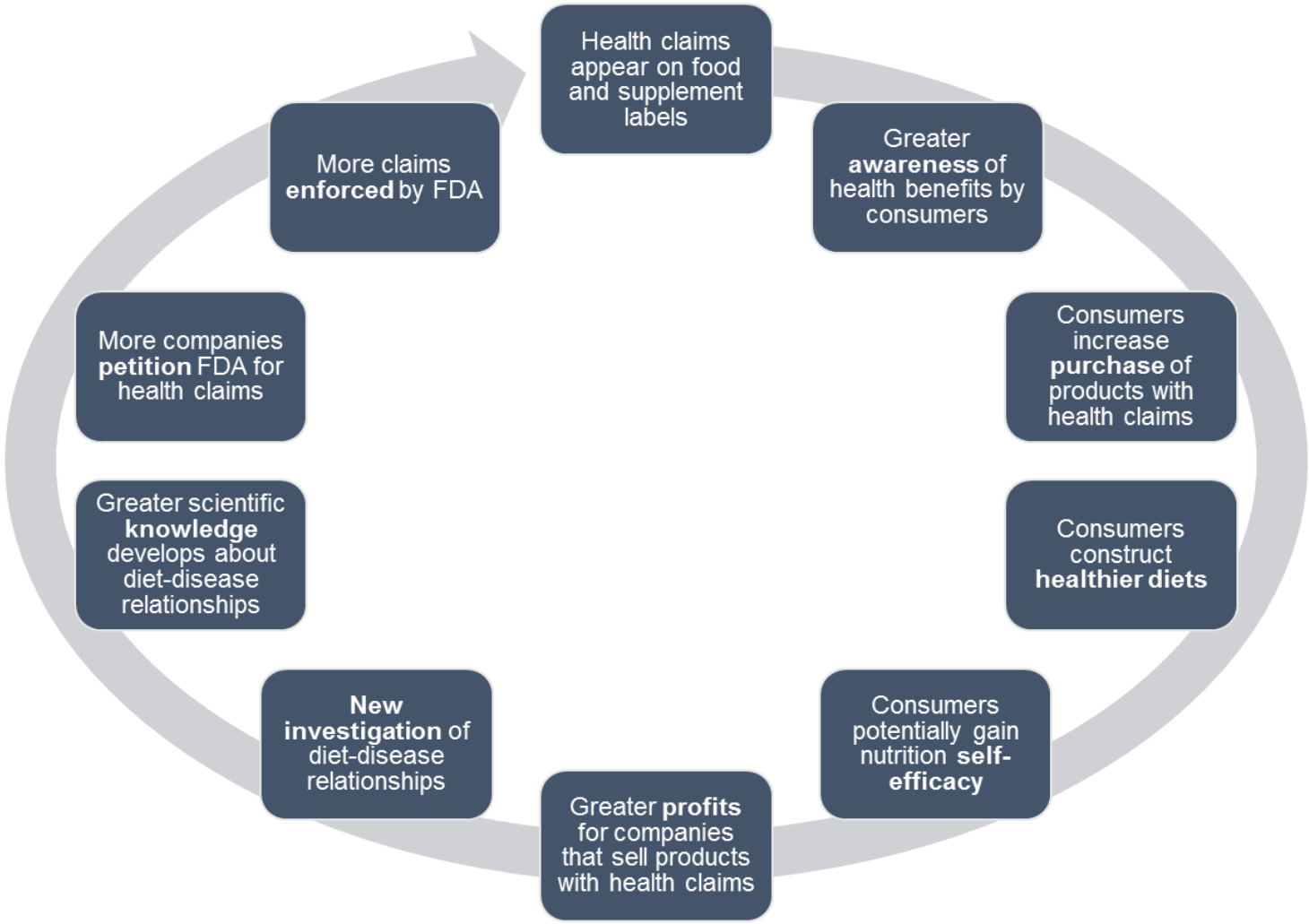


Table 1. Formats of the description of evidence in Qualified Health Claims

	Claim Format	Definition	Example
FDA Evaluative Parameters	**Quantity**	The number of studies, sample size, and generalizability of results.	Some [evidence]
	Consistency	Indicates, "whether studies…report similar findings."	Inconsistent [evidence]
	Relevance	To the general population or a subgroup	Healthy infants
Position of Evidence	**Point-Counterpoint**	The diet-disease relationship is first introduced and then the evidence for the relationship is described	Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.
	Embedded	The evidence is stated first, followed by the diet-disease relationship	Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.
Description of Evidence	**Qualitative**	A description of evidence without quantification	Very limited [evidence]
	Quantitative	A description of evidence in terms of the number of studies	Two studies
	Mixed Model	A description of evidence that is both quantitative and qualitative	Two weak studies
FDA Summary Statement		A summary of the evidence positioned at the end of the QHC	FDA has determined that this evidence is limited and not conclusive.

Table 2: Qualified Health Claims Organized by Evidence Levels

Evidence Level	Qualified Health Claim	†Product Eligibility	††Flesch-Kincaid Grade	FDA Summary Statement	Position of Evidence	Description of Evidence	§FDA Evaluative Parameters
B	Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most **nuts** [such as name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of **heart disease**. [See nutrition information for fat content.]	F	17.12	---	Embedded	Qualitative	C, R
B	Supportive but not conclusive research shows that eating 1.5 ounces per day of **walnuts**, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of **coronary heart disease**. See nutrition information for fat [and calorie] content.	F	19.78	---	Embedded	Qualitative	C, R
B	Supportive but not conclusive research shows that consumption of EPA and DHA **omega-3 fatty acids** may reduce the risk of **coronary heart disease**. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]	F, DS	11.47	---	Embedded	Qualitative	C, R
C	Some scientific evidence suggests that **calcium** supplements may reduce the risk of **hypertension**. However, FDA has determined that the evidence is inconsistent and not conclusive.	DS	11.94	✓	Embedded	Qualitative	Q, C, R
C	Little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a **100 % Whey-Protein Partially Hydrolyzed infant formula** from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may	F	27.93	---	Embedded	Qualitative	Q, C, R

	reduce the risk of developing **atopic dermatitis** throughout the 1st year of life.						
C	For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a **100% Whey-Protein Partially Hydrolyzed infant formula** from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of **atopic dermatitis** is uncertain, because there is little scientific evidence for the relationship.	F	22.17	✓	Point-counterpoint	Qualitative	Q, C, R
C	Some evidence suggests that **calcium** supplements may reduce the risk of **colon/rectal cancer**, however, FDA has determined that this evidence is limited and not conclusive.	DS	16.34	✓	Embedded	Qualitative	Q, C, R
C	**Selenium** may reduce the risk of **certain cancers**. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.	DS	9.95	✓	Point-counterpoint	Qualitative	Q, C, R
C	**Selenium** may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce **anticarcinogenic effects** in the body. However, FDA has determined that this evidence is limited and not conclusive.	DS	14.25	✓	Point-counterpoint	Qualitative	Q, C, R
C	Some scientific evidence suggests that consumption of **antioxidant vitamins** may reduce the risk of certain forms of **cancer**. However, FDA has determined that this evidence is limited and not conclusive.	DS	11.89	✓	Embedded	Qualitative	Q, C, R

C	Some scientific evidence suggests that consumption of **antioxidant vitamins** may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive.	DS	11.58	✓	Embedded	Qualitative	Q, C, R
C	FDA has determined that although some scientific evidence suggests that consumption of **antioxidant vitamins** may reduce the risk of certain forms of **cancer**, this evidence is limited and not conclusive.	DS	17.35	✓	Embedded	Qualitative	Q, C, R
C	As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, **Vitamin B6 and Vitamin B12** may reduce the risk of **vascular disease**. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.	DS	16.93	✓	Point-counterpoint	Qualitative	C, R
C	Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of **olive oil** daily may reduce the risk of **coronary heart disease** due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.	F	13.64	---	Embedded	Qualitative	Q, C, R
C	Limited and not conclusive scientific evidence suggests that eating about 1 1/2 tablespoons (19 grams) of **canola oil** daily may reduce the risk of **coronary heart disease** due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of	F	13.95	---	Embedded	Qualitative	Q, C, R

	calories you eat in a day. One serving of this product contains [x] grams of canola oil.						
D	Two weak studies and one study with inconsistent results suggest that **vitamin E** supplements may reduce the risk of **colorectal cancer**. However, another limited study showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of colorectal cancer.	DS	11.86	✓	Embedded	Mixed model	Q, C, R
D	**Vitamin E** may reduce the risk of **colorectal cancer** although the FDA has concluded that there is very little scientific evidence for this claim.	DS	12.95	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Vitamin E** may reduce the risk of **colorectal cancer**. FDA has concluded that there is very little scientific evidence for this claim.	DS	8.01	✓	Point-counterpoint	Qualitative	Q, C, R
D	One weak and limited study suggests that **vitamin E** supplements may reduce the risk of **renal cell cancer**. FDA concludes that it is highly uncertain that vitamin E supplements reduce the risk of renal cell cancer.	DS	10.44	✓	Embedded	Mixed model	Q, C, R
D	**Vitamin E** may reduce the risk of **renal cancer** although the FDA has concluded that there is very little scientific evidence for this claim.	DS	11.96	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Vitamin E** may reduce the risk of **renal cancer**. FDA has concluded that there is very little scientific evidence for this claim.	DS	6.94	✓	Point-counterpoint	Qualitative	Q, C, R
D	One small study suggests that **vitamin E** supplements may reduce the risk of **bladder cancer**. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer.	DS	8.88	✓	Embedded	Mixed model	Q, C, R

D	**Vitamin E** may reduce the risk of **bladder cancer** although the FDA has concluded that there is very little scientific evidence for this claim.	DS	11.96	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Vitamin E** may reduce the risk of **bladder cancer**. FDA has concluded that there is very little scientific evidence for this claim.	DS	6.94	✓	Point-counterpoint	Qualitative	Q, C, R
D	One weak study and one study with inconsistent results suggest that **vitamin C** supplements may reduce the risk of **gastric cancer**. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer.	DS	11.70	✓	Embedded	Mixed model	Q, C, R
D	**Vitamin C** may reduce the risk of **gastric cancer** although the FDA has concluded that there is very little scientific evidence for this claim.	DS	11.96	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Vitamin C** may reduce the risk of **gastric cancer**. FDA has concluded that there is very little scientific evidence for this claim.	DS	6.94	✓	Point-counterpoint	Qualitative	Q, C, R
D	One study suggests that **selenium** intake may reduce the risk of **bladder cancer** in women. However, one smaller study showed no reduction in risk. Based on these studies, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of bladder cancer in women.	DS	9.89	✓	Embedded	Mixed model	Q, C, R
D	Two weak studies suggest that **selenium** intake may reduce the risk of **prostate cancer**. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.	DS	9.60	✓	Embedded	Mixed model	Q, C, R

D	**Selenium** may reduce the risk of **prostate cancer**. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer.	DS	8.48	✓	Point-counterpoint	Qualitative	C, R
D	One weak, small study suggests that **selenium** intake may reduce the risk of **thyroid cancer**. Based on this study, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of thyroid cancer.	DS	10.45	✓	Embedded	Mixed model	Q, R
D	**Selenium** may reduce the risk of **colorectal cancer**. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colorectal cancer.	DS	9.96	✓	Point-counterpoint	Qualitative	C, R
D	**Selenium** may reduce the risk of **colon and rectal cancer**. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colon and rectal cancer.	DS	8.76	✓	Point-counterpoint	Qualitative	C, R
D	**Selenium** may reduce the risk of **colon cancer**. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of colon.	DS	8.23	✓	Point-counterpoint	Qualitative	C, R
D	**Selenium** may reduce the risk of **bladder, colon, prostate, rectal and thyroid cancers**. Based on its review, FDA does not agree that selenium may reduce the risk of these cancers.	DS	8.75	✓	Point-counterpoint	Qualitative	R
D	Very limited and preliminary evidence suggests that **calcium** supplements may reduce the risk of **colon/rectal polyps**. FDA concludes that there is little scientific evidence to support this claim.	DS	12.21	✓	Embedded	Qualitative	Q, C, R

D	Very little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a **100 % Whey-Protein Partially Hydrolyzed infant formula** from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing **atopic dermatitis** throughout the 1st year of life and up to 3 years of age.	F	30.30	---	Embedded	Qualitative	Q, C, R
D	For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a **100% Whey-Protein Partially Hydrolyzed infant formula** from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing **atopic dermatitis** throughout the 1st year of life and up to 3 years of age. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is very little scientific evidence for the relationship.	F	23.08	✓	Point-counterpoint	Qualitative	Q, C, R
D	Very limited and preliminary scientific research suggests that eating one-half to one cup of **tomatoes and/or tomato sauce** a week may reduce the risk of **prostate cancer**. FDA concludes that there is little scientific evidence supporting this claim.	F	12.31	✓	Embedded	Qualitative	Q, C, R
D	One study suggests that consumption of **tomato sauce** two times per week may reduce the risk of **ovarian cancer**; while this same study shows that consumption of tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer.	F	14.61	✓	Embedded	Quantitative	Q, R

D	Four studies did not show that **tomato** intake reduces the risk of **gastric cancer**, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer.	F	11.18	✓	Embedded	Quantitative	Q, C, R
D	One study suggests that consuming **tomatoes** does not reduce the risk of **pancreatic cancer**, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.	F	14.41	✓	Embedded	Mixed model	Q, C, R
D	**Green tea** may reduce the risk of **breast or prostate cancer** although the FDA has concluded that there is very little scientific evidence for this claim.	F, DS	11.34	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Green tea** may reduce the risk of **breast or prostate cancer**. FDA has concluded that there is very little scientific evidence for this claim.	F, DS	5.81	✓	Point-counterpoint	Qualitative	Q, C, R
D	Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of **corn oil** daily may reduce the risk of **heart disease** due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil.	F	11.58	✓	Embedded	Qualitative	Q, C, R
D	Consumption of **phosphatidylserine** may reduce the risk of **dementia** in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia	DS	12.76	✓	Point-counterpoint	Qualitative	Q, C, R

	in the elderly. FDA concludes that there is little scientific evidence supporting this claim.						
D	Consumption of **phosphatidylserine** may reduce the risk of **cognitive dysfunction** in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim.	DS	13.60	✓	Point-counterpoint	Qualitative	Q, C, R
D	One small study suggests that **chromium picolinate** may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of **type 2 diabetes**. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain.	DS	15.88	✓	Embedded	Mixed model	Q, R
D	Four studies, including a large clinical trial, do not show that **calcium** supplements reduce the risk of **pregnancy-induced hypertension** during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension.	DS	13.79	✓	Embedded	Mixed model	Q, C, R
D	Three studies, including a large clinical trial, do not show that **calcium** supplements reduce the risk of **preeclampsia** during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of preeclampsia.	DS	11.63	✓	Embedded	Mixed model	Q, C, R

D	**0.8 mg folic acid** in a dietary supplement is more effective in reducing the risk of **neural tube defects** than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.	DS	11.88	✓	Point-counterpoint	Qualitative	R
D	**Whole grains** may reduce the risk of **type 2 diabetes**, although the FDA has concluded that there is very limited scientific evidence for this claim.	F	5.37	✓	Point-counterpoint	Qualitative	Q, C, R
D	**Whole grains** may reduce the risk of **type 2 diabetes**. FDA has concluded that there is very limited scientific evidence for this claim.	F	6.85	✓	Point-counterpoint	Qualitative	Q, C, R

† F = foods, DS = dietary supplement
†† Centers for Medicare and Medicaid Services reading range (Easy: 4th, 5th, 6th grades, Average: 7th, 8th, 9th grades, Difficult: ≥ 10th grade)
§ Reference to the (Q: Quantity of evidence, C: Consistency of evidence, R: Relevance to the general population or a subgroup

CHAPTER FOUR
A Consumer Profile of Older Adults who Drink Green Tea

1. Introduction

American consumers are attracted to functional foods (Reinhardt Kapsak, Rahavi, Childs, & White, 2011) that "provide a health benefit beyond basic nutrition" (International Food Information Council, 2011). Shoppers consume functional products for many reasons, including to maintain and improve their overall physical health and well-being (International Food Information Council, Academy of Nutrition and Dietetics, 2011), to lose weight, and to prevent or ameliorate specific health conditions (Reinhardt Kapsak et al., 2011). Most consumers can name a functional food and its associated health benefit, unaided, (Reinhardt Kapsak et al., 2011) and are also guided to use them by Registered Dietitians (Berhaupt-Glickstein & Enrione, 2011).

Green tea is a well-known functional food (Reinhardt Kapsak et al., 2011) whose popularity has increased in the beverage (Tea Association of the USA, Inc., 2014) and dietary supplement categories (Council for Responsible Nutrition, 2015). Green tea is often associated with its ability to reduce the risk of cancer (National Cancer Institute, 2015; Samavat et al., 2015; Seely, Mills, Wu, Verma, & Guyatt, 2005), which is a common health concern among American consumers (International Food Information Council, 2011; Nielsen & National Marketing Institute, 2014).

The purpose of this paper is to identify the sociodemographic and psychographic characteristics related to green tea consumers. By understanding this segment's background, perceptions, and behaviors related to diet and health, food and nutrition communicators can tailor messages to help clients and consumers achieve their health

goals (Reinhardt Kapsak et al., 2011). This is because different communication strategies may be more effective for some audiences than others (Hilgartner & Nelkin, 1987; Nagler, 2014; Walker Naylor, Droms, & Haws, 2009). Tailored health messages speak to the audience's values and motivations that will, theoretically, inspire action (Glanz, Rimer, & Viswanath, 2008).

Previous research has explored the consumer characteristics associated with accepting functional foods (Contini et al., 2015; Cox, Evans, & Lease, 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009; Reinhardt Kapsak et al., 2011). These studies suggest that functional foods are most appealing and accepted by healthy (Cox et al., 2011; Reinhardt Kapsak et al., 2011), educated (Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009) women (Contini et al., 2015; Pothoulaki & Chryssochoidis, 2009; Reinhardt Kapsak et al., 2011) with a high socioeconomic status (Pothoulaki & Chryssochoidis, 2009), who also take dietary supplements (Reinhardt Kapsak et al., 2011). Age has been associated with acceptance and appeal of functional products in some cases (Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009). However, to our knowledge, no peer-reviewed study has elucidated the characteristics of older green tea consumers. The current paper aims to answer the following research questions:

1) Is this segment of consumers characterized by the same sociodemographic variables associated with interest and acceptance of other functional food products (described above)?
2) Is this segment of consumers characterized by perceptions of good health, and knowledge about diet and health?

3) Is this segment of consumers characterized by other health-related behaviors such as dietary supplement use and making dietary changes for health reasons?

2. Methods

Data were collected through an online survey using a panel maintained by GfK Custom Research, LLC (GfK). A nationally representative sample of English-speaking adults aged 55 years and older participated in the study in January 2014 (n=1,335). This group was selected for study because in the US, many functional foods claim to reduce the risk of a chronic disease, such as cancer, which is most prevalent in this demographic (American Cancer Society, 2015; King, Matheson, Chirina, Shankar, & Broman-Fulks, 2013). In addition, compared to younger adults, older adults are more knowledgeable about nutrition and more likely to adopt preventive behaviors (Nocella & Kennedy, 2012) including using food labels to make dietary choices (Academy of Nutrition and Dietetics, 2011; Govindasamy & Italia, 1999) and to use dietary supplements (Balluz, Kieszak, Philen, & Mulinare, 2000; Council for Responsible Nutrition, 2015; Gray, Hanlon, Fillenbaum, Wall, & Bales, 1996; Slesinski, Subar, & Kahle, 1995), which are all characteristics associated with functional food acceptance and interest.

Descriptive statistics were generated for all items. Binomial logistic regression was used to test sociodemographic and psychographic variables as single regressors to understand their predictive value of having consumed green tea in the past year. Then, statistically significant predictors ($p < .05$) were entered into one logistic regression model using hierarchical entry to understand their predictive contribution of the odds of drinking green tea (Naes, Kubberod, & Sivertsen, 2001). $P < 0.05$ was considered

statistically significant. All analyses were conducted using SPSS, version 22.0 (SPSS Inc., Chicago, IL, USA).

2.1. Measures

Green tea is a well-known functional food (Reinhardt Kapsak et al., 2011). Therefore, in addition to known sociodemographic measures predictive of the appeal and acceptance of functional foods (Glanz et al., 2008), additional predictors were identified from a conceptual framework about consumer purchase behavior of functional foods in the presence of a health claim (Wills, Storcksdieck genannt Bonsmann, Kolka, & Grunert, 2012). The following consumer-related measures were captured to understand their value in predicting green tea consumption over the past year:

2.2. Sociodemographic measures

Measures of: race/ethnicity, sex, education, age, household income, current employment status, home ownership, and marital status were used to characterize the demographics of those who drink green tea (Table 1). Because the current sample was composed of older adults aged 55 years and older, it was understood that employment and income might not accurately capture socioeconomic status. To account for this, we also included home ownership, which served as a proxy for long-term financial standing. GfK collected these measures prior to the current survey as part of the participant's profile maintained within the national panel.

2.3. Psychographic measures

Our sample was asked several questions about their personal health, perceptions, and beliefs that may predict the odds of drinking green tea. Questions about health included: health status and whether a doctor had diagnosed them with cancer. They were

also asked about how much they worry about their overall health and about becoming sick with cancer. Behavioral measures included questions about dietary change in the past year due to a health concern and dietary supplement use. Participants also reported their perceived knowledge of diet and health (i.e. nutrition knowledge), their familiarity with the relationship between green tea and cancer, their reason(s) for drinking green tea, as well as the importance they placed on health statements found on the labels of food and supplement products (Table 1).

3. Results

A total of 687 of the 1335 survey participants (51.5%) reported that they had consumed green tea in the past year because they enjoyed the taste (n=215, 62.3%). Fewer participants drank green tea to reduce their risk of cancer (n=32, 9.8%), for other health reasons (n=73, 21.2%), or other reasons (n=85, 24.6%).

Univariate analysis showed that compared to those who had not consumed green tea, a greater percentage of tea drinkers are Black or Hispanic, employed, females, who hold a Bachelor's degree or more, with an annual income of more than $100,000 and are home owners (Table 2). More green tea drinkers are worried about getting sick with cancer than non-tea drinkers. Over the past year, more took a dietary supplement(s) most days of the week, and had made a dietary change for a health worry. In addition, a greater proportion of green tea drinkers are very or extremely informed about diet and health, take a dietary supplement(s) most days of the week, and consider health claims on food supplement products to be very important or absolutely essential when making a purchase decision (Table 3).

3.1. Predictors of green tea consumption

We wanted to create a parsimonious predictive model of the odds that an older adult drinks green tea. To do this, we first tested the sociodemographic variables. When tested as single regressors, ethnicity, sex, education, income, home ownership, and employment were statistically significant predictors of being a green tea consumer. Marital status and age did not predict consumption, and as a result, were not included in further analyses.

A hierarchical binomial logistic regression was performed to determine the effects of race/ethnicity, sex, education, income, home ownership, and employment on the odds that participants consume green tea. The logistic regression model was statistically significant, $\chi 2\ (10) = 101.680$, $p < .0001$. The model explained 9.8% (Nagelkerke R^2) of the variance and correctly classified 61.5% of cases. Sensitivity was 66.8%, specificity was 55.9%, positive predictive value was 61.8% and negative predictive value was 61.2%. Of the six predictor variables, four were statistically significant: race/ethnicity, sex, education, and home ownership (Table 2). There were greater odds that homeowners and women drank green tea in the past year than non-homeowners or men. The odds that participants consumed green tea were two to three times greater if they were Black, Hispanic, or from another non-Hispanic race/ethnicity than if they were White. Also, the odds of being a green tea consumer increased with greater education. Participants with a Bachelor's degree or advanced degree had 3.951 times greater odds of drinking green tea in the past year than those with less than a high school education (Table 4).

Next, logistic regression was used to determine the predictive value of the psychographic predictors of green tea consumption (Table 1). Similarly, psychographic factors were tested individually to identify significance, then non-significant variables

were withheld from further analysis, and a final binomial logistic regression model was built using statistically significant predictors only. The seven predictive psychographic variables for the odds that a participant consumed green tea were: self-reported health status and nutrition knowledge, dietary supplement use and having made a dietary change for a health concern, the importance of health statements on food and supplement labels, and familiarity with the green tea-cancer relationship. A previous cancer diagnosis, worry about becoming sick with cancer, as well as worry about general health did not increase the odds of consuming green tea in the past year.

Binomial logistic regression with hierarchical entry determined the predictive value of the psychographic variables for green tea consumption in the past year. The model was statistically significant, $\chi 2\ (7) = 57.003$, $p < .0001$. The model explained 14.4% (Nagelkerke R^2) of the variance in predicting green tea consumers and correctly classified 63.4% of cases. Sensitivity was 74.1%, specificity was 50.0%, positive predictive value was 65.0% and negative predictive value was 60.7%. Five of the seven variables significantly contributed to the odds of past green tea consumption; self-reported health status, self-reported nutrition knowledge, having made a dietary change for a health concern in the past year, considering health statements on food labels, and familiarity with the relationship between green tea and cancer (as shown in Table 5).

The odds that a participant drank green tea are increased by one and half times with each step increase in self-reported health status, and with familiarity with the green tea-cancer relationship. Moreover, the odds were five times greater that participants drank green tea if they were extremely informed about nutrition, or had made dietary

changes in the past year, than if they were not informed or had not made a dietary change.

The final logistic regression model included all statistically significant variables (Tables B and C) which were added in a two-step process, where (1) the four sociodemographic variables were added, followed by (2) the four psychographic variables. The model was statistically significant, $\chi 2\ (11) = 118.110$, $p < .0001$. The model explained 22.1% (Nagelkerke R^2) of the variance and correctly classified 67.6% of cases. Sensitivity was 70.0%, specificity was 65.1%, positive predictive value was 68.6% and negative predictive value was 66.6%. Six of the eight predictor variables were statistically significant: race/ethnicity, sex, health status, nutrition knowledge, worry that led to dietary change(s), and familiarity with the relationship between green tea and cancer (Table 6).

4. Discussion

The strongest predictors of green tea consumers are race/ethnicity and familiarity. The odds are greater that a woman who identifies as Black, Hispanic, or another non-Hispanic race/ethnicity consumes green tea. She is informed about diet and health, and familiar with the green tea-cancer relationship. This person feels she is in good health and in the past year, has made a dietary change to address a health concern.

These variables are similar to previously identified predictors of healthy behavior with the exception of race/ethnicity. Whereas nutrition-related health behaviors have been associated with Whites (Chena, Jahnsa, Gittelsohna, & Wanga, 2011; National Research Council (US) Panel on Race, Ethnicity, and Health in Later Life, 2004), in this

sample the odds of green tea consumption are greater if a person is Black, Hispanic, and from another non-Hispanic race/ethnicity.

Interestingly, green tea consumption was not predicted by the importance placed on health statements found on food supplement labels, but familiarity with the green tea cancer relationship was a strong predictor. This may explain the results of a survey of green tea product labels that demonstrated that none included a claim about the green tea-cancer relationship (Hooker, 2007). This suggests consumers learned about this functional food relationship from another nutrition information source, perhaps through "health-conscious raising" marketing strategies (Walker Naylor et al., 2009) or through advertisements (Abbatangelo-Gray, Byrd-Bredbenner, & Byrn Austin, 2008; Mazis & Raymond, 1997).

4.1. Conclusions

Understanding the green tea consumer is important for health and marketing professionals who would like to tailor messages to help clients and consumers succeed in attaining their health goals (Glanz et al., 2008; Reinhardt Kapsak et al., 2011). Since health behaviors tend to be associated with each other, perhaps knowing about the characteristics of green tea consumers can help to target a receptive audience for other health-related products or behaviors (Spring, Moller, & Coons, 2012). This profile may also be useful for marketers who want to craft messages that better resonate with clientele who drink green tea as a way to increase market share, or try to expand their potential clientele by targeting messages to those who are not already drinking green tea.

Table 1. Sociodemographic and Psychographic Variables for Green Tea Consumption.

Variable name	Scale	Description
Dependent variable		
Buy It	Dummy (0–1)	0 = No, 1 = Yes
Independent variables		
Sociodemographic		
Gender	Dummy (0–1)	1 = Female, 0 = Male
Age	Scale (1–3)	1 = 55-64, 2 = 65-74, 3 = ≥75
Race/Ethnicity	Scale (1–5)	1 = White, 2 = Black, 3 = Other, 4 = Hispanic, 5 = 2+ Races
Education	Scale (1–4)	1 = Less than high school, 2 = High school, 3 = Some college, 4 = Bachelor's degree or higher
Income	Scale (1–4)	1 = $0-$49,999, 2 = $50,000-$99,999, 3 = $100,000-$149,999, 4 = ≥ $150,000
Employment	Scale (1–3)	1 = Working, 2 = Not Working, 3 = Retired
Marital Status	Dummy (0–1)	1 = Married/partnered, 0 = Not married/partnered
Home Ownership	Dummy (0–1)	0 = Not owned, 1 = Owned
Psychographic		
Health Status	Scale (1–5)	1 = Poor, 2 = Fair, 3 = Good, 4 = Very good, 5 = Excellent
Health Worry	Scale (1–5)	1 = Not at all, 2 = A little, 3 = Somewhat, 4 = Quite a bit, 5 = All the time
Cancer Diagnosis	Dummy (0–1)	Doctor diagnosis 0 = No, 1 = Yes
Cancer Worry	Scale (1–5)	1 = Not at all, 2 = Somewhat, 3 = Moderately, 4 = Very, 5 = Extremely
Nutrition Knowledge	Scale (1–5)	1 = Not informed, 2 = Somewhat, 3 = Fairly, 4 = Very, 5 = Extremely informed
Familiarity	Dummy (0–1)	Of green tea-cancer relationship 0 = No, 1 = Yes
Importance of label Health Claims on:		
Foods	Scale (1–5)	1 = Not at all important, 2 = Somewhat, 3 = Important, 4 = Very, 5 = Absolutely essential
Dietary supplements	Scale (1–5)	1 = Not at all important, 2 = Somewhat, 3 = Important, 4 = Very, 5 = Absolutely essential
Supplement User	Scale (1–5)	1 = Never, 2 = Less than 1 day/month, 3 = 1-3 days/month, 4 = 1-3 days/week, 5 = 4-6 days/week, 6 = Everyday
Health-related worry	Scale (1–5)	1 = Not at all, 2 = A little, 3 = Somewhat, 4 = Quite a bit, 5 = All the time
Diet Δ		

Table 2. Frequencies and percentages [n (%)] of sociodemographic characteristics of participants who did and did not drink green tea last year. Means and standard deviation reported for continuous variables.

	Did you drink green tea last year?			
	Yes n=687		No n=644	
	n (%)	M, SD	n (%)	M, SD
Sex*				
Male	278 (40.5)		367 (57.0)	
Female	409 (59.5)		277 (43.0)	
Age		1.63, .717		1.69, .753
55 to 64	345 (50.2)		311 (48.3)	
65 to 75	245 (35.7)		219 (34.0)	
75 or older	97 (14.1)		114 (17.7)	
Race/Ethnicity*				
White Hispanic	512 (74.5)		545 (84.6)	
Black	73 (10.6)		41 (6.4)	
Other, non-Hispanic	26 (3.8)		8 (1.2)	
Hispanic	48 (7.0)		29 (4.5)	
2 + races, non-Hispanic	28 (4.1)		21 (3.3)	
Education[t]		2.92, .924		2.67, .955
Less than high school	34 (4.9)		68 (10.6)	
High school	221 (32.2)		232 (36.0)	
Some college	199 (29.0)		190 (29.5)	
Bachelor's degree +	233 (33.9)		154 (23.9)	
Household Income[t]		1.94, .983		1.78, .885
$0 to $49,999	293 (42.6)		298 (46.3)	
$50,000 to $99,999	207 (30.1)		227 (35.2)	
$100,000 to $149,999	125 (18.2)		80 (12.4)	
$150,000 +	62 (9.0)		39 (6.1)	
Employment*				
Working	268 (39.0)		208 (32.3)	
Not Working	95 (13.8)		106 (16.5)	
Retired	324 (47.2)		330 (51.2)	
Marital Status*				
Married	429 (62.4)		403 (62.6)	
Not married	258 (37.6)		241 (37.4)	
Homeownership*				
Homeowner	599 (87.2)		529 (82.1)	
Non-homeowner	88 (12.8)		115 (17.9)	

t indicates a statistically significant difference between groups as determined by independent samples t-test for continuous variables at $p < .05$ level.

* indicates a statistically significant difference between groups as determined by Chi-square test for independence for categorical variables at $p < .05$ level.

Table 3. Frequencies and percentages [n (%)] of psychographic measures separated by participants who did and did not drink green tea last year. Means and standard deviation reported for continuous variables.

	Did you drink green tea last year?			
	Yes n=687		No n=644	
	n (%)	M, SD	n (%)	M, SD
Health Status		3.51, .861		3.18, .902
Excellent	69 (10.1)		37 (5.8)	
Very good	297 (43.4)		198 (30.9)	
Good	240 (35.0)		273 (42.6)	
Fair	69 (10.1)		112 (17.5)	
Poor	10 (1.5)		21 (3.3)	
Health Worry		2.50, .931		2.55, 1.02
All the time	15 (2.2)		19 (3.0)	
Quite a bit	79 (11.5)		95 (14.8)	
Somewhat	225 (32.8)		206 (32.2)	
A little	279 (40.7)		217 (33.9)	
Not at all	87 (12.7)		103 (16.1)	
Cancer Diagnosis				
Yes	101 (14.8)		102 (15.9)	
No	583 (85.2)		540 (84.1)	
Cancer Worry [t]		2.16, .967		2.25, 1.02
Extremely	13 (2.2)		15 (2.8)	
Very	37 (6.4)		45 (8.3)	
Moderately	136 (23.4)		139 (25.7)	
Somewhat	239 (41.1)		202 (37.4)	
Not at all	157 (27.0)		139 (25.7)	
Nutrition Knowledge [t]		3.42, .808		3.03, .938
Extremely informed	56 (8.2)		33 (5.2)	
Very	262 (38.2)		163 (25.5)	
Fairly	286 (41.7)		260 (40.8)	
Somewhat	81 (11.8)		154 (24.1)	
Not informed	1 (0.1)		28 (4.4)	
Supplement User [t]		4.61, 1.93		4.06, 2.26
Everyday	385 (56.0)		329 (51.1)	
4-6 days per week	86 (12.5)		50 (7.8)	
1-3 days per week	44 (6.4)		24 (3.7)	
1-3 days per month	21 (3.1)		15 (2.3)	
< 1 day per month	37 (5.4)		25 (3.9)	
Never	114 (16.6)		201 (31.2)	
Health claims - supplement [t]		3.35, 1.19		3.14, 1.21
Absolutely essential	112 (19.7)		60 (13.6)	
Very	160 (28.2)		128 (29.0)	

Important	148 (26.1)		113 (25.6)	
Somewhat	109 (19.2)		94 (21.3)	
Not at all important	39 (6.9)		47 (10.6)	
Health claims - food [t]		3.09, 1.16		2.63, 1.13
Absolutely essential	83 (12.2)		37 (5.8)	
Very	190 (27.8)		117 (18.2)	
Important	171 (25.0)		167 (26.0)	
Somewhat	184 (26.9)		216 (33.6)	
Not at all important	55 (8.1)		105 (16.4)	
Health-related worry diet Δ [t]		2.53, 1.05		2.26, 1.03
All the time	16 (2.3)		9 (1.4)	
Quite a bit	115 (16.8)		70 (10.9)	
Somewhat	216 (31.5)		180 (28.0)	
A little	211 (30.8)		203 (31.5)	
Not at all	128 (18.7)		182 (28.3)	

t indicates a statistically significant difference between groups as determined by independent samples t-test for continuous variables at $p < .05$ level. Chi-square test for independence were used for the categorical variable, cancer diagnosis.

Table 4. Logistic regression predicting Odds of Consuming Green Tea in the Past Year based on Race/Ethnicity, Sex, Education, Income, Employment, and Home Ownership.

							95% CI for Odds Ratio	
	B	**SE**	**Wald**	***df***	***p***	**Odds**	**Lower**	**Upper**
Race/Ethnicity			27.310	4	.000			
Black, non-Hispanic	.813	.217	14.117	1	.000	2.256	1.476	3.448
Other, non-Hispanic	1.104	.422	6.839	1	.009	3.017	1.319	6.904
Hispanic	.768	.252	9.266	1	.002	2.156	1.315	3.535
2+ Races, non-Hispanic	.380	.306	1.548	1	.213	1.463	.804	2.663
Sex	.718	.115	39.059	1	.000	2.050	1.637	2.568
Education	.275	.067	16.822	1	.000	1.317	1.154	1.501
Income	.051	.069	.546	1	.460	1.052	.919	1.205
Employment			2.709	2	.258			
Not working	-.231	.183	1.597	1	.206	.793	.554	1.136
Retired	-.191	.128	2.230	1	.135	.826	.643	1.061
Home Ownership	.479	.170	7.913	1	.005	1.615	1.156	2.255
Constant	-1.594	.273	34.076	1	.000	.203		

Note: The reference group for Race/Ethnicity is White, non-Hispanic compared with Black, non-Hispanic, Other, non-Hispanic, Hispanic, and 2+ Races, non-Hispanic. Sex refers to males compared to females. The reference for Education is "less than high school" compared to high school, some college, or a Bachelor's degree or more. Income reference category is "less than $50,000/year" compared to $50,000 - $99,999, $100,000 - $149,999, or over $150,000. The reference for Employment is Working compared with Not Working, or Retired. Home Ownership refers to"does not own a home" compared to "owns a home". R^2 = .871 (Hosmer & Lemeshow) .098 (Nagelkerke) .074 (Cox & Snell). Model $X^2(10)=101.680$, $p < .0001$.

Table 5. Logistic regression predicting Odds of Consuming Green Tea in the Past Year based on self-reported health status, nutrition knowledge, supplement use, dietary change for health worry, perceived importance of health claims on food supplement labels, and familiarity with the green tea-cancer relationship.

						95% CI for Odds Ratio		
	B	**SE**	**Wald**	***df***	***p***	**Odds**	**Lower**	**Upper**
Health status	.410	.118	12.123	1	.000	1.507	1.196	1.898
Nutrition knowledge	.268	.126	4.538	1	.033	1.308	1.022	1.673
Dietary supplement use	-.124	.084	2.182	1	.140	.883	.749	1.041
Diet change for health worry	.302	.097	9.759	1	.002	1.352	1.119	1.635
Importance of health claims on supplements	-.024	.116	.043	1	.835	.976	.777	1.226
Importance of health claims on foods	.182	.122	2.247	1	.134	1.200	.945	1.524
Familiarity	.542	.193	7.850	1	.005	1.719	1.177	2.510
Constant	-2.872	.726	15.669	1	.000	.057		

Note: The reference category for Health status is poor health compared with fair, good, very good, or excellent health. Nutrition knowledge refers to people who are *not* informed about diet and health compared with people who are somewhat, fairly, very, or extremely informed. The reference group for dietary supplement use is never compared to less than 1 day/month, 1-3 days/month, 1-3 days/week, 4-6 days/week, and every day. Diet change for health worry refers to people who did *not* make a dietary change last year compared to people who made changes a little, somewhat, quite a bit, or all the time. Importance of health claims on supplement labels refers to people who do *not* find them important compared with people who find them somewhat important, important, very important, or absolutely essential. Importance of health claims on food labels refers to people who do *not* find them important compared with people who find them somewhat important, important, very important, or absolutely essential. The Familiarity reference group is people who are not at all familiar with the green tea and cancer relationship compared to people who are somewhat, fairly, very, or extremely familiar. R^2 = .217 (Hosmer & Lemeshow) .144 (Nagelkerke) .108 (Cox & Snell). Model $X^2(7)=57.003$, $p < .0001$.

Table 6. Logistic regression predicting Odds of Consuming Green Tea in the Past Year based on sociodemographic variables (race/ethnicity, sex, education, homeownership) and psychographic variables (self-reported health status, nutrition knowledge, supplement use, dietary change for health worry, perceived importance of health claims on food supplement labels, and familiarity with the green tea-cancer relationship).

						95% CI for Odds Ratio		
	B	**SE**	**Wald**	***df***	***p***	**Odds**	**Lower**	**Upper**
Race/Ethnicity			21.300	4	.000			
Black, non-Hispanic	.969	.362	7.167	1	.007	2.636	1.297	5.361
Other, non-Hispanic	1.829	.681	7.205	1	.007	6.229	1.638	23.685
Hispanic	1.219	.404	9.101	1	.003	3.383	1.533	7.468
2+ Races, non-Hispanic	.224	.444	.254	1	.614	1.251	.524	2.985
Sex	.402	.177	5.141	1	.023	1.495	1.056	2.116
Education	.077	.099	.608	1	.436	1.081	.889	1.313
Home Ownership	.380	.247	2.371	1	.124	1.462	.902	2.371
Health status	.436	.106	16.909	1	.000	1.547	1.256	1.904
Nutrition knowledge	.330	.112	8.641	1	.003	1.391	1.116	1.733
Diet change for health worry	.276	.087	9.998	1	.002	1.318	1.111	1.563
Familiarity	.675	.175	14.812	1	.000	1.964	1.393	2.769
Constant	-4.370	.561	60.756	1	.000	.013		

Note: The reference group for Race/Ethnicity is White, non-Hispanic compared to Black, non-Hispanic, other, non-Hispanic, Hispanic, and 2+ Races, non-Hispanic. Sex refers to males compared to females. The reference for Education is less than high school compared to high school, some college, or a Bachelor's degree or more. Home Ownership refers to people who do not own a home compared to people who do own a home. The reference category for Health status is poor health compared to those in fair, good, very good, or excellent health. Nutrition knowledge refers to people who are *not* informed about diet and health compared to people who are somewhat, fairly, very, or extremely informed. Diet change for health worry refers to people who did *not* make a diet change last year compared to people who made changes a little, somewhat, quite a bit, or all the time. Familiarity refers to people not familiar with the green tea and cancer relationship compared to people who are familiar. R^2 = .185 (Hosmer & Lemeshow) .221 (Nagelkerke) .166 (Cox & Snell). Model X^2 (11)=118.110, $p < .0001$

CHAPTER FIVE
Green Tea and Cancer: An Investigation of the Contested Qualified Health Claims

Introduction

The seminal court ruling, Pearson vs. Shalala, allowed companies to market health benefits that are not supported by significant scientific agreement[1] on food and dietary supplement product labels (Pearson, Shaw, American Preventive Medical Association, & Citizens for Health, 1999). These claims, known as qualified health claims (QHC), describe the relationship between a dietary component or food and the reduced risk for a disease or health-related condition, as well as the scientific certainty for the claimed relationship, which is also known as the disclaimer (Government Accountability Office, 2011).

Since their introduction in 1999, qualified health claims have been a source of contention between the US Food and Drug Administration and the food and dietary supplement industry (Berhaupt-Glickstein, Nucci, Hooker, & Hallman, 2014). The opposing perspectives, interests, and assumptions held by these stakeholders have led to several subsequent lawsuits about how to accurately and appropriately describe scientific evidence for diet-disease relationships supported by partial but credible evidence (Berhaupt-Glickstein et al., 2014).

A good example of this contention relates to the relationship between green tea and cancer. Since 2004, there have been seven QHCs on food and dietary supplement

[1] *"…based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence [21 U.S.C. § 343(r)(3)(B)(i)]"* (Ippolito & Mathios, 1993).

labels and websites about the relationship between green tea and its ability to reduce the risk of breast and prostate cancers (Fleminger, 2012). While the evidence for the green tea-cancer relationship has not changed over the past 11 years, the claim language and the description of evidence have evolved. The several iterations of the green tea claim can be attributed to an escalating debate between the FDA and the green tea manufacturer, Fleminger, Inc. which peaked in 2011 with a federal lawsuit (Fleminger, 2012). The dispute over the green tea-cancer claims and how it unfolded is demonstrative of the disagreements over QHCs in general, and so the evolution of the green tea QHCs and the arguments about them serve as a microcosm of the QHC system as a whole.

The purpose of this paper is to empirically examine some of the assertions made by parties in the activities leading up to the 2011 lawsuit as well as those disputed in the proceedings. We first give an overview of the QHC system and then provide a brief history of the evolution of the green tea QHCs including the disagreements and assertions of the stakeholders involved. We then test these assertions regarding how the QHCs are understood by consumers in a way that may serve as a model for testing other QHCs.

The System of Qualified Health Claims

The FDA regulates health claims on food and dietary supplement products under the Nutrition Labeling and Education Act of 1990. Health claims describe the relationship between a food or ingredient and a disease or health-related condition (i.e. diet-disease relationship). The FDA requires companies to petition the agency for authorized use of health claims on products and must meet specific requirements[2] for

[2] Petitions require a definition of the dietary substance(s), diseases/health conditions, copies of a literature search and summary of the scientific data about the diet-disease relationship, information about adverse effects, and proposed health claims (Kavanaugh, Trumbo, & Ellwood, 2007).

consideration (Office of Information and Regulatory Affairs, 2015). The agency then reviews the scientific literature about the claimed relationship to determine if it meets the criteria of Significant Scientific Agreement[1 above] (SSA) (Food and Drug Administration, 2013b).

The FDA authorizes health claims for diet-disease relationships that meet SSA and offers model health claims on their website for companies to use (Food and Drug Administration, 2013b) on their product labels. The agency also allows companies to write their own claims, so long as they meet technical requirements[3]. One example of a model health claim for the relationship between calcium and osteoporosis is, "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis." The FDA has approved a dozen health claims that meet SSA criteria such as the relationships between sodium and hypertension and soluble fiber and coronary heart disease (Food and Drug Administration, 2013b).

Qualified Health Claims

There are 53 other diet-disease relationships that do not meet SSA but are supported by partial or emerging evidence. In these circumstances, the FDA is compelled by law to permit companies to use a qualified health claim (Pearson et al., 1999) which has specific language prescribed by the agency. As stated, a QHC describes a diet-disease relationship and the totality of evidence for the claimed relationship (Food and Drug Administration, 2011c).

[3] Technical requirements refer to nutrient levels, language (i.e. must include "may" or "might"), and the nature of the product (Food and Drug Administration, 2013b). For example, to use a health claim on a food label about the relationship between calcium and osteoporosis, the product must meet the "high" nutrient criteria for calcium [21CFR1.101.72 (2015)], meaning that it contains 20% or more of the daily calcium requirement [21CFR1.101.54 (2015)].

To differentiate among the levels of evidence for diet-disease relationships, the FDA designed an evidence grading system (Food and Drug Administration, 2003a). Health claims that meet SSA are assigned an A grade because there is a "high level of comfort" that the claimed relationship is "scientifically valid" (Federal Trade Commission, 2006; Food and Drug Administration, 2003a). Qualified health claims are assigned an evidence grade of B, C, or D. Claims with a B grade indicates a "moderate or good level of comfort" among scientists about the scientific validity for the claimed relationship while a C grade represents a "low level of comfort" and a D grade, a "very low level of comfort" (Food and Drug Administration, 2003a). See Table 1 for examples of a B, C, and D-graded QHCs (Berhaupt-Glickstein & Hallman, 2015).

However, these evidence grades are not included in the QHC since previous research demonstrated that they confuse consumers (Hasler, 2008) and were altogether abandoned in 2009 (Food and Drug Administration, 2011c). Instead, an implicit scale of evidence remains that relies on the assumption that consumers can use these disclaimers to appropriately distinguish the level of evidence implied (Berhaupt-Glickstein & Hallman, 2015). For the purposes of the current paper, we refer to these evidence grades with the understanding that they are no longer in formal use.

To ensure the evidence is accurately characterized, the FDA preauthorizes the language in QHCs that may be used by marketers on their products; any deviation from this approved language is unlawful (Food and Drug Administration, 2011e). The FDA prescribes QHC language to ensure that foods and dietary supplements are properly labeled (Food and Drug Administration, 2012) so that consumers can "protect themselves from misleading claims…about health benefits that are not supported by science" (Food

and Drug Administration, 2011a). The FDA's aim is to ensure that consumers understand the partial scientific evidence for the claimed relationship in a QHC.

Companies are also interested in the QHCs because if effective, they may make a product more competitive by differentiating it from others in the same category, which may lead to greater purchases, and profits (Emord & Schwitters, 2012; Ippolito & Mathios, 1993; Pearson et al., 1999). Therefore, the food and dietary supplement industry's goal is for the evidence to be described accurately, yet in the most favorable way, so that consumers focus on the potential health benefits of their products. Consequently, when companies believe a diet-disease relationship is described in terms that are unfavorable within the prescribed language of a QHC, they are willing to take the FDA to court to change it (Berhaupt-Glickstein et al., 2014).

Qualified Health Claims and Consumers

QHCs are meant to communicate to consumers the quality and strength of the scientific evidence for diet-disease relationships (Government Accountability Office, 2011). Unfortunately, studies that have explored consumer understanding of QHCs demonstrate that they are not perceived as intended.

Researchers have tested different formats to measure the message clarity of scientific evidence in QHCs. Some of these studies have tested graphic formats both with and without the inclusion of an evidence grade (i.e. A, B, C, D) (Derby & Levy, 2005; Fitzgerald Bone, Kees, France, & Kozup, 2012; Food and Drug Administration, 2009; Hooker & Teratanavat, 2008; Kim, Kang, Kwon, & Kim, 2010; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008). Other studies have examined text-only claims, also with and without a letter grade (Derby & Levy, 2005; Fitzgerald Bone et al.,

2012; Food and Drug Administration, 2009; Food and Drug Administration, 2011b; Hooker & Teratanavat, 2008; Kim et al., 2010; Reinhardt-Kapsak et al., 2008). Since the unique feature of a QHC is the inclusion of a description of evidence, all studies measured the perception of scientific certainty for the claimed relationships.

Overall, the research demonstrated that consumers were unable to distinguish between the levels of evidence (Derby, 1999; Hooker, 2008; Reinhardt, 2008; FDA, 2009). However, when looking at D-level QHCs only, two studies have shown that consumers can accurately rate the evidence. Two green tea QHCs (Table 2, 2005p; 2005b) were tested for their ability to communicate the degree of scientific certainty and consumers were able to accurately rate the certainty of evidence for these D-grade claims on a 7-point scale (1-very uncertain; 7=very certain) (Derby & Levy, 2005; Food and Drug Administration, 2009). Another study similarly found that consumers appropriately rated their confidence in the scientific studies for a diet-disease relationship based on a D-level QHC (1-Not at all confident; 7=Very confident) (Hooker & Teratanavat, 2008). Using the information about the scientific certainty for a diet-disease relationship in a QHC, consumers should be able to make an informed decision about whether there is enough evidence to be confident that the claimed relationship exists.

Few eligible food and dietary supplement products include a QHC on their label. Three studies have found that fewer than 5% of the products that could use a QHC on their labels did so (Fitzgerald Bone & Russo France, 2009; Government Accountability Office, 2011; Hooker, 2007). Yet, the paucity of their use of QHCs does not imply that companies lack interest in making health claims for their products. On the contrary, the industry's continued pursuit of federal lawsuits to change the language of existing QHCs

suggests that they view such claims as a valuable way to influence consumer's purchase intentions. However, the nature of the lawsuits suggests that companies believe that the health claims they wish to make are rendered ineffective by the specific disclaimer language in currently enforced QHCs (Fitzgerald Bone & Russo France, 2009).

Green Tea QHCs as a Reflection of Competing Stakeholder Interests

The most recent claims that have come under legal scrutiny are about green tea and cancer (Fleminger, 2012). Based on its review of the available evidence, the FDA concluded that "[it is] highly unlikely that green tea reduces the risk of" breast or prostate cancer (Food and Drug Administration, 2011d) which represents a D-grade QHC (Berhaupt-Glickstein & Hallman, 2015; Food and Drug Administration, 2014).

Since 2004, there have been seven iterations of the green tea QHC. Each of these claims is based on exactly the same scientific evidence but communicates it in a unique way that reflects the interests and assumptions of the stakeholders who authored them. For ease of reference and comparison, these claims are presented as a group in Table 2, and are referred to in the text by the year in which they appeared (e.g. 2004, 2008, etc.).

Fleminger, Inc. wrote three of the seven claims (2004; 2008; 2010). Presumably, their interest is to use a claim that they believe will increase the purchases of their products (Emord & Schwitters, 2012; Pearson et al., 1999). The FDA also wrote three claims (2005p; 2005b; 2011). The agency's stated interest in authoring these claims was to accurately describe the evidence for the green tea-cancer relationship (Food and Drug Administration, 2013a) to prevent consumers from being misled (Food and Drug Administration, 2012). Lastly, the federal court suggested a QHC that is currently enforced by FDA (2012). The court's interest in QHCs is to support First Amendment

rights for the food and dietary supplement industry, as well as to support the federal government in protecting the public's health through the least restrictive means necessary (Pearson et al., 1999). The evolution of these seven QHCs is instructive, both because it illustrates the competing interests of the stakeholders involved, and because each iteration was driven by stakeholder assertions that were largely untested.

A Brief History of Green Tea QHCs

In 2004, Fleminger, Inc. petitioned FDA to use a green tea claim that the company had written, which linked consumption of green tea with the reduced risk of certain cancers (Table 2, 2004),

> Daily consumption of 40 ounces of typical green tea containing 170µg/ml of natural (-) epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive.

The FDA refused to enforce this proposed claim and so companies were never allowed to use it on green tea products. It is likely that the agency refused its enforcement because the company's characterization of evidence was inaccurate and because it did not specify which types of cancer risks could be reduced by consumption of green tea.

As an alternative to the proposed claim, FDA wrote and began enforcement of two QHCs that they believed "appropriately worded [the evidence] so as to not mislead consumers" (Food and Drug Administration, 2011d) (Table 2 2005p; 2005b):

> One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.
>
> Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea

> may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.

What differentiated the 2005 FDA claims from the 2004 Fleminger, Inc. claim was that the FDA specified the type of cancer (i.e. breast or prostate) risks reduced by the consumption of green tea. The claim also indicated the number and character of the studies (e.g. "one weak and limited study") for these relationships. These two claims, named mixed model claims, represent a mix between a qualitative QHC that describes the evidence with purely qualitative descriptors (e.g. "very limited") and a quantitative QHC which simply states the number of studies evaluated by the FDA for the claimed relationship (Berhaupt-Glickstein & Hallman, 2015). Nevertheless, the two 2005 QHCs were the only legally permissible QHCs for use on green tea products between 2005 and 2011.

However, Fleminger, Inc. was not satisfied with the 2005 QHCs and proposed an alternative claim in a letter to the FDA. The agency denied their request because the language in the 2005 QHCs was scientifically accurate (Berhaupt-Glickstein et al., 2014; Fleminger, 2012). Yet, the company responded in protest to the FDA in a letter that said the,

> "FDA ruling reiterates a qualified green tea health claim language for the Agency's discretion enforcement consideration for the time being as follows: Green tea may reduce the risk of cancer of the breast and the prostate. There is credible evidence supporting this claim although the evidence is limited" (Fleminger, 2012) (Table 2, 2008).

When the FDA did not respond to the letter, Fleminger, Inc. elected to post this QHC to their website. Two years later, the company further modified their claim on their website to specify that the FDA had concluded that there is credible evidence behind the

relationship between drinking green tea and reductions in cancer; (Table 2, 2010), "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited" (Fleminger, 2012).

These two claims (Table 2, 2008; 2010) were unregulated, meaning the company used them without prior approval of the language from FDA, which is illegal. The FDA regulations specify that companies may only use QHCs vetted by the agency for scientific accuracy and that are posted to the FDA website. Therefore between 2004 and 2011, there were potentially four QHCs in use in the marketplace; two QHCs enforced by FDA (2005p, 2005b) and two illegal QHCs written by Fleminger, Inc. and unenforced by FDA (2008, 2010).

Around the same time, there was a lawsuit about a QHC for selenium that included a description of evidence similar to that used in the 2005 FDA green tea QHCs (Alliance for Natural Health U.S., 2010). The court ruled that the language in the selenium QHCs was restrictive; meaning the description of evidence was more technical than necessary and could be described more plainly (Alliance for Natural Health U.S., 2010). As a result, the court required the agency to rewrite the selenium QHCs (Alliance for Natural Health U.S., 2010). Perhaps to hedge against the possibility of a lawsuit about green tea, the FDA elected to revise and combine its enforced 2005 green tea claims to reflect this ruling (2011): "Drinking green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce that risk because there is very little scientific evidence for the claim" (Fleminger, 2012).

However, the revised QHC prompted Fleminger, Inc. to file a lawsuit against the FDA, arguing that because the disclaimer began with, "FDA does not agree . . ." it effectively negated the claim that drinking green tea can reduce the risk of prostate and breast cancers. Further, the company asserted that the enforced language infringed upon its First Amendment rights.

The FDA then filed counter-complaints about the two illegal QHCs on the Fleminger, Inc. website (Table 2 2008; 2010), asserting that by calling it "credible," the claims mischaracterized the evidence for the relationship between the consumption of green tea and cancer risk reductions. The agency also asserted that by invoking the "FDA" in its disclaimer, Fleminger, Inc. misled consumers to believe that the agency endorsed the characterization of the evidence in the illegal QHCs (Fleminger, 2012).

In its ruling, the court agreed with the assertions of both Fleminger, Inc. and the FDA. Consequently, the FDA was required to stop enforcement of the 2011 QHC because it presumably negated the green tea-cancer relationship. At the same time, Fleminger, Inc. was also mandated to remove the unregulated claims (2008, 2010) from its website and to refrain from writing QHCs independent of FDA.

Finally, to ameliorate the situation, the court also suggested an alternative QHC (Fleminger, 2012), which is now enforced by FDA. It is now one of two green tea QHCs that are legally permissible for companies to use (2012): "Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim" (Food and Drug Administration, 2011e).

The Current Study

While the FDA's main interest in enforcing QHCs is to accurately communicate the level of scientific evidence for the relationship, only two green tea QHCs have been tested to determine the degree of consumer's comprehension or interpretation of this evidence (Food and Drug Administration, 2009). However, the FDA no longer enforces these two QHCs (Table 2, 2005p; 2005b).

Moreover, none of the assertions made by FDA, the courts, or by Fleminger, Inc. regarding alleged deficiencies of the various claims appear to have been tested. The key untested assertions include those made by the FDA that the QHCs proposed by Fleminger, Inc. do not accurately characterize the scientific evidence.

The QHCs authored by the FDA suggest that the available evidence warrants a D-level QHC, and as such, has a very "low consistency with conclusions from authoritative bodies or ranked very low by qualified scientists" (Food and Drug Administration, 2003a). In fact, the currently enforced green tea QHC specifically states, "FDA has concluded that there is very little scientific evidence for this claim."

In contrast, the 2004 QHC proposed by Fleminger, Inc. described the evidence as "supportive but not conclusive," which the FDA asserted was inaccurate. The FDA similarly objected to the 2008 and 2010 QHCs written by Fleminger, Inc., which described the scientific evidence as "credible but limited," asserting that this characterization was also inaccurate (Fleminger, 2012).

Indeed, the Fleminger, Inc. 2008 and 2010 disclaimers, which describe the evidence as "supportive but not conclusive," and as "credible but limited" seem to suggest more scientific support than that suggested in the FDA's 2011 and 2012 QHCs which state, "there is very little scientific evidence for this claim." Further, the

descriptions of evidence in the same two Fleminger, Inc. claims also appear to suggest more scientific evidence for the green tea-cancer relationship than the FDA's 2005 QHCs, which describe the quantity and quality of the studies that examined the green tea relationship, and conclude that, "…it is highly unlikely that green tea reduces the risk of breast/prostate cancer." Based on this, we hypothesize that:

H1: Consumers will perceive significantly greater scientific support for the 2004, 2008 and 2010 Fleminger, Inc. QHCs than for the FDA's 2005, 2011, and 2012 QHCs.

The 2010 Fleminger, Inc. QHC went so far as to specify the FDA as the reviewer of evidence, perhaps to increase the claim's credibility, a point that FDA strongly contested (Fleminger, 2012). The FDA pointed to an agency study to support their assertion that making reference to the agency in the QHC implied that it endorsed the claim. While the Court agreed with FDA based on the Nutrition Labeling and Education Act of 1990, which charged the FDA with approving health claims, it found the FDA study inapplicable to their argument because it showed that consumers believed that FDA only regulated advertising for dietary supplements, not foods (Food and Drug Administration, 2015). To test this assumption, we hypothesize that:

H2: QHCs that reference the FDA will be seen as required by the government to be included on green tea/yukichi fruit juice labels.

H3: QHCs that do not make reference to the FDA will be seen as voluntarily added to green tea/yukichi fruit juice labels by companies.

As already described, the FDA's 2005 QHCs quantified and qualified the strength of the scientific studies that have examined the claimed green tea-cancer relationship

(Berhaupt-Glickstein & Hallman, 2015; Food and Drug Administration, 2009). The FDA voluntarily revised these claims in reaction to a lawsuit about other similarly worded QHCs, which caused the agency to rewrite the disputed QHCs with less technical language (Alliance for Natural Health U.S., 2010; Berhaupt-Glickstein et al., 2014). The resulting 2011 FDA QHC summarizes the evidence without technical jargon, perhaps making it easier for consumers to read and to comprehend. However, the revised QHC no longer mentioned the number of studies that form the basis for the scientific evidence behind the green tea-cancer relationship. As a result, we hypothesize:

H4: Consumers are likely to misestimate the number of studies evaluated by FDA for the diet-disease relationship without inclusion of the study details in the QHC.

The 2011 FDA QHC states that "FDA does not agree that green tea may reduce that risk because there is very little scientific evidence …" However, it was the phrase "FDA does not agree…" that provoked Fleminger, Inc. to file suit against the agency, and which the court ruled as a contradiction of the claimed green tea-cancer relationship (Fleminger, 2012). Yet, no direct evidence was collected from consumers to determine whether they perceived the disclaimer as negating the claim of green tea's ability to reduce the risk of breast and prostate cancers.

While the language of the summary disclaimer in FDA's 2011 QHC is different from the 2005 and 2012 FDA QHCs, the conclusion is consistent. Therefore, there is little reason to believe that consumers would view the 2011 QHC as fundamentally different from the other FDA QHCs in terms of whether the evidence supports or does

not support (i.e. negates) the relationship between green tea and the reduced risk of cancer. In contrast, we hypothesize that:

H5: Consumers will not interpret the 2011 FDA QHC as suggesting that green tea is not effective at reducing the risk of cancer.

Methods

A 2 (diet-disease relationship: green tea-cancer vs. yukichi fruit juice-gastrocoridalis) by 7 (QHC: 2004, 2005p, 2005b, 2008, 2010, 2011, 2012) between-subjects study tested these hypotheses through an online survey. To test the hypotheses based on the Fleminger, Inc. lawsuit about claim language or wording, each participant viewed one QHC. Participants were randomized to one of two conditions: (1) green tea-breast/prostate cancer, or (2) yukichi fruit juice-gastrocoridalis, a fictitious but comparable diet-disease relationship. Yukichi fruit juice was described as a typical drink sold in stores and gastrocoridalis was introduced as a potentially painful and fatal disease, similar to cancer.

Given the popularity of green tea in the US (Tea Association of the USA, Inc., 2014) and its familiar health benefits (National Cancer Institute, 2015; Samavat et al., 2015; Singh, Shankar, & Srivastavaa, 2011), a between-subjects study design with a novel diet-disease relationship is an appropriate approach. The intention of the yukichi fruit juice-gastrocoridalis condition was to determine the effects of the health claim language without the potential interaction of existing beliefs about green tea and/or cancer. These interactions may be important because the healthier a product is viewed (American Cancer Society, 2015b; International Food Information Council, 2011), the

more favorably a health claim is perceived (Wills, Storcksdieck genannt Bonsmann, Kolka, & Grunert, 2012).

Once assigned to the green tea or yukichi fruit juice condition, participants were randomized to view one of the seven QHCs (Table 2). However, the difference between the QHCs in the two conditions was that for those assigned to the yukichi fruit juice condition: (a) yukichi fruit juice substituted for green tea as the dietary component and (b) gastrocoridalis replaced breast and/or prostate cancer as the target disease in the claims.

The seven green tea QHCs differ in terms of their length and in their nuanced scientific descriptions of evidence. Some green tea QHCs include "FDA" (Table 2, 2005p; 2005b; 2010; 2011; 2012), and some specify the number of studies for the relationship (Table 2, 2005p; 2005b). One QHC disclaimer potentially negates the green tea claim (Table 2, 2011) while another potentially strikes a balance by communicating the low-level of scientific evidence without nullifying the claim (Table 2, 2012).

This was a text-only study; label images were not included. Once the QHC stimuli were revealed, the text of the QHC remained at the top of the screen and participants responded to a battery of questions that correspond with the measures outlined below.

To minimize participant burden, the survey underwent several rounds of cognitive testing until further clarification was not warranted. Subsequent pretesting minimized the time burden for completion. The Institutional Review Board at Rutgers, The State University of New Jersey approved the study.

Participants

Data was collected through an online survey using a panel maintained by GfK Custom Research, LLC (GfK). A nationally representative sample of English-speaking adults aged 55 years and older was recruited to participate in the study in January 2014. Participants in this age group were selected because the majority of the health outcomes described in the currently enforced QHCs concern chronic diseases, which are likely to be of greater concern to older adults, including cancer, hypertension, diabetes, cardiovascular disease, and cognitive dementia. For example, more than three-quarters of all cancer diagnoses are in older adults (American Cancer Society, 2015a; King, Matheson, Chirina, Shankar, & Broman-Fulks, 2013). In addition, older adults are more health-oriented than younger adults, (Nocella & Kennedy, 2012)and are knowledgeable about diet and health, they adopt preventive behaviors (Nocella & Kennedy, 2012), and are more likely to use food labels (Academy of Nutrition and Dietetics, 2011; Govindasamy & Italia, 1999).

Measures

Dependent Measures

A key outcome measure is understanding of the description of evidence (i.e. disclaimer) for the claimed relationship. The description of the level of scientific evidence is the quintessential element of QHCs and is the primary outcome of interest for stakeholders. All seven claims in the current study represent a D-grade QHC and are based on the same scientific evidence. Thus, they should elicit from consumers the same sense of evidence supporting the relationship between the consumption of green tea and reductions in the risk of cancer.

To test whether the specific language in each of the seven versions of the QHC led to different perceptions of evidence, participants rated the level of evidence on a 13-point scale (i.e. 0-no evidence to 12-complete evidence) (Table 3). The 13-point scale was designed so that participants had a wide range of ordinal responses available to them, and so that the scale could be separated into the four evidence grades; 0=no evidence, 1-3=D-grade, 4-6=C-grade, 7-9=B-grade, 10-12=A-grade. The question asked, "Based on this statement, how much evidence is there that drinking green tea [yukichi fruit juice] may reduce the risk of certain forms of cancer/breast and/or prostate cancer [gastrocoridalis]?

The participants were also asked to tally the evidence, indicating both the number of supportive and unsupportive studies they believed were evaluated by FDA to reach a conclusion about the claimed relationship. The answers to these questions were summed to yield the total number of studies that participants thought had examined the relationship between drinking green tea and cancer risk reduction. As noted earlier, two of the seven QHCs specify the number of studies that did or did not support the green tea-cancer relationship (Table 2 2005p 2005b); the remaining five do not quantify the evidence.

In the 2012 lawsuit, FDA asserted that consumers were misled by the unregulated QHC (see Table 2, 2010) because Fleminger, Inc. included the agency's name, misleading consumers to believe that FDA agreed with the claim (Fleminger, 2012). While the FDA provided evidence to support their assertion, the Court found it inapplicable because the study showed that consumers believed that FDA regulated advertising for dietary supplements, not foods. To explore whether consumers believe the

QHCs are voluntarily included on a label or are required, the participants were asked, "Do you think this statement was: voluntarily added by the company, required by the government, or put there for some other reason."

The Fleminger lawsuit highlighted the 2011 FDA QHC and the phrase, "FDA does not agree…" as a negation of the green tea-cancer relationship. To measure the meta-message or "implicit message" of the QHC, participants were asked if the claim suggested, did not suggest, or made no suggestion that green tea [yukichi fruit juice] is effective at reducing the risk of cancer [gastrocoridalis]. The word, effective, was purposely used in this question since we aimed to measure if the disclaimer negated the claimed relationship. Negate is defined as, "to cause (something) to not be effective" (Merriam-Webster, 2015). The correct answer is that QHCs make no suggestion about the effect of dietary components on reducing the risk of a disease/health condition. However, this question also aimed to measure whether any of the QHCs negated the claim, by prompting participants to think the claim suggested that green tea [yukichi fruit juice] was not effective (i.e. negated) at reducing the risk of cancer [gastrocoridalis].

Similar to being familiar with a diet-disease relationship, experience with a product (Mazis & Raymond, 1997) could influence perceptions of evidence. To account for existing behavior, participants responded to the question, "Over the past 12 months, how often did you drink green tea [yukichi fruit juice]?" on a five-point scale (1-never, 2-less than once a month, 3-once a month, 4-two to three times a month to 5-at least once a week). This question was adapted from the Food Frequency Questionnaire of the National Health and Nutrition Examination Survey (Centers for Disease Control and Prevention, National Center for Health Statistics, 2004).

Finally, socio-demographic factors including, sex, race/ethnicity age, marital status, education, employment, and income were measured because there is evidence that they influence consumer understanding of health claims (Nocella & Kennedy, 2012). We expected a considerable portion of participants would be retired, and so included home ownership as an additional measure of socioeconomic status. It should be noted that GfK collected this data prior to the current study as part of each panel member's demographic profile and so neither the questions nor applicable response categories were specifically designed for this study.

Statistical analyses

Descriptive statistics summarized the study sample and Spearman correlation coefficient tests identified associations between variables. Group comparisons of categorical variables were tested with Chi-square tests for association. Cramer's V is reported to indicate the strength of association between two categorical variables. The distribution for the estimated number of total studies evaluated by the FDA for the claimed relationship had positive skew and kurtosis. It was therefore reciprocally transformed with a constant of one. Univariate analysis of variance with bootstrapping compared continuous variable responses between QHC groups. For univariate tests that violated the assumption of homogeneity of variances, the Welch's *F*-test results are presented. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using the Statistical Package for Social Sciences, version 22 (SPSS Inc., Chicago, IL, USA).

Results

The online survey was completed by 1,335 older adults. Most participants were between the ages of 55 and 74 years old (n=1,123, 89.1%), White (n=1,060, 79.4%), with a high school degree or more (n=1,233, 92.4%), and a household income under $100,000 (n=1,028, 77.0%). Half of the participants reported that they had consumed green tea in the 12 months prior to the survey (n=691, 51.8%).

Half of the participants were assigned to view a QHC about green tea and cancer (n=669) and the other half viewed one claim about the yukichi fruit juice-gastrocoridalis relationship (n=666). There were no differences between conditions by race/ethnicity, age, education, employment, household income, home ownership, incidence of gastrocoridalis, and cancer, including breast and prostate cancers, or consumption of green tea (Table 4). No differences were found between QHC groups for these same sociodemographic characteristics (Table 5).

Participants rated the level of scientific evidence for the claimed relationship in the QHC they viewed using a 13-point scale. Points on the scale were collapsed to represent the four grades of evidence where zero meant "No evidence", 1-3 represented a D-grade, 4-6 equaled a C-grade, 7-9, a B-grade, and 10-12 an A-grade (see Table 3). When the scale was separated into evidence grades, the average rating was a "2", or a D-grade, which is accurate (Berhaupt-Glickstein et al., 2014; Food and Drug Administration, 2009). The total number of studies participants reported they believed the FDA evaluated for the claimed relationship varied widely (range: 0-100,000) with a median of four studies (IQR= 2 - 20) (Figure 2). There was a statistically significant positive and weak correlation between the estimated total number of studies evaluated for the claimed relationship and the ratings of evidence, $r_s(1,288) = .279$, $p < .0001$.

When asked why they thought the QHC they viewed would be affixed to a food label, 44.8% thought it was a government requirement (n=592,) and 38.1% believed that a company had voluntarily added it (n=504). Seventeen percent (n=226) thought it was there for some other reason. Nearly half (n=607, 46.3%) of all participants thought the QHC suggested that green tea/yukichi fruit juice was effective at reducing the risk of cancer/gastrocoridalis. The other half thought the claim suggested it was ineffective (n=347, 26.4%) or that it made no suggestion about the effect (n=358, 26.8%), the latter being the correct answer.

Group comparison, QHC – FDA/Fleminger, Inc.

To determine whether the Fleminger, Inc. QHCs produce greater perceptions of evidence, claims were separated based on authorship by the two stakeholder groups: (1) the QHCs written and enforced by the FDA (n=789) and (2) the QHCs written by Fleminger, Inc. (n=546). For this analysis, the QHC written by the court (2012) was included in the FDA QHC group since it is currently enforced by the agency. A one-way ANOVA test demonstrated statistically significant group differences for perceptions of evidence *Welch's F*(1, 907.111) = 132.949, $p < .0001$. On a 13-point scale of evidence, the approximate mean group score was two for the FDA QHC group and four in the Fleminger, Inc. QHC group (Table 6).

A one-way ANOVA also compared group mean responses of the estimated total number of studies evaluated by the FDA for the diet-disease relationship. There was no difference between the FDA and Fleminger, Inc. QHC groups for the estimated total number of studies thought to be the basis for the green tea-cancer/yukichi fruit juice-gastrocoridalis relationship, $F(1, 1{,}296) = 2.604$, $p = .107$. However, participants

correctly estimated the number of studies for the two 2005 FDA QHCs. This was expected, since these two claims specify the number of supportive and unsupportive studies within the text of the QHC (Table 6).

Chi-square was used to test for associations between FDA/Fleminger, Inc. QHC groups and the participants' categorical responses regarding: (1) reason for the label claim on a product, and (2) the meta-message of the claim. Sixty percent (n=329) of the participants who saw a Fleminger, Inc. claim thought the QHC would appear on a label because the manufacturer voluntarily used it. In contrast, 60% (n=490) of participants assigned to view FDA claims thought the government required the claim, $\chi^2(2, N = 1{,}322) = 266.259$, $p < .0001$; V = 0.449, $p < .0001$. Nearly three-quarters (n=394, 73.4%) of the participants who viewed a Fleminger, Inc. QHC thought the claim suggested that green tea/yukichi fruit juice was effective at reducing the risk of cancer/gastrocoridalis compared with only 27.5% (n=213) of those who viewed QHCs from the FDA group, $\chi^2(2, N = 1{,}312) = 303.246$, $p < .0001$; V = 0.481, $p < .0001$.

Group comparison, QHC – Year

In this analysis, we examined participant responses to the seven individual QHCs (see Table 2). A one-way ANOVA indicated significant differences in group responses about perceptions of evidence *Welch's F*(6, 572.549) = 23.954, $p < .0001$ (Table 6). Games-Howell post hoc test confirmed the mean differences were statistically significant at the $p < .05$ level with greater perceptions of evidence by participants who viewed the 2004, 2008, and 2010 claims (i.e. Fleminger, Inc.) (Figure 3). Further, there were also significant differences among the seven QHCs with regard to the total number of studies

that participants thought had been evaluated by the FDA as the basis for the QHC, *Welch's F*(6, 567.085) = 3.045, p = .006 (Figure 2).

Chi-square tests again demonstrated that more than half of the participants in the 2004, 2008, or 2010 QHC groups (i.e. Fleminger, Inc.) thought the claims were voluntarily used by a company whereas people who viewed the 2005p, 2005b, 2011, or 2012 QHCs (i.e. FDA) believed it was required by government, $\chi^2(12, N = 1{,}322) = 289.006$, $p < .0001$; V = 0.468, $p < .0001$.

A statistically significant association was also found between the QHC viewed by the participant and the perceived meta-message of the claim, $\chi^2(12, N = 1{,}312) = 395.535$, $p < .0001$; V = 0.388, $p < .0001$. Similar to the findings of the group comparisons between the FDA and Fleminger, Inc QHCs, over 70% of participants in the 2004, 2008, or 2010 (i.e. Fleminger, Inc.) QHC groups believed the claim suggested that green tea/yukichi fruit juice was effective at reducing the risk of cancer/gastrocoridalis. Moreover, 60.5% (n=104) of the 2005b respondents thought the QHC suggested that green tea or yukichi fruit juice was not effective at reducing the risk of cancer or gastrocoridalis, which was 15.7% greater than the 2005p group, 25.9% more than the 2012 FDA QHC group, and 35.4% more than the 2011 QHC group, the impetus for the Fleminger, Inc. lawsuit (Figure 1).

Group comparison, QHC – "FDA" vs. no "FDA"

We then compared "FDA" QHC group responses (n=974) (2005p, 2005b, 2010, 2011, 2012) with no-"FDA" responses (n=361) (2004, 2008; both written by Fleminger, Inc.) to understand if reference to "FDA" is related to consumer belief that the claim is

agency endorsed or government required on food labels. And if "FDA" was not referenced, do consumers believe companies voluntarily add the claim to the label?

A Chi-square test indicated a statistically significant association between QHC group and whether the claim was seen as voluntary, required, or placed on a label for some other reason, $\chi^2(2, N = 1{,}322) = 131.568$, $p < .0001$, $V = 0.315$, $p < .0001$. When "FDA" was included in the QHC, 59% (n=212) of the participants reported that they thought a company had voluntarily added the claim to a product label. In contrast, when "FDA" was mentioned, 54.1% (n=522) believed the claim was required by the government on labels. The "FDA" QHC group includes five claims that were written by Fleminger, Inc., FDA, or the court. The no-"FDA" QHC group includes two claims both written by Fleminger, Inc. that inaccurately characterize the evidence (Fleminger, 2012).

Therefore, to further examine the effect of the inclusion of "FDA" in a QHC, we compared responses to the 2008 and 2010 Fleminger, Inc. QHCs. These are of particular interest because the language in these claims is almost identical except that one claim mentions "FDA" and the other does not. However, a Chi-square test indicated no differences in participant's beliefs about whether the claim was required by the government, voluntarily added, or put there for some other reason, $\chi^2(2, N = 356) = .416$, $p = .812$.

A statistically significant association was identified between QHC groups and perceived meta-message of the claim, $\chi^2(2, N = 365) = 142.152$, $p < .0001$, $V = 0.329$, $p < .0001$. When comparing the no-"FDA" group to the "FDA" group, there was a 35% increase in the number of participants who thought the QHC suggested that green tea or

yukichi fruit juice was effective at reducing the risk of cancer or gastrocoridalis (36.8% vs. 71.8%).

A one-way ANOVA indicated a significant difference between the "FDA" and no-"FDA" QHC groups, in terms of participant's perceptions of the amount of evidence behind the diet-disease relationship, *Welch's F*(1, 548.695) = 56.341, $p < .0001$. Participants in the no-"FDA" QHC group perceived that there was a greater amount of evidence behind the claim (M=3.90, SD=2.69 vs. M=2.70, SD=2.23) than the "FDA" QHC group. However, no differences were found between the "FDA" and no-"FDA" QHC groups on estimated total number of studies, $F(1, 1{,}296) = 2.204$, $p = .138$.

Group comparison, QHC – Mixed Model (#) vs. Qualitative

Next, we wanted to understand whether qualitative QHCs yield different perceptions of evidence compared with mixed model claims. Two groups of claims were created. Group one is termed qualitative QHCs because they describe the evidence and do not specify the number of studies (n=945) (2004, 2008, 2010, 2011, 2012). Group two includes QHCs that quantify and critique the number of studies for the claimed relationship; this group is called mixed model QHCs (n=390) (2005p, 2005b).

One-way ANOVA was used to test group responses. Statistically significant differences were observed between mixed model and qualitative QHC groups in terms of the participants' estimated total number of studies, *Welch's F*(1, 1,065.875) = 4.831, $p = .028$. Significant differences also existed between groups for perceptions of evidence *Welch's F*(1, 929.705) = 51.156, $p < .0001$. Participants who viewed a qualitative QHC had greater perceptions of evidence (3.29 vs. 2.36).

The majority of the participants in the mixed model QHC groups thought the QHC was required by the government (n=225, 58.4%), in contrast, those in the qualitative QHC group were equivocal as to whether the claim was voluntary (n=416, 44.4%) or required by the government (n=367, 39.2%), $\chi^2(2, N = 1{,}322) = 56.666$, p < .0001; V = .207, $p < .0001$. Most in the mixed model QHC group also thought that the meta-message was that green tea/yukichi fruit juice is not effective at reducing the risk of cancer/gastrocoridalis (n=198, 51.8%), whereas people in the qualitative QHC group mainly believed green tea/yukichi fruit juice was effective (n=548, 58.9%), $\chi^2(2, N = 1{,}312) = 247.776$, p < .0001; V = .435, $p < .0001$.

Condition comparison, green tea/yukichi fruit juice

We then wanted to remove the familiarity of the green tea-cancer relationship because prior familiarity with diet-disease relationships has been shown to influence perceptions of health claims through confirmatory bias (Walker Naylor, Droms, & Haws, 2009). So, we compared group responses between the green tea-cancer (n=666) and yukichi fruit juice-gastrocoridalis (n=669) conditions.

On average, participants in the green tea condition reported greater evidence for the claimed relationship (M=3.39, SD=2.58) than participants in the yukichi fruit juice (M=2.65, SD=2.19) conditions. This difference, -.733, 95% CI [-.99313, -.46832], was statistically significant *Welch's F*(1, 1,283.496) = 30.807, p < .0001.

A one-way ANOVA test determined if there were differences in the estimated number of total studies for the green tea-cancer and yukichi fruit juice-gastrocoridalis relationships. The estimated number of studies was higher in the green tea condition than

in the yukichi fruit juice condition *Welch's F*(1, 1,277.196) = 15.914, p < .0001 (Figure 2).

A statistically significant association was found between the green tea and yukichi fruit juice conditions for the meta-message, $\chi^2(2, N = 1{,}312) = 23.807$, p < .0001, V = .135, *p* = .0001. While the greatest proportion of respondents thought the QHC suggested that green tea/yukichi fruit juice was effective at reducing the risk of cancer/gastrocoridalis, (n=339, 51.4% and n=268, 41.0%, respectively), a greater percentage of participants in the yukichi fruit juice condition thought the claim did not make any suggestion about its effect on gastrocoridalis (n=216, 33.1%) in comparison with the green tea condition (n=142, 21.5%).

A Chi-square test also showed associations between conditions and whether the claim was required or voluntary, $\chi^2(2, N = 1{,}322) = 15.827$, p < .0001, V = .109, *p* < .0001. Just under half of the participants in the yukichi fruit juice condition reported that the QHC was required on labels by the government (n=327, 49.5%) while a greater percentage in the green tea condition thought the QHC was voluntarily added by the company (n=286, 43.3%).

<u>Condition and group comparisons, green tea/yukichi fruit juice & QHC group – Year</u>

Finally, we compared measures by the assigned green tea/yukichi fruit juice condition as well as the seven QHC groups. Univariate analysis of variance tests demonstrated significant interactions between the condition and QHC group on perceptions of evidence, *F*(6, 1,304) = 2.924, p = .008, partial η2= .013. No interactions were found between groups and conditions on the estimated number of studies completed for the claimed relationships, *F*(6, 1,284) = .901, *p* = .467 (Figure 2).

Participants who saw the 2010 Fleminger, Inc. QHC rated the evidence significantly higher (1.437, 95% CI [0.78, 2.10]) in the green tea condition, $F(1, 1{,}304) = 18.184$, $p < .0001$, partial $\eta^2 = .014$ than those in the yukichi fruit juice condition. The mean rating of evidence for the 2012 FDA QHC was also higher in the green tea condition (+1.418, 95% [0.78, 2.06]), $F(1, 1{,}304) = 18.814$, $p < .0001$, partial $\eta^2 = .014$ (Figure 3).

Within the green tea condition, there was a statistically significant difference in the mean evidence rating between the seven QHC groups, $F(6, 1{,}304) = 15.730$, $p < .0001$, partial $\eta 2 = .067$. Participants in the green tea condition who viewed the 2010 Fleminger, Inc. QHC rated the "evidence" significantly higher than the four FDA QHC groups; 2005p: 2.26 points, 95% CI [1.27, 3.25], 2005b: 1.98 points, 95% CI [.98, 2.98], 2011: 2.32 points. 95% CI [1.34, 3.30], and 2012: 1.46 points, 95% CI [0.48, 2.45], $p < .05$ (Figure 3).

Multinomial logistic regression tested for significance between groups and conditions for the measures of meta-message and reason for a QHC on a product label. However, some cell sizes were too small to detect significance and therefore, the observed frequencies and percentages are reported in Tables 7 and 8.

Discussion

Our study tested assertions made by the green tea manufacturer, Fleminger, Inc. and the FDA in the activities that led to the 2011 lawsuit as well as complaints from the proceedings. Overall, our findings demonstrate that specific claim language does matter in D-graded claims because different disclaimer language affects consumer perceptions of the evidence.

Evidence perceptions

The FDA took issue with the Fleminger, Inc. QHCs (2004, 2008, 2010) because they inaccurately characterized the evidence (Fleminger, 2012). We agreed with FDA's assumption about the Fleminger, Inc. QHCs and hypothesized they would produce greater evidence perceptions than any of the FDA claims (2005p, 2005b, 2011, 2012). Planned comparisons between QHC groups demonstrated that some claims produce greater perceptions of evidence than others, suggesting that the disclaimers are impactful. Consumers rated the evidence higher for the Fleminger, Inc. QHC group than the FDA QHC group. Moreover, the perceptions of the level of evidence behind the Fleminger QHCs more closely represents a C-grade of evidence rather than a D-grade, and so does not match FDA's evaluation of the scientific evidence.

This difference in evidence perceptions remained statistically significant for the Fleminger, Inc. QHCs when the seven claims were individually compared (e.g. 2004 vs. 2005p; 2008 vs. 2012). The perceptions of the level of evidence for each of the FDA QHCs (see Table 2) corresponded to a D-grade, and so were accurate, which is consistent with prior research (Berhaupt-Glickstein & Hallman, 2015; Food and Drug Administration, 2009). Since FDA is most concerned with scientific accuracy and we only examined D-grade QHCs in this study, we assume the evidence perceptions for the FDA QHC group are accurate. With this assumption, these results suggest the language proposed or illegally used in Fleminger, Inc. QHCs was scientifically inaccurate, and was likely to result in consumers' overestimating the amount of evidence behind the green tea/cancer relationship.

Tallying the evidence

A second measure of understanding of claim was the estimate of the number of studies that serve as the basis for the claimed relationship. There were significant differences between groups when QHCs were compared individually and when grouped as qualitative or mixed model claims. In actuality, three studies were evaluated by the FDA for the green tea-breast cancer relationship and two studies for green tea and prostate cancer.

In addition, the ratings of perceived evidence on the 13-point scale (Table 3) were greater in the qualitative QHC group than the mixed model group. This suggests that less explicit disclaimers or perhaps those that lead with positive language may produce greater evidence perceptions. For example, the Fleminger, Inc. QHCs describe the evidence as "supporting…although…not conclusive" and "credible…although…limited" (Table 2, 2008; 2010) whereas the FDA QHCs describe the evidence as "one weak and limited study", "highly unlikely" or "very little". Still, it should be noted that only D-grade QHCs were included in the study and the greater challenge is for consumers to be able to accurately judge the level of evidence when confronted with QHCs of different grades of evidence (Derby & Levy, 2005; Food and Drug Administration, 2009).

Responses for the estimated number of studies that served as the basis for the evaluation of the claims also demonstrated that the participants accurately read the 2005 QHCs because they gave the correct number. This suggests that consumers, at least in this study, understand the quantitative evidence as intended. Based on this finding and the fact that the two 2005 FDA QHCs were rated as having a D-grade of evidence, it seems that these claims communicate the scientific support thereby fulfilling agency's goal of accurate evidence characterization (Food and Drug Administration, 2012).

However, the federal court ruled that these types of QHCs are more technical and burdensome than necessary to describe the scientific support for a claimed relationship (i.e. restrictive) (Alliance for Natural Health U.S., 2010). The revised FDA claim (2011) also produced an accurate estimation of the number of studies for the green tea-breast cancer relationship as well as an accurate rating of evidence as a D-grade QHC, even though it does not mention the number of studies evaluated within the QHC itself. Yet, this is also the claim that prompted Fleminger, Inc. to file a lawsuit against the FDA for being contradictory of the green tea-cancer relationship (Fleminger, 2012).

The exact nature of consumer confusion with QHCs is not well understood (Hooker & Teratanavat, 2008). There are several potential reasons for the differences in the perception of evidence between claims. The evidence description may truly be more favorable in the Fleminger, Inc. claims (i.e. "credible but limited"; "supportive but not conclusive") than the FDA QHCs (i.e. "highly unlikely"; "very little"). The Fleminger, Inc. QHCs are also shorter in length than the 2005 FDA QHCs, which appeals to consumers (Dodds, Tseelon, & Weitkamp, 2008; Reinhardt-Kapsak et al., 2008) as less "costly" to read and use (Kiesel, McCluskkey, & Villas-Boas, 2011). However, the length does not appear to impact evidence perceptions in this instance since all Fleminger, Inc. QHCs were rated as having greater evidence than all FDA QHCs, some of which are longer (2005p, 2005b) and some, shorter (2011, 2012).

Court-suggested QHC

Even when controlling for familiarity with a novel diet-disease relationship, the Fleminger, Inc. QHCs still produced greater evidence perceptions than FDA claims. This finding provides more support that the company's claims describe the scientific evidence

more favorably and inaccurately. The 2012 FDA QHC (i.e. court-suggested) holds promise of balancing stakeholder interests since the evidence rating represents a middle ground between the overstated evidence in the Fleminger, Inc. QHCs and the low ratings demonstrated in response to the FDA QHCs. Further, participants rated the 2012 FDA QHC as having enough evidence for a D-grade claim. This claim appears to achieve the "fundamental goal…to present uncertainty in a way that is not overly complicated, yet sufficiently detailed…" (Dieckmann, Peters, Gregory, & Tusler, 2012). Although, the greater challenge is not with any single QHC but rather the system of QHCs and their comparison with others of different evidence grades.

"FDA" vs. No "FDA"

The FDA's assertion (Table 2, 2010) that the inclusion of "FDA" in the illegal Fleminger, Inc. claim misled consumers to believe the agency approved the relationship was both supported and refuted in our study. When "FDA" and non-"FDA" QHC groups were compared, more participants reported that the government required the label claim, which suggests that its inclusion affected responses. However, in this comparison, two Fleminger, Inc. claims composed the no-"FDA" QHC group, which also mischaracterized the evidence.

So, it was unexpected that two very similarly worded QHCs ([1] "FDA" [2] no "FDA") were perceived no differently in terms of whether the label claim was required by government or voluntarily added by a company. However, these two comparable claims were written by Fleminger, Inc. and describe the evidence both favorably and inaccurately (Fleminger, 2012). Therefore we cannot say with confidence that the inclusion of "FDA" led this sample to believe the government required the QHC on the

product or that the exclusion of "FDA" led to the perception that the QHC is voluntarily added by companies.

There are other differences between QHC groups that may affect beliefs. One Fleminger, Inc. QHC is non-specific and indicates the bioactive compound "epigallocatechin gallate" in green tea (2004) while the other two characterize the evidence as "credible but…limited". Two FDA QHCs quantify and characterize the evidence (2005p, 2005b) and mention one or two diseases (2005p, 2005b), while the 2011 FDA QHC includes the phrase, "FDA does not agree…" which may have affected participant perceptions of the reason why a QHC would be included on a product label.

Does the claim negate the diet-disease relationship?

While the court ruled that the disclaimer phrase, "FDA does not agree…" (2011) negated the green tea-cancer relationship, participants in the current study understood the QHC differently. Rather, participants thought the QHC suggested that green tea/yukichi fruit juice was *effective* at reducing the risk of cancer/gastrocoridalis. This finding indicates that the disclaimer, including the phrase "FDA does not agree…" does not negate the claimed relationship or render it ineffective. Moreover, compared to the 2005 and 2012 FDA QHCs, the 2011 claim demonstrated the greatest proportion of participants who thought it suggested that green tea/yukichi fruit juice was *effective* at reducing the cancer/gastrocoridalis risk. Once again however, there are other aspects to each QHC that make it difficult to pinpoint the language that produces any response.

Strengths and Limitations

Few studies have examined how consumers interpret the strength and consistency of the scientific evidence in qualified health claims (International Food Information

Council, 2013). A major strength of this study is that it tests claims that were petitioned, previously enforced by FDA, or illegally used by the green tea manufacturer, comparing each of these in a single experimental design. Another strength was that this was a text-only study, so participants focused on the claims versus other physical product attributes such as the aesthetics of packaging or other label information, which introduces further potential biases.

One potential limitation is that the study did not include a control group of participants who did not view any claim. However, while this was considered, a control group was not included because the main focus of the study was to evaluate the differences among the various QHCs and to test the assertions made about those claims by the FDA, Fleminger Inc., and the courts. Testing the differences between no green tea QHC and the currently enforced green tea QHC is a subject for further investigation.

Conclusions

This is the first study to empirically investigate a series of contested qualified health claims, both inside and outside the federal courts, by examining the assertions made by the food and dietary supplement industry and the FDA through a social science approach. The history of the evolution of QHCs related to the relationship between consumption of green tea and reductions in breast and prostate cancers has been contentious. Much of the disagreement has focused on how to best provide a clear and accurate description of the level of scientific evidence that neither overstates the level of certainty that a relationship between drinking green tea and cancer reduction exists, nor denies that one exists.

The Fleminger, Inc. court case echoes the challenges surrounding the QHC system as a whole. To satisfy stakeholders, an ideal QHC would inform decision-making about the added health value of a product (Lahteenmaki, 2012) by accurately describing the evidence to produce "a significant linear effect of disclaimer level on consumer perceptions of scientific certainty"(Food and Drug Administration, 2009) that would not undermine the claim of a diet-disease relationship (Alliance for Natural Health U.S., 2011).

The results from the current study suggest that the 2012 FDA QHC may appropriately fulfill the goals of both the government and the food and dietary supplement industry. It appears to accurately communicate to consumers the level of scientific evidence for the green tea-cancer relationship.

Finally, the disagreements over green tea QHCs have been marked by a number of untested assertions made by the FDA, the industry, and the courts. This study shows that given appropriate resources, it is possible to examine these assumptions and to evaluate QHCs in terms of multiple measures of consumer understanding. Using these measures to evaluate other QHCs, and in the development of new QHCs is called for.

Future Research

Our study provides more evidence that words hold different meanings for different people (Michie & Lester, 2005; Reinhardt-Kapsak et al., 2008). In addition, familiarity with a diet-disease relationship impacts perceptions of evidence from the QHC. Since consumers' *product* perceptions are loosely based on claims, relating more to prior beliefs (Nocella & Kennedy, 2012), future research may explore health benefit

perceptions and purchase intentions in response to the green tea QHCs and familiarity with the diet-disease relationship.

Table 1. Examples of a B, C, and D-level qualified health claims

Evidence Grade	Qualified health claim
B	Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]
C	FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.
D	Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension.

Table 2. Qualified health claims that were petitioned, illegally used by Fleminger, Inc., or prescribed by the US Food and Drug Administration from 2004 to 2012.

Author	Status	Year	Qualified Health Claim	Specifies "FDA"	Quantifies Evidence	Negates Claim
Fleminger	Petitioned	2004	Daily consumption of 40 ounces of typical green tea containing 170μg/ml of natural (-) epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive.	No	No	No
Fleminger	Illegal	2008	Green tea may reduce the risk of cancer of the breast and the prostate. There is credible evidence supporting this claim although the evidence is limited.	No	No	No
Fleminger	Illegal	2010	Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited.	Yes	No	No
FDA	Restrictive	2005p	One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.	Yes	Yes	No
FDA	Restrictive	2005b	Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.	Yes	Yes	No
FDA	Restrictive	2011	Drinking green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce that risk because there is very little scientific evidence for the claim.	Yes	No	Yes
FDA	Appropriate	2012	Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.	Yes	No	No

Table 3. Semantic differential scale of evidence separated by grades of evidence for health claims and qualified health claims defined in the 2003 FDA Draft Guidance for Qualified Health Claims.

Semantic differential scale of evidence	**Evidence**												
	None	Minimal			Some						Complete		
	0	1	2	3	4	5	6	7	8	9	10	11	12

Type of Health Claim	N/A	QUALIFIED HEALTH CLAIMS	HEALTH CLAIMS
Grade of evidence	N/A	D C B	A
Language and description of evidence requirements	N/A	Requires qualifying statement about degree of evidence for the claimed diet-disease relationship.	Requires NO qualifier because the evidence meets *SSA standards.*
Requirements for use by manufacturers and suppliers of eligible products	N/A	FDA prescribes exact language for the claim.	Allows manufacturers to write a health claim so long as it is truthful and not misleading.

**A footnote in the 2009 Final Guidance indicated the health claim grading system was no longer in effect* (Food and Drug Administration, 2003b; Food and Drug Administration, 2011c). *However, an implicit scale of evidence remains, as it is the fundamental difference between health claims and qualified health claims. For this reason, the 2003 scale of evidence was used for the purpose of exploring consumer perceptions of evidence.*

Table 4. Sociodemographic characteristics of study participants by condition

Characteristics	**Green Tea** (n=666)	**Yukichi Fruit Juice** (n=669)	**All Participants** (n=1,335)
Sex*			
Female	323 (46.9)	365 (53.0)	688 (51.5)
Male	343 (53.0)	304 (46.9)	647 (48.5)
Race/Ethnicity			
White	532 (39.9)	528 (39.6)	1,060 (79.4)
Black	65 (4.9)	49 (3.7)	114 (8.5)
Hispanic	39 (3.0)	39 (3.0)	77 (6.0)
Other	20 (1.5)	15 (1.1)	35 (2.6)
2 or more races	26 (1.9)	23 (1.7)	49 (3.7)
Age			
55 to 64 years old	330 (24.7)	328 (24.6)	658 (49.3)
65 to 74 years old	229 (17.2)	236 (17.7)	465 (34.8)
75 or older	107 (8.0)	105 (7.9)	212 (15.9)
Education			
Less than high school	52 (7.8)	50 (7.5)	102 (7.6)
High school	244 (36.6)	209 (31.2)	453 (33.9)
Some college	195 (29.3)	197 (29.4)	392 (29.4)
Bachelor's degree or higher	175 (26.3)	213 (31.8)	388 (29.1)
Employment			
Working	246 (18.4)	231 (17.3)	477 (35.7)
Not Working	109 (8.1)	93 (6.9)	202 (15.1)
Retired	327 (24.5)	329 (24.6)	656 (49.1)
Household Income			
$0 - $49,999	283 (21.2)	309 (23.1)	592 (44.3)
$50,000 - $99,999	229 (17.2)	207 (15.5)	436 (32.7)
$100,000 - $149,999	98 (7.3)	107 (8.0)	205 (15.4)
$150,000 and above	52 (3.9)	50 (3.7)	102 (7.6)
Home Ownership			
Yes	565 (84.8)	567 (84.8)	1,132 (84.8)
No	101 (15.2)	102 (15.2)	203 (15.2)
Health Status			
Cancer (general)	104 (7.8)	99 (7.4)	203 (15.2)
Breast cancer	19 (1.4)	28 (2.1)	47 (3.5)
Prostate cancer	25 (1.9)	20 (1.5)	45 (3.4)
Gastrocoridalis	7 (0.5)	8 (0.6)	15 (1.1)

***** $p < 0.05$

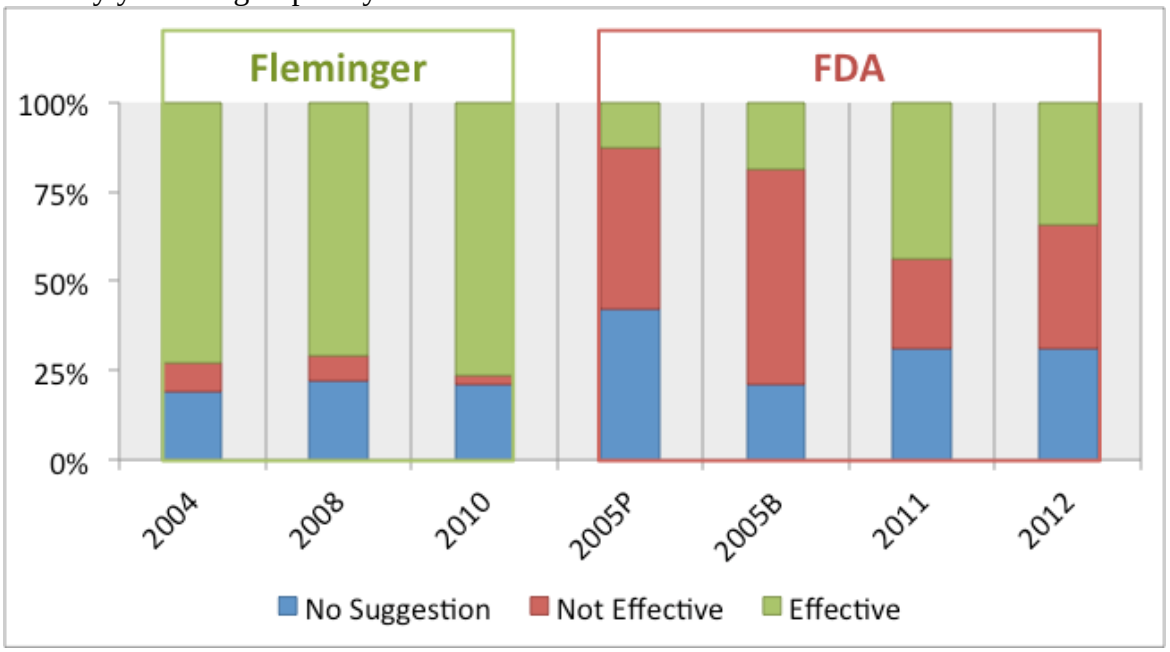
Table 5. Sociodemographic characteristics of study participants by QHC groups

	Fleminger, Inc.			US Food and Drug Administration			
	2004 (n=185)	**2008** (n=176)	**2010** (n=185)	**2005p** (n=211)	**2005b** (n=179)	**2011** (n=206)	**2012** (n=193)
Characteristics							
Sex							
Female	84 (45.4)	88 (50.0)	93 (50.3)	94 (44.5)	86 (48.0)	93 (45.1)	92 (47.7)
Male	101 (54.6)	88 (50.0)	92 (49.7)	117 (55.5)	93 (52.0)	113 (54.9)	101 (52.3)
Race/Ethnicity							
White	149 (80.5)	140 (79.5)	146 (78.9)	165 (78.2)	140 (78.2)	165 (80.1)	155 (80.3)
Black	11 (5.9)	18 (10.2)	14 (7.6)	19 (9.0)	13 (7.3)	20 (9.7)	19 (9.8)
Hispanic	4 (2.2)	2 (1.1)	5 (2.7)	6 (2.8)	4 (2.2)	8 (3.9)	6 (3.1)
Other	13 (7.0)	8 (4.5)	13 (7.0)	15 (7.1)	15 (8.4)	8 (3.9)	5 (2.6)
2 + races, non-Hispanic	8 (4.3)	8 (4.5)	7 (3.8)	6 (2.8)	7 (3.9)	5 (2.4)	8 (4.1)
Age							
55 to 64 years old	92 (49.7)	92 (52.3)	88 (47.6)	99 (46.9)	93 (52.0)	109 (52.9)	85 (44.0)
65 to 74 years old	63 (34.1)	46 (26.1)	65 (35.1)	85 (40.3)	61 (34.1)	68 (33.0)	77 (39.9)
75 or older	30 (16.2)	38 (21.6)	32 (17.3)	27 (12.8)	25 (14.0)	29 (14.1)	31 (16.1)
Education							
Less than high school	11 (5.9)	15 (8.5)	15 (8.1)	15 (7.1)	10 (5.6)	18 (8.7)	18 (9.3)
High school	58 (31.4)	62 (35.2)	65 (35.1)	71 (33.6)	72 (40.2)	62 (30.1)	63 (32.6)
Some college	54 (29.2)	51 (29.0)	56 (30.3)	62 (29.4)	49 (27.4)	59 (32.5)	61 (31.6)
Bachelor's degree +	62 (33.5)	48 (27.3)	49 (26.5)	63 (29.9)	48 (26.8)	67 (26.4)	51 (26.4)
Employment							
Working	68 (36.8)	56 (31.8)	78 (42.2)	69 (32.7)	61 (34.1)	80 (38.8)	65 (33.7)

Not Working	27 (14.6)	28 (15.9)	23 (12.4)	29 (13.7)	39 (21.8)	29 (14.1)	27 (29.2)
Retired	90 (48.6)	92 (52.3)	84 (45.4)	113 (53.6)	79 (44.1)	97 (47.1)	101 (52.3)
Household Income							
$0 - $49,999	78 (42.2)	94 (53.4)	84 (45.4)	83 (39.3)	75 (41.9)	91 (44.2)	87 (45.1)
$50,000 - $99,999	66 (35.7)	46 (26.1)	50 (27.0)	78 (37.0)	62 (34.6)	63 (30.6)	71 (36.8)
$100,000 - $149,999	30 (16.2)	22 (12.5)	28 (15.1)	34 (16.1)	34 (19.0)	32 (15.5)	25 (13.0)
$150,000 and above	11 (5.9)	14 (8.0)	23 (12.4)	16 (7.6)	8 (4.5)	20 (9.7)	10 (5.2)
Home Ownership*							
Yes	162 (87.6)	148 (84.1)	156 (84.3)	177 (83.9)	158 (88.3)	159 (77.2)	172 (89.1)
No	23 (12.4)	28 (15.9)	29 (15.7)	34 (32.1)	21 (27.2)	47 (22.8)	21 (29.3)
Health Status							
Cancer (general)	22 (12.0)	32 (18.3)	29 (15.8)	33 (15.6)	22 (12.4)	33 (16.2)	32 (16.6)
Breast cancer	3 (1.6)	7 (4.0)	6 (3.2)	8 (3.8)	6 (3.4)	12 (5.8)	5 (2.6)
Prostate cancer	9 (4.9)	8 (4.6)	6 (3.2)	6 (2.8)	5 (2.8)	6 (2.9)	5 (2.6)
Gastrocoridalis	2 (1.1)	2 (1.1)	3 (1.6)	4 (1.9)	2 (1.1)	1 (0.5)	1 (0.5)

***** $p < 0.05$

Figure 1. Consumer perceptions of the meta-message for the seven qualified health claims, listed by year and grouped by author.



See Table 2 for the qualified health claim language.

Figure 2. Average estimate of the total number of studies evaluated by the FDA for the relationship between green tea-cancer [yukichi fruit juice-gastrocoridalis] relationships. Bars represent responses by condition; years indicate the claim.

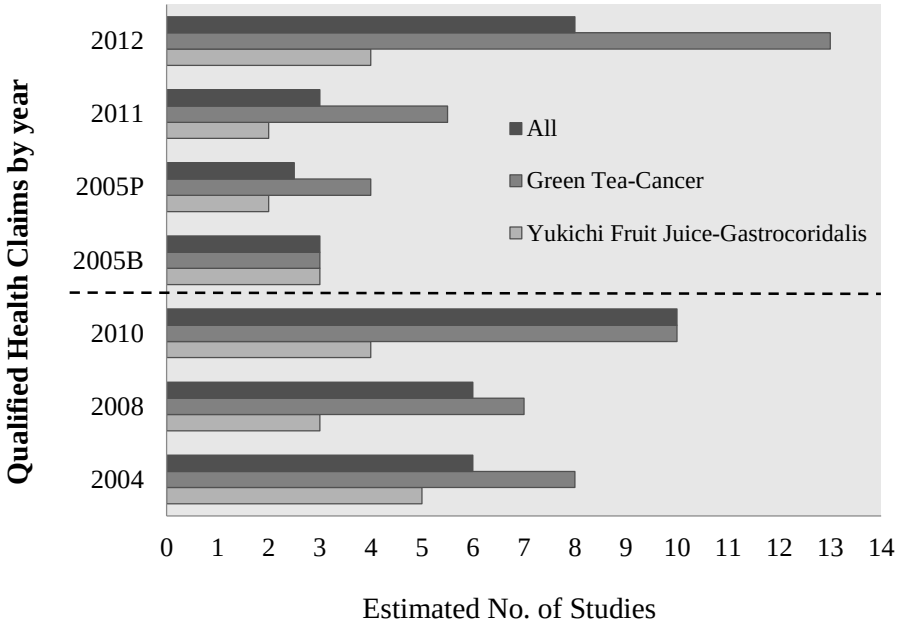


Table 6. Measures of Evidence Perceptions by QHC groups – FDA or Fleminger, Inc., and Year.

	Evidence					No. Studies*				
	n	Min	Max	M	SD	n	Min	Max	Mdn	IQR
Fleminger, Inc.	540	0	12	3.95	2.73	530	0	100,000	6	62 (64-2)
2004	183	0	12	4.15	2.80	182	0	100,000	6	86.75 (88.75-2)
2008	174	0	12	3.62	2.55	173	0	6,000	6	35.5 (37.5-2)
2010	183	0	12	4.06	2.81	175	0	29,000	10	58 (60-2)
FDA	778	0	11	2.38	1.94	773	0	15,000	3	15 (17-2)
2005p	208	0	10	2.22	1.77	204	0	2,000	2.5	13 (15-2)
2005b	173	0	11	2.53	2.08	175	0	11,000	3	2 (5-3)
2011	205	0	9	2.27	1.74	205	0	15,000	3	19.5 (20-0.5)
2012	192	0	11	2.51	2.19	189	0	2,000	8	36 (38-2)

**Median (Mdn) and interquartile range (IQR) reported to account for wide range of estimates for total number of studies completed for the diet-disease relationship.*
Response scales: Evidence 0 = no evidence to 12 = complete evidence; No. of studies FDA evaluated for diet-disease relationship = open response

Figure 3. Evidence ratings compared by green tea or yukichi fruit juice condition and QHC groups – year.

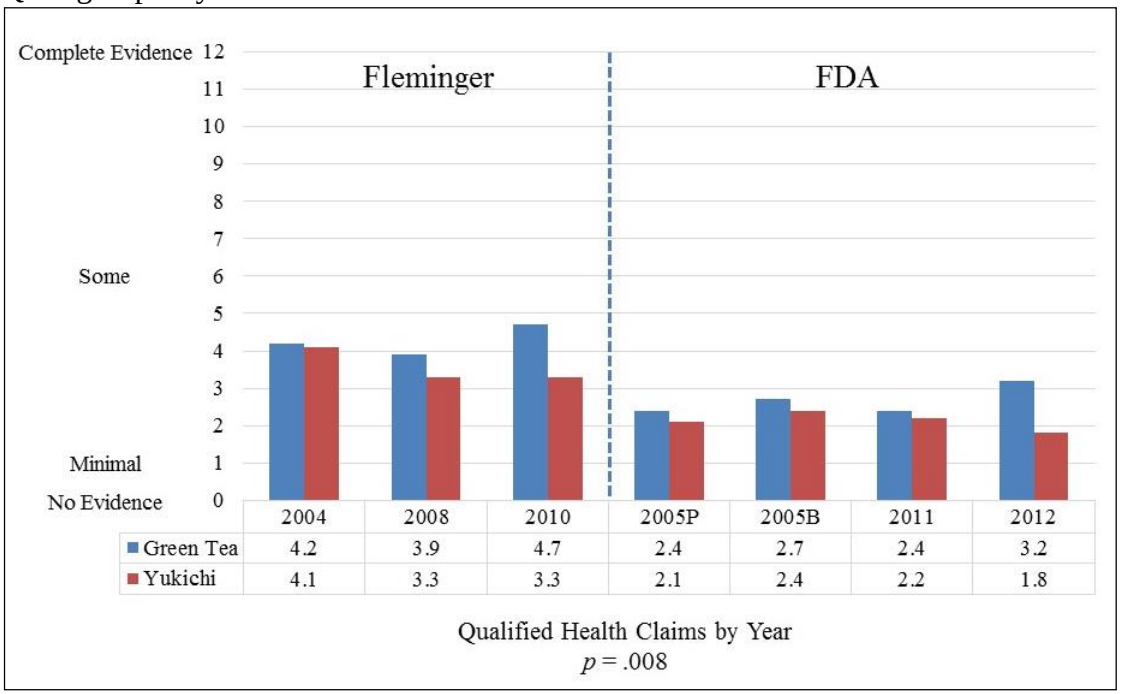


Table 7. Frequencies and percentages of the perceived reason for the qualified health claim on a product label by condition and group.

QHC Group	Condition	Reason for QHC	Freq	%
2004	Yukichi Fruit	Voluntarily Added	47	52.8%
		Required by Gov't	27	30.3%
		Some other reason	15	16.9%
	Green Tea	Voluntarily Added	55	57.9%
		Required by Gov't	16	16.8%
		Some other reason	24	25.3%
2008	Yukichi Fruit	Voluntarily Added	42	51.9%
		Required by Gov't	21	25.9%
		Some other reason	18	22.2%
	Green Tea	Voluntarily Added	68	73.9%
		Required by Gov't	6	6.5%
		Some other reason	18	19.6%
2010	Yukichi Fruit	Voluntarily Added	48	59.3%
		Required by Gov't	16	19.8%
		Some other reason	17	21.0%
	Green Tea	Voluntarily Added	69	67.6%
		Required by Gov't	16	15.7%
		Some other reason	17	16.7%
2005P	Yukichi Fruit	Voluntarily Added	20	17.1%
		Required by Gov't	70	59.8%
		Some other reason	27	23.1%
	Green Tea	Voluntarily Added	22	23.7%
		Required by Gov't	56	60.2%
		Some other reason	15	16.1%
2005B	Yukichi Fruit	Voluntarily Added	21	24.4%
		Required by Gov't	48	55.8%
		Some other reason	17	19.8%
	Green Tea	Voluntarily Added	25	28.1%
		Required by Gov't	51	57.3%
		Some other reason	13	14.6%
2011	Yukichi Fruit	Voluntarily Added	26	23.9%
		Required by Gov't	71	65.1%
		Some other reason	12	11.0%
	Green Tea	Voluntarily Added	28	29.2%

		Required by Gov't	52	54.2%
		Some other reason	16	16.7%
2012	Yukichi Fruit	Voluntarily Added	14	14.3%
		Required by Gov't	74	75.5%
		Some other reason	10	10.2%
	Green Tea	Voluntarily Added	19	20.2%
		Required by Gov't	68	72.3%
		Some other reason	7	7.4%

Table 8. Frequencies and percentages of meta-message of the QHC between groups and conditions.

QHC Group	Condition	Meta-message of QHC	Freq	%
2004	Yukichi Fruit	Suggests NOT effective	8	9.0%
		No suggestion	22	24.7%
		Suggests effective	59	66.3%
	Green Tea	Suggests NOT effective	7	7.4%
		No suggestion	13	13.8%
		Suggests effective	74	78.7%
2008	Yukichi Fruit	Suggests NOT effective	6	7.5%
		No suggestion	21	26.3%
		Suggests effective	53	66.3%
	Green Tea	Suggests NOT effective	6	6.5%
		No suggestion	17	18.5%
		Suggests effective	69	75.0%
2010	Yukichi Fruit	Suggests NOT effective	2	2.5%
		No suggestion	23	28.7%
		Suggests effective	55	68.8%
	Green Tea	Suggests NOT effective	3	2.9%
		No suggestion	15	14.7%
		Suggests effective	84	82.4%
2005P	Yukichi Fruit	Suggests NOT effective	50	42.7%
		No suggestion	55	47.0%
		Suggests effective	12	10.3%
	Green Tea	Suggests NOT effective	44	47.3%
		No suggestion	34	36.6%
		Suggests effective	15	16.1%
2005B	Yukichi Fruit	Suggests NOT effective	43	51.2%
		No suggestion	26	31.0%
		Suggests effective	15	17.9%
	Green Tea	Suggests NOT effective	61	69.3%
		No suggestion	10	11.4%
		Suggests effective	17	19.3%
2011	Yukichi Fruit	Suggests NOT effective	25	23.4%
		No suggestion	35	32.7%
		Suggests effective	47	43.9%
	Green Tea	Suggests NOT effective	26	27.1%
		No suggestion	28	29.2%

		Suggests effective	42	43.8%
2012	Yukichi Fruit	Suggests NOT effective	35	36.5%
		No suggestion	34	35.4%
		Suggests effective	27	28.1%
	Green Tea	Suggests NOT effective	31	33.0%
		No suggestion	25	26.6%
		Suggests effective	38	40.4%

CHAPTER SIX
Does the Language Matter in Qualified Health Claims? A Case Study of Purchase Intentions for Green Tea.

Introduction

The food and dietary supplement industry is interested in qualified health claims (QHC) because of their potential to increase the sales of their products (Emord & Schwitters, 2012; Grocery Manufacturers Association, 2003; Pearson, Shaw, American Preventive Medical Association, & Citizens for Health, 1999). Qualified health claims offer a way to communicate about a relationship between the consumption of a dietary substance and the reduced risk for a disease or health condition, while characterizing the level of scientific support for that claimed relationship (Food and Drug Administration, 2003a).

Fundamentally, the value of a qualified health claim for the food and dietary supplement industry is the degree to which it persuades consumers to purchase their products. The description of evidence of the link between the dietary component and the health benefit, known as the disclaimer, is perhaps the crucial component of a QHC in determining product appeal to consumers. That manufacturers and marketers believe this to be true is richly illustrated by the lawsuits filed against the US Food and Drug Administration (FDA) by these industries, which have sought to significantly alter the wording of these disclaimers in QHCs (Berhaupt-Glickstein, Nucci, Hooker, & Hallman, 2014).

There has been continuous disagreement between the industry and the FDA about how to fairly and accurately characterize the level of evidence for diet-disease relationships (Berhaupt-Glickstein et al., 2014). This has led to several iterations of

claims for the *same* relationship. For example, there have been seven qualified health claims about the link between consumption of green tea and the reduced risk of cancer (Table 1). Six of the seven claims are no longer in use, mainly because the federal court determined that they mischaracterized the evidence (Alliance for Natural Health U.S., 2010; Fleminger, 2012).

However, despite the fact that the industry has spent substantial amounts of time and money to file lawsuits against the FDA to change the disclaimer language in green tea QHCs, it is unclear whether their efforts have resulted in claims that are more likely to generate greater sales. Anecdotally, companies find qualified health claims to be valuable means to increase product sales (Emord & Schwitters, 2012; Grocery Manufacturers Association, 2003). Yet, there is no published data that indicates the extent to which any of the seven green tea QHCs are likely to affect consumers' intentions to purchase green tea products.

To explore the practical use of qualified health claims, we use green tea as a case study and examine the progressive iterations of claims to understand their potential to influence consumer purchase of green tea products. We aim to understand whether exposure to the current qualified health claim (QHC) suggested by the court and enforced by the FDA increases the purchase intentions for green tea products in comparison with earlier QHCs that have been rejected, and are no longer in use.

Qualified Health Claims

Qualified Health Claims exist as a way to permit the marketing of products with potential health benefits where the scientific evidence of those benefits is emerging or uncertain. To prevent consumer confusion about the level of scientific support for a

claimed diet-disease relationship, the FDA prescribes the language in QHCs that companies may then use on food and dietary supplement products. However, the QHCs do not explicitly state a level of evidence in a claim. Instead, the disclaimer describes the scientific support that will theoretically allow consumers to make an informed purchase decision.

The continuum of evidence for diet-disease relationships was originally organized by a letter grade system. At the top, are "A" grade relationships that are supported by strong scientific evidence from well-designed studies. These are known as health claims and because of the high degree of scientific certainty behind the diet-disease relationship, they do not include a disclaimer.

In this system, there were three other grades, "B", "C", and "D" that respectively meant there was "promising", "low", or "very low" consistency of evidence for a claimed relationship (Food and Drug Administration, 2003a). The last three levels signify QHCs. That is, the level of evidence behind the diet-disease relationships are not certain enough to permit a straightforward health claim, but instead need to be "qualified" by a disclaimer characterizing the scientific evidence that exists for the claim.

The letter grades were never included in claims because research that tested their inclusion indicated that they confused consumers (Food and Drug Administration, 2009a; Food and Drug Administration, 2009b; Hooker & Teratanavat, 2008; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008). While this evidence grade system is no longer used by FDA, we use it as a reference point to discuss the QHCs for the green tea-cancer relationship which is supported by a "D" grade of evidence (Berhaupt-Glickstein & Hallman, 2015).

Green Tea QHCs as a Reflection of Competing Stakeholder Interests

The FDA has maintained since 2004 that the scientific support for the green tea-cancer relationship represents the lowest level of evidence (Food and Drug Administration, 2012). Therefore, each of the seven green tea QHCs intends to communicate the same scientific evidence in a unique way that reflects the authors.

Of the seven claims, three were written by a green tea manufacturer, Fleminger, Inc. (Table 1, 2004; 2008; 2010) and highlight the health value of their products (Emord & Schwitters, 2012; Pearson et al., 1999). The FDA found that these claims described the evidence inaccurately for the green tea-cancer relationship and because of this, they are not permitted to be used. The FDA wrote three additional claims (Table 1, 2005p; 2005b; 2011) and while they are scientifically accurate (Food and Drug Administration, 2013), the federal courts found them to be overly technical and are also not in use (Table 1, 2005p; 2005b; 2011). The seventh claim was written by the federal court (Table 1, 2012) (Fleminger, 2012) and the FDA currently allows companies to use it on their product labels. In writing this claim, the court aimed to balance stakeholder interests by protecting the ability of companies to communicate a health benefit of their products, while also supporting the federal government's role in protecting the public's health by ensuring that consumers are not misled by the description of evidence (Pearson et al., 1999). The seven claims are presented in Table 1 and identify the language contested by stakeholders. Claims are referenced by the year in which they appeared (e.g. 2004, 2008, etc.). For a detailed history of the seven green tea QHCs, see (Berhaupt-Glickstein & Hallman, In preparationa).

There has been limited testing with consumers about QHCs, and in particular, very little testing of the green tea QHCs. When two green tea QHCs (Table 1, 2005p; 2005b) were tested with consumers, they correctly rated the level of evidence (Food and Drug Administration, 2009a). However, the FDA no longer enforces these two claims since a federal court indicated that their disclaimers were too technical (Alliance for Natural Health U.S., 2010).

Other consumer research demonstrates that shoppers do not perceive QHCs as indicators of scientific support for diet-disease relationships (Government Accountability Office, 2011). Consumers are unable to distinguish between different levels of evidence and therefore are not meeting the FDA's goal of accurate characterization of scientific support for a diet-disease relationship (Derby & Levy, 2005; Food and Drug Administration, 2009a; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008).

There are also potential unintended consequences associated with QHCs. Some studies have demonstrated they lead to lower perceived health benefits of a product (Food and Drug Administration, 2009a), reduced purchase intentions for products with QHCs that indicate lower levels of evidence (Government Accountability Office, 2011), as well as a perception of overall lower quality and/or safety of a product (Government Accountability Office, 2011).

While some companies have said they find QHCs useful to market their products (Emord & Schwitters, 2012; Grocery Manufacturers Association, 2003) and some of our research suggests there is a segment of consumers who respond positively to them, they are seldom used by marketers (Fitzgerald Bone & Russo France, 2009; Government Accountability Office, 2011; Hooker, 2007). Two studies examined QHC-eligible

products. A 2009 content analysis of 1,200 QHC-eligible products from retail stores in West Virginia revealed that fewer than 5% used a QHC on their labels (Fitzgerald Bone & Russo France, 2009); while an analysis of QHC-eligible green tea product labels revealed that none included a QHC (Hooker, 2007). Furthermore, a national survey of food product labels found that less than 1% of all products used a QHC (Government Accountability Office, 2011).

The reason for their limited use on products is the technical language prescribed by the FDA that must be used by companies if they wish to make a QHC for their product (Fitzgerald Bone & Russo France, 2009) and the resulting difficultly consumers have in understanding the claims (Food and Drug Administration, 2009a; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008).

The food and dietary supplement industry expect that QHCs will lead to increased purchases of food and dietary supplement products. Their potential to increase product sales is what drives companies to take legal action against the FDA about claim language and the description of evidence (Pearson et al., 1999).

However, the expectation that QHCs will increase product purchases is based on prior research concerning the impact of [unqualified] health claims, which do not include a disclaimer and do not describe the scientific evidence for a claimed relationship. Overall, this research demonstrates a financial advantage to using a health claim on food and dietary supplement products (Williams, 2005). A study of market share found that within six months of a health claim being introduced on a breakfast cereal, the share grew by 0.47 share points, a 47% increase from 0.99 to 1.46 (Freimuth, Hammond, & Stein, 1988; Levy & Stokes, 1987). However, this success cannot be solely attributed to the

health claim on the breakfast cereal box since it was also advertised on television. A separate mall-intercept study completed by the FDA found that when a product included a health claim on its label, shoppers reported greater purchase intentions than products without a health claim (Roe, Levy, & Derby, 1999). And consumers are willing to pay 50% to 200% more for products with health claims when compared to conventional counterparts (Nakaweesa Munene, 2006).

While the evidence is supportive of the financial benefit of using health claims on food and dietary supplement products, the evidence is less compelling, and more scant, for a financial advantage when QHCs are displayed on their labels. Only one study explored purchase intentions related to QHCs and in this case, researchers were testing a graphic representation of an evidence grade. Participants were shown a graphic scale showing the range of letter grades (A to D) representing the level of scientific evidence behind the diet-disease relationship, with an indication of what letter grade had been assigned to the QHC to which they were asked to respond. Participants who viewed a product label with a "C" or "D" QHC reported lower purchases than those who saw product labels with "A" or "B" claims (Reinhardt-Kapsak et al., 2008). However, this effect was only found when participants were shown the graphic. It was not found with text-only formats. This is significant because FDA currently enforces text-only QHCs and does not use the graphic that was tested.

The Current Study

Consumers may be motivated to drink green tea for its potential protective effects against cancer and companies may capitalize on this interest by marketing this health attribute to cue consumers to purchase their green tea products. However, theory

suggests that getting consumers to purchase green tea may not be as simple as providing external cues, such as a qualified health claim, to take advantage of personal motivations to reduce cancer risks (Lahteenmaki, 2012; Nocella & Kennedy, 2012; Pothoulaki & Chryssochoidis, 2009; Wills, Storcksdieck genannt Bonsmann, Kolka, & Grunert, 2012).

There are several consumer-specific and product-specific factors that may explain or mitigate consumer's perceptions and future behaviors regarding the consumption of green tea (Pothoulaki & Chryssochoidis, 2009; Wills et al., 2012). These include perceived benefits (Glanz, Rimer, & Viswanath, 2008) of green tea products (i.e. cancer risk reduction; taste and other hedonic qualities) that may affect perceptions about the relationship between green tea and the reduced risk of cancer and subsequently, purchase intentions.

Having past experience with green tea and/or knowledge of the association between the consumption of green tea and the reduced risk of cancer may motivate consumers to begin drinking green tea (Dobrenova & Terlutter, 2015; Lahteenmaki, 2012; Wills et al., 2012), and lead consumers who already drink green tea to have a greater perception of behavioral control over their risks of cancer (Contento, 2007).

Some consumers are more likely to read nutrition information on food and supplement labels than others, and these sociodemographic characteristics influence perceptions and future behavior as well. Research has identified consumer characteristics associated with accepting functional foods (Contini et al., 2015; Cox, Evans, & Lease, 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009; Reinhardt Kapsak, Rahavi, Childs, & White, 2011). These studies suggest that functional foods are most appealing and accepted by healthy (Cox et al., 2011; Reinhardt Kapsak et al., 2011), educated

(Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009) women (Contini et al., 2015; Pothoulaki & Chryssochoidis, 2009; Reinhardt Kapsak et al., 2011) with a high socioeconomic status (Pothoulaki & Chryssochoidis, 2009), who also take dietary supplements (Reinhardt Kapsak et al., 2011). Further, research from our group has identified race/ethnicity and familiarity as strong predictors of *existing* green tea consumers (Berhaupt-Glickstein & Hallman, In preparation-b). It is possible that some of these characteristics may also be predictors of purchase intentions for green tea among consumers who typically do not consume it. The current study explores some of these consumer and product-specific characteristics that contribute to behavioral intentions (European Food Information Council, 2015).

We aim to understand if and how exposure to green tea QHCs affects purchase intentions, while taking these potential consumer-specific and product-specific factors into consideration. We used two theoretical models to guide the development of the study. The first, The Health Belief Model (HBM), is a well-established theory, which posits that health behavior is the result of personal beliefs and perceptions about a disease (or health-condition) and the strategies needed to reduce the risk for that disease (Glanz et al., 2008). The second, is the Health Claims Framework or HCF, which is a newer "conceptual framework of how health claims affect consumers" (Wills et al., 2012). The HCF was based on a review of literature by researchers aiming to understand "how consumers interpret health information on food labels, and how this affects their purchasing and consumption behavior" (European Food Information Council, 2015). The strength of this model is its focus on health claims, albeit unqualified, and its incorporation of product and consumer-specific predictors of future purchase behavior.

Methods

Participants

The sample of English-speaking adults aged 55 years and older was recruited to participate in the study in January 2014. Participants in this age group were selected since most QHCs specify a disease or health-related condition that affects this population, including cancer, hypertension, diabetes, cardiovascular disease, and cognitive dementia. In fact, more than three-quarters of all cancer diagnoses are in older adults (American Cancer Society, 2015; King, Matheson, Chirina, Shankar, & Broman-Fulks, 2013). Older adults were also selected as participants because they are more health-oriented than younger adults (Nocella & Kennedy, 2012), and are more knowledgeable about diet and health, often adopting preventive behaviors (Nocella & Kennedy, 2012). Older adults are also more likely to use food labels (Academy of Nutrition and Dietetics, 2011; Govindasamy & Italia, 1999) and to take dietary supplements than younger adults (Balluz, Kieszak, Philen, & Mulinare, 2000; Gray, Hanlon, Fillenbaum, Wall, & Bales, 1996; Slesinski, Subar, & Kahle, 1995).

Study Design

This was a two (diet-disease relationship: green tea-cancer vs. yukichi fruit juice-gastrocoridalis) by seven (QHC: 2004, 2005p, 2005b, 2008, 2010, 2011, 2012) between-subjects study design. To determine the effects of the health claim language without the potential interaction of existing beliefs or behaviors associated with green tea and cancer, participants were randomized into one of two conditions: (1) green tea-breast/ prostate cancer, or (2) yukichi fruit juice-gastrocoridalis, a fictitious but comparable diet-disease

relationship. Yukichi fruit juice was described as a typical drink sold in stores and gastrocoridalis was introduced as a potentially painful and fatal disease.

Participants were then randomized into seven groups, each viewing one of the seven QHCs (Table 1). The difference between QHCs in the two conditions was that (a) yukichi fruit juice substituted for green tea, and (b) gastrocoridalis replaced breast and/or prostate cancer in the claims seen by the participants. To prevent priming effects, and to reduce participant burden, each participant viewed and answered questions related to a single QHC describing the green tea – cancer relationship.

Unfortunately, it was not possible to screen participants for their prior familiarity with the green tea – cancer relationship without also unintentionally priming them before assessing their responses to the green tea QHCs that were presented to them in the experimental design. Therefore, it was not possible to create a control group naïve to both the benefits of drinking green tea and to the potential. In place of prior screening and assignment of naïve participants to a control group, participants indicated the extent of their existing consumption of green tea, and their familiarity with the green tea-cancer relationship and with the specific QHC presented *after* seeing it.

This was a text-only study; label images were not included. Once the QHC stimuli were revealed, it remained on screen so participants could refer to it to respond to questions. The Institutional Review Board at Rutgers, The State University of New Jersey approved the study.

Measures

Purchase intention, which is of key interest to the food and dietary supplement industry, serves as the principle health behavior in this study (Glanz et al., 2008; Wills et

al., 2012). Participants answered the question, "If priced the same as other green teas without this statement, how likely is it that you would purchase a bottle of green tea with this statement?" A standard seven-point Likert scale provided participants with a range of possible responses (1-Not at all likely to 7-Absolutely certain). Price equivalency was included in the question since price is known to be a key predictor of purchase behavior (International Food Information Council, 2013; Wills et al., 2012).

Predictors of Purchase Intentions

The HCF construct, understanding of the claim (Wills et al., 2012) was applied in this study to mean consumer understanding of the level of scientific evidence. The disclaimer is the quintessential element of QHCs and this measure is the primary outcome of interest for the FDA. Since all seven green tea claims represent a D-grade QHC and are based on the same scientific evidence, they should elicit the same sense of evidence for the green tea-cancer relationship. To test whether the specific language in each of the seven versions of the QHC led to different perceptions of the level of scientific evidence behind the QHC, the participants were asked, "Based on this statement, how much evidence is there that drinking green tea [yukichi fruit juice] may reduce the risk of certain forms of cancer/breast and/or prostate cancer [gastrocoridalis]? The level of evidence was rated on a 13-point scale (i.e. 0-no evidence to 12-complete evidence) (Table 2). The 13-point scale was designed so that participants had a wide range of ordinal responses available to them, and so that the scale could be separated into the four evidence grades; 0=no evidence, 1-3=D-grade, 4-6=C-grade, 7-9=B-grade, 10-12=A-grade.

Existing behavior undoubtedly influences future purchase intentions for green tea, regardless of the presence of a QHC (Mazis & Raymond, 1997). To account for existing behavior, participants responded to the question, "Over the past 12 months, how often did you drink green tea [yukichi fruit juice]?" using a five-point scale (1-never to 5-at least once a week). This question was adapted from the National Health and Nutrition Examination Survey (Centers for Disease Control and Prevention, National Center for Health Statistics, 2004).

A critical construct in the HBM, we hypothesized that the more technical the QHC language as determined by the federal courts, the greater the barrier to understanding the benefits, resulting in lower perceived benefit(s) of the behavior (Glanz et al., 2008). Two questions were grouped to represent the perceived benefit(s) construct and participants responded on seven-point Likert scales. Participants responded to a question about confidence, "Based on this statement, how confident are you that drinking this green tea [yukichi fruit juice] will reduce the risk of certain forms of cancer/breast and/or prostate cancers [gastrocoridalis]?" (1-not at all confident to 7-absolutely confident). They were also asked about their perception of cancer risk reduction, "Based on this statement, how much can drinking green tea [yukichi fruit juice] (as part of a regular diet) reduce the risk of certain forms of cancer/breast and/or prostate cancers [gastrocoridalis]?" (1-not at all to 7-complete reduction). These perceived benefits may promote judgement of the value of a product (Lahteenmaki, 2012) through a "kind of nonconscious, cost-benefit analysis" that will determine the likelihood of future behavior (Glanz et al., 2008).

One requirement of health claims for consumers is that they understand the diet-disease relationship in the context of overall diet (Food and Drug Administration, 2009a). Simply stated, consumers need to understand how much of a product they would need to consume to realize the purported benefits. However, the 2004 QHC is the only claim of the seven that specifies the need to consume 40 ounces of green tea daily need to achieve the health benefit. Therefore, Dose was measured to understand if the claim language affected perceptions of how often one needed to drink green to reduce their risk of breast/prostate cancer. The response categories were 1-never to 5-at least once a week.

Predictors of purchase intentions of green tea were identified in the HBM and HCF. There are consumer-specific and product-specific perceptions/beliefs as well as modifying factors that may influence future behavior. The purpose of measuring these variables was to understand if and how they influence consumer perceptions of evidence for the green tea-cancer relationship, their confidence in the claimed relationship, their perceived risk reduction, and ultimately their purchase intentions.

Consumer-Specific Perceptions and Beliefs

Familiarity with a diet-disease relationship or a claim increases the acceptance of functional food supplement products with health claims (Dean et al., 2012; Hasler, 2008; Pothoulaki & Chryssochoidis, 2009; Reinhardt-Kapsak et al., 2008; Saldanha, 2006; Wills et al., 2012). Past research has shown that when health conscious people have existing beliefs or expectations about a functional food product, they will seek or interpret information to confirm what they already think (Walker Naylor, Droms, & Haws, 2009). In other words, when a diet-disease relationship is familiar to consumers, some may interpret the evidence description in a QHC to fit with their existing thoughts

and opinions. Therefore, "the content of a health message is irrelevant to their [consumers] recognition of the health benefit" (Lin, 2008) because of their "confirmatory bias" (Walker Naylor et al., 2009). To account for this phenomenon, panelists indicated if they had seen the claim before on either a food supplement label or in an advertisement (-1-no to +1-yes). They also responded to the question, "Whether you have seen this statement or not, how familiar are you with the idea that drinking green tea [yukichi fruit juice] can reduce the risk of certain forms of cancer/breast and/or prostate cancers [gastrocoridalis]?" using a five-point response scale (1-not at all familiar to 5-extremely familiar).

The HBM theorizes that the greater the perceived susceptibility or risk of a disease, the more likely a person will engage in behavior to reduce their risk (Glanz et al., 2008). There are four survey items that aim to measure this concept. Panelists reported their general health (1-poor to 5-excellent), which is associated with the use of claims (Barreiro-Hurle, Gracia, & de-Magistris, 2010) and functional foods (International Food Information Council, 2011). Worry has also been identified as a potential predictor of health-related behaviors (Ferrer, Bergman, & Klein, 2013; Nocella & Kennedy, 2012; Wang et al., 2009). Therefore, participants were asked, "How often have you worried about your overall health in the past year?" and "How worried are you about becoming ill with cancer?" Their responses were recorded on a five point scale (1-not at all to 5-extremely). Participants also indicated whether their concerns prompted them to take action. They were asked, "How much has worrying about your health led you to change the way you ate in the past year?" (1-not at all to 5-all the time).

The HCF incorporates a closely related concept, personal relevance, which also increases the acceptability of products that bear health claims (Dean et al., 2012; Lahteenmaki, 2012). If someone is personally affected by a health condition or fears an illness, than she will be motivated to accept a product with a health claim (Pothoulaki & Chryssochoidis, 2009). To capture this concept, participants were asked if a doctor had previously told them they had cancer, including breast or prostate cancer (0-no to 1-yes).

The HCF also specifies nutrition knowledge as a predictor of acceptance of functional foods and purchase intentions (Wills et al., 2012). We measured perceived nutrition knowledge since health claims are more acceptable to those who perceive they are more knowledgeable about nutrition (Baglione, Tucci, & Stanton, 2012). Participants were asked, "How well informed are you about diet and health?" (1-not at all informed to 5-extremely informed).

Product Perceptions and Beliefs

There are also product-specific perceptions and beliefs that can contribute to a person's perceptions and future behavior (Dean et al., 2012; Wills et al., 2012). In particular, taste is an essential measure because it often supersedes perceived healthfulness when selecting foods (International Food Information Council, 2015; Nielsen & National Marketing Institute, 2014; Wills et al., 2012). Even the most consumer-friendly QHC might not influence a person's intentions if the food product is believed to taste unpleasant. Further, the healthfulness of a product suggests to some that the associated hedonic qualities suffer as a result (Lahteenmaki, 2012). To account for taste, participants who drank green tea in the past year were asked, "Why do you drink green tea [yukichi fruit juice]?" This was a multiple response question in which

participants could endorse: taste, risk reduction of certain forms of cancer/breast and/or prostate cancers, for another specific health reason, or for other reasons.

Modifying Factors

Finally, several known modifying factors from the Health Belief Model were measured that are unrelated to green tea or cancer, although may mitigate purchase intentions for green tea [yukichi fruit juice]. Past research has identified these factors to influence perceptions and indirectly influence health-related behaviors including, age, sex, race/ethnicity, education, employment, and income (Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Glanz et al., 2008; Pothoulaki & Chryssochoidis, 2009; Reinhardt-Kapsak et al., 2008). There are also other measures associated with purchase intentions of functional food products with health claims such as: dietary supplement use, and the importance placed on health claims (Wills et al., 2012).

Statistical analyses

Descriptive statistics characterized the study sample. Chi-square tests for association and Spearman Rank correlation tests identified relationships between variables. The Health Claims Framework suggests predictors of purchase intentions. Since the description of evidence in QHCs is contested between stakeholders, the measures considered to influence purchase intentions were: perceived evidence, risk reduction, and confidence in the claimed relationship. A multivariate analysis of variance test measured interactions between these dependent variables in the green tea/yukichi fruit juice conditions and QHC groups, followed by univariate tests. Independent t-tests and Chi-square tests examined group and condition differences in terms of: health status, worry about health, worry about cancer, worry that led to dietary change, dietary

supplement use, importance of health statements on food and dietary supplement package labels, previous diagnosis of cancer, and sociodemographics.

Next, hierarchical multiple linear regression was used to determine the predictive value of measures on purchase intentions for green tea in the presence of a QHC. Using the HCF and HBM as a guide, measures were grouped and entered into the regression model. The analysis focused on the green tea condition since the yukichi fruit juice-gastrocoridalis condition was fictitious. Respondents in the green tea condition reported their enjoyment (or not) of the taste of green tea, whether they drank green tea in the past year, and their familiarity with the green tea-cancer relationship and with the actual claim statement. One-way analysis of variance (ANOVA) compared responses between QHC groups. The *Welch's F*-test results are reported when the assumption of homogeneity of variances is violated. For non-normal distributions, the potential bias was corrected with the resampling method of bootstraps. Non-significant variables were withheld from entry into the regression model analysis to create a parsimonious predictive model for purchase intentions for green tea (Field, 2013) and significant predictors were added as blocks.

The HCF and HBM guided the addition of specific variables to the hierarchical model in discrete steps. At step one were the sociodemographic, consumer-specific, and perceived susceptibility measures, step two was existing green tea consumption, step three was familiarity with the green tea-cancer relationship, and step four were the QHCs which were entered as a block of dummy-coded variables. This was done to understand how the claim statements may contribute to purchase intentions for green tea. A second regression model was created to isolate the effects of the dependent measures (confidence, risk reduction, evidence perceptions, purchase intentions) from the QHCs

and included steps one through three with the removal of the dummy-coded QHCs. Adjusted R^2 is reported to account for the number of predictor variables and change in R^2 is reported to indicate the contribution of each variable to the predictive model. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using the Statistical Package for Social Sciences, version 22 (SPSS Inc., Chicago, IL, USA).

Results

Sample

GfK administered the online survey to 1,335 older adult consumers who either viewed a QHC about green tea and cancer (n=669) or the yukichi fruit juice and gastrocoridalis relationship (n=666). Most participants were between the ages of 55 and 74 years old (n=1,123, 89.1%), White (n=1,060, 79.4%), with a high school degree or more (n=1,233, 92.4%), and a household income under $100,000 (n=1,028, 77.0%), There were no differences between conditions or across groups (i.e. QHC) by race and ethnicity, age, education, employment, household income or incidence of breast or prostate cancer (Table 3).

Overall, the participants reported that they were in good health (n=1,010, 76%) and most had never had cancer (n=1,132, 84.8%). The participants reported that they worried “a little” or “somewhat” about their health overall (n=929, 69.9%) but were less worried about specifically becoming sick with cancer (“somewhat” n=441, 39.2%; “not at all” n=296, 26.3%). However, more than three-quarters reported that they had made a dietary change in the past year (n=1,022, 76.8%) due to a health-related concern. While half of our sample reported that they had consumed green tea in the 12 months prior to the survey (n=691, 51.8%), most reported that they did so because they enjoy the taste of

green tea (n=215, 62.5%) and not to reduce their risk of cancer (n=32, 9.3%). The participants felt that they were well informed about diet and health (perceived nutrition knowledge) (n=1,298, 97.2%). Participants also consider health statements to be important on food (n=1,168, 88.0%) and dietary supplement product labels (n=926, 91.5%) and were strongly correlated, $r(1,007)$, $p < .01$ (Table 9). No differences were found between groups or conditions with respect to general health, self-reported nutrition knowledge, green tea consumption during the previous 12 months, worry about cancer, or health-related dietary changes.

Half of the sample [green tea only] was familiar with the green tea-cancer relationship (n=343, 51.9%) but the majority also reported that they had not seen the claim on a label (n=480, 73.5%) or in an advertisement (n=453, 70.9%).

Participants used a 13-point scale to rate the level of scientific evidence for the claimed relationship based on the QHC they viewed. When the scale was collapsed to represent the four grades of evidence, where zero meant "No evidence," 1-3 represented a D-grade, 4-6 equaled a C-grade, 7-9, a B-grade, and 10-12 an A-grade (see Table 2), the average rating was a "2", or a D-grade, which is consistent with the level of evidence concluded by the FDA (Berhaupt-Glickstein & Hallman, 2015; Food and Drug Administration, 2009a).

Most participants were not at all confident in the ability of green tea/yukichi fruit juice to reduce the risk of cancer/gastrocoridalis (n=709, 53.5%) ($M = 1.83$, $SD = 1.10$). However, when asked how much green tea/yukichi fruit juice could reduce the risk for cancer/gastrocoridalis, 57% (n=757) thought there would be at a least a slight risk reduction ($M = 1.98$, $SD = 1.10$). And most thought they would need to drink green

tea/yukichi fruit juice once a week or more (n=601, 80%) to achieve the health benefit. Even so, more than half would not buy green tea/yukichi fruit juice with the QHC (n=755, 57.1%).

Purchase intentions for green tea and yukichi fruit juice

To explore the differences in mean responses between groups and conditions, we then compared responses about purchase intentions, evidence, risk reduction, and confidence in the claimed relationship. Looking at all survey participants (n=1,335), we found that the condition (i.e. green tea-cancer or yukichi fruit juice-gastrocoridalis) had a significant effect on perceptions of confidence, evidence, risk reduction, and purchase intentions (Pillai's Trace = .102, F=36.896, df=4, 1,296, $p < 0.0001$). We also found that the QHC had a statistically significant effect on perceptions of confidence, evidence, risk reduction, and purchase intentions (Pillai's Trace = .138, F=7.719, df=24, 5,196, $p < 0.0001$) and that there was a statistically significant interaction between the condition and the QHC on these same variables (Pillai's Trace = .034, F=1.834, df=24, 5,196, $p < 0.0001$).

However, these measures are strongly correlated (Table 8) as the HCF posits that purchase intentions are a function of confidence, perceptions of evidence, and disease risk reduction. Univariate tests demonstrated a significant main effect of condition, such that participants reported greater intentions to purchase green tea than yukichi fruit juice $F(1, 1,299) = 132.320$, $p < .0001$. There was also a significant main effect of QHC, such that claims written by the green tea manufacturer resulted in greater purchase intentions than those written by the FDA, $F(6, 1,299) = 8.047$, $p < .0001$. However there was no interaction effect between condition and QHC, $F(6, 1,299) = 1.713$, $p = .114$ (Figure 1).

Significant differences were found between conditions such that participants in the green tea condition perceived greater evidence than in the yukichi fruit juice condition, $F(1, 1{,}299) = 25.407$, $p < .0001$. There was also a significant main effect of the QHC group with greater perceptions of evidence by participants in groups that viewed claims written by Fleminger, Inc. than FDA, $F(6, 1{,}299) = 25.491$, $p < .0001$. There was a significant interaction between the condition and QHC group on evidence ratings, $F(6, 1{,}299) = 2.804$, $p = .010$.

Similarly, there were statistically significant differences in group responses to risk reduction between conditions such that participants in the green tea condition reported greater risk reduction with consuming green tea than yukichi fruit juice, $F(1, 1{,}299) = 36.369$, $p < .0001$. There was a significant main effect for the QHC group on reported risk reduction such that the reported risk reduction was greater in groups that viewed a Fleminger, Inc. QHC versus an FDA claim, $F(6, 1{,}299) = 19.263$, $p < .0001$. A statistically significant interaction was also found between conditions and QHC groups on perceived risk reduction, $F(6, 1{,}299) = 3.085$, $p = .005$.

Finally, statistically significant difference in reported confidence in the claimed relationship with greater confidence in the green tea condition than the yukichi fruit juice condition, $F(1, 1{,}299) = 78.922$, $p < .0001$. A main effect was identified between QHC groups such that participants who viewed a Fleminger, Inc. claim reported greater confidence in the claimed relationship than in other groups, $F(6, 1{,}299) = 16.919$, $p < .0001$. There was also a statistically significant interaction between the QHC group and condition, $F(6, 1{,}299) = 2.917$, $p = .008$.

There were no statistically significant differences between the green tea and yukichi fruit juice conditions for dietary supplement use (p =.993), reported importance of health claims on dietary supplement or food labels (p =.505; p = .138, respectively), perceived nutrition knowledge (p = .837), worry about overall health (p = .979), worry about becoming ill with gastrocoridalis (p = .240) or cancer (p = .066), worry that led to a dietary change in the past year (p = .360), or previous diagnosis of gastrocoridalis (p =.800) or cancer (p =.677) (Table 4). There were no sociodemographic statistically significant differences between conditions with the exception of sex with more males in the green tea condition and more females in the yukichi fruit juice condition (Table 3).

The Health Claims Framework indicates other consumer and product-specific factors that influence purchase intentions for a functional food product, such as green tea. Experience (Mazis & Raymond, 1997) and familiarity (Wills et al., 2012) with a product, health condition, and perhaps claim may influence behavior. Since the yukichi fruit juice-gastrocoridalis relationship was fictitious, the subsequent analysis focuses on green tea and cancer to understand the influence of other factors.

Predictors of purchase intentions for green tea

Familiarity and experience with a product and/or a health-condition have been found to significantly influence future behavior (Dean et al., 2012; Hasler, 2008; Pothoulaki & Chryssochoidis, 2009; Reinhardt-Kapsak et al., 2008; Saldanha, 2006; Wills et al., 2012) so we tested relevant measures to determine their predictive value for purchase intentions for green tea. Looking at the green tea condition only (n=666), consumer-specific and modifying sociodemographic variables were individually tested for their predictive value for purchase intentions for green tea.

The significant sociodemographic predictors, age and race or ethnicity, account for 3.5% of the variation in purchase intentions for green tea, $F(5, 656) = 5.857$, $p < .0001$. Black ($b = .126$, $t(656) = 3.274$, $p = .001$) and Hispanic ($b = .141$, $t(656) = 3.670$, $p < .0001$) participants reported statistically significantly greater purchase intentions for green tea than White participants. Similarly, with each incremental increase in age, participants had lower purchase intentions, $b = -.0.90$, $t(661) = -2.334$, $p < .05$. The consumer specific variables that demonstrate significant predictive value and accounted for 4.1% of the variance in purchase intentions were: dietary supplement use, and the perceived importance of health claims on food products and on dietary supplement products, $F(3, 501) = 8.162$, $p < .0001$. For each incremental increase in dietary supplement use in the past year, participants were less likely to intend to purchase green tea, ($b = -.114$, $t(503) = -2.582$, $p = .01$. The more important participants consider health statements on dietary supplement products, the greater their purchase intentions ($b = .135$, $t(501) = 2.209$, $p < .05$). Measures of perceived susceptibility that significantly predict green tea purchase intentions are: general health, worry about overall health, worry about becoming ill with cancer, and worry that led to a dietary change in the past year $F(4, 548) = 8.876$, $p < .0001$. The better participants rated their general health, the greater their purchase intentions for green tea, $b = .126$, $t(548) = 2.722$, $p < .0001$. Similarly, participants who were more worried about their overall health ($b = .105$, $t(550) = 2.228$) or becoming ill with cancer ($b = .103$, $t(549) = 2.262$) demonstrated greater purchase intentions, $p < .05$. For each incremental increase in dietary changes made in response to a health worry, participants were .212 greater purchase intentions, $t(548) = 4.423$, $p < .0001$. The non-explanatory predictors were removed from further analysis;

sex, education, employment, income, perceived nutrition knowledge, and past cancer diagnosis.

A block of the modifying sociodemographic, consumer-specific, and perceived susceptibility predictors were entered, including race/ethnicity, age, perceived importance of health claims on food products and on dietary supplement products, and dietary supplement use, and self-reported health status, worry about overall health, worry about becoming ill with cancer, and worry that led to a dietary change in the past year as independent variables. This model significantly predicted purchase intentions for green tea and accounted for 9.3% of the variance in the dependent variable, $F(12, 406) = 4.581$, $p < .0001$ (Table 6).

Participants who consumed green tea in the past year had significantly greater purchase intentions (M=2.73, SD=1.49) than those who did not, *Welch's* $F(1, 640.890) = 87.810$, $p < .001$. Further, participants who did not drink green tea in the past year were "slightly likely" (M=1.76, SD=1.17) to buy it in the future. As a result, current consumption was added to the model at step 2, with a resulting significant R^2 change =.052, $F(13, 403) = 6.404$, $p < .0001$, adj. $R^2 = .144$ (Table 6).

Familiarity with the green tea-cancer relationship or the claim itself may lead to greater purchase intentions for green tea (Wills et al., 2012). There were no differences between people who consumed green tea in the past year and people who did not in terms of whether they had seen the claim on a label, *Welch's* $F(2,114.967) = 2.826$, $p = .063$, website, in an advertisement, or an article, *Welch's* $F(2, 148.997) = 2.270$, $p = .107$. However, there was a significant difference in familiarity with the green tea-cancer relationship between those who drank green tea ($M = 2.11$, $SD = 1.10$) and those who did

not (*M* = 1.61, *SD* = 0.87), *Welch's F*(1, 642.179) = 42.389, *p* < .0001. Familiarity with the green tea-cancer relationship was then added to the model at step 3, and results indicated that it is a significant predictor of purchase intentions for green tea, *F*(14, 401) = 7.685, *p* < .0001, and accounted for 18.4% of the variance in the model, R^2 change = .041 (Table 6).

We then entered the QHCs at step 4 to understand how the claims may contribute to purchase intentions for green tea. The QHCs were identified as a significant predictor of future behavior, *F*(20, 395) = 6.263, *p* < .0001, though they accounted for a small amount of variance in the model, adj. R^2 = .202, R^2 change = .029 (Table 6). In the full model, the significant predictors of purchase intentions for green tea were the reported importance of health statements on dietary supplements, worry about health that led to dietary change in the past year, having drank green tea in the past year, familiarity with the green tea-cancer relationship, and having seen a QHC written by the green tea manufacturer, Fleminger, Inc. while dietary supplement use was negatively related to purchase intentions for green tea. There was no interaction found between QHC and existing behavior, *F*(6, 646) = .743, *p* = 6.16, meaning there are other factors influencing purchase intentions.

To understand if perceptions of evidence for the green tea-cancer relationship, risk reduction for cancer, and confidence in the claimed relationship predict purchase intentions for green tea, three additional steps were added to the model; ratings for evidence, risk reduction, and confidence in the green tea-cancer relationship as predictors of purchase intentions. To isolate the effects of these variables from the associated QHCs, a second predictive regression model was created to include steps 1 (i.e.

sociodemographics, consumer-specific, and perceived susceptibility variables), 2 (i.e. past behavior), and 3 (i.e. familiarity), and the dummy-coded QHCs were removed. The following analysis represents steps 4, 5, and 6 for the second predictive regression model.

The entry of perception of evidence indicated that it is a strong and significant predictor of purchase intentions for green tea, $F(15, 399) = 19.781$, $p < .0001$, adj. $R^2 = .315$, R^2 change = .128, $p < .0001$. The next block, showed that confidence in the green tea-cancer relationship, was also a significantly strong predictor of future intentions to purchase green tea, $F(16, 398) = 16.345$, $p < .0001$, adj. $R^2 = .372$, R^2 change = .056, $p < .0001$. Entry of the third variable, perception of cancer risk reduction, showed that the overall model was significant for predicting purchase intentions for green tea, $F(1, 400) = 18.736$, $p < .0001$, although the variable did not add any more to the model, adj. $R^2 = .371$, R^2 change = .000, $p = .896$ (Table 6).

However, there are strong positive correlations between these measures of evidence, risk, and confidence (Table 78). This multicollinearity likely explains the weak predictive value of perceived risk reduction on purchase intentions. To explore this, a backwards stepwise regression was run with the three predictors in a single block. The model removed risk reduction and maintained evidence perceptions and confidence in the green tea-cancer relationship, indicating that it did not account for any more variance and so was removed.

We removed all three predictors and re-entered the two significant predictors, perceived evidence and confidence in the claimed relationship, as a block at step 4. This step, as expected, was a significantly strong predictor of purchase intentions, $F(16, 398) = 16.345$, $p < .0001$, adj. $R^2 = .372$, R^2 change = .185 (Table 6). For every incremental

increase in perceived evidence, there was a .130 increase in purchase intention for green tea, and for every incremental increase in confidence in the green tea-cancer relationship, there was a .369 increase in purchase intention. Dietary supplement use was again negatively related to purchase intentions for green tea and the importance of health statements on dietary supplements, worry that led to dietary change, green tea consumption in the past year, and familiarity with the green tea-cancer relationship were all predictive of purchase intentions for green tea (Table 6).

Since health claims must ‘'enable the public to comprehend the information…in the context of a total daily diet'’” (21 CFR 101.14(c)(d), 101.70) (Food and Drug Administration, 2009a) we wanted to explore the contribution of perceptions of the how often one would need to drink green tea (i.e. dose) to achieve the health benefit. No association was detected for dose and purchase intentions and therefore was not tested in a predictive model, $\chi^2(24) = 29.845$, $p = .190$ (Table 9).

Because of its strong influence on food choice, taste was explored for its role in purchase intentions for green tea (Nielsen & National Marketing Institute, 2014; Wills et al., 2012). However, there was no association between enjoying the taste of green tea and intent to purchase green tea, and so it was not added to the model, $\chi2(6) = 7.284$, $p = .295$ (Table 9).

To summarize, race/ethnicity, age, the importance of health claims on food and dietary supplement labels, dietary supplement use, general health, worry about overall health, worry about becoming ill with cancer, worry that led a dietary change, existing behavior of green tea consumption, and familiarity with the green tea-cancer relationship, and the seven QHCs were statistically significant predictors for green tea purchase

intentions, $F(16, 400) = 7.841$, $p < .0001$, adj. $R^2 = .208$, R^2 change = .028. The addition of evidence perceptions and reported confidence in the green tea-cancer relationship (and removal of QHCs) led to a statistically significant increase in R^2 of .185, $F(13, 401) = 20.225$, $p < .0001$, adj. $R^2 = .376$.

Discussion

With respect to their future intentions to purchase green tea, the data suggests that participants are influenced by their past behaviors and preferences regarding that particular product. However, even after controlling for those preferences and experiences, exposure to specific green tea QHCs seem to increase stated intentions to purchase green tea. In particular, exposure to the 2004, 2008, and 2010 claims written by Fleminger, Inc., the green tea manufacturer, appear to increase purchase intentions. Our results demonstrate that different QHCs affect consumer perceptions of the scientific evidence, linking green tea consumption and their confidence in the relationship between green tea and the reduced risk of cancer, and purchase intentions.

Several sociodemographic characteristics have been associated with greater acceptance of functional foods with health claims. We expected some overlap between these same characteristics of consumers who are receptive to health claims and QHCs.

In the current study, race or ethnicity was a strong predictor of purchase intentions for green tea when entered at step one in the regression model. Black and Hispanic consumers intended to purchase green tea more than White consumers. This finding is in contrast with previous research, which has pointed to White adults as more accepting of functional food products (Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009; Reinhardt Kapsak et al., 2011) although this difference may be

explained in part by the presence of a QHC which is unique to the current study. However, race or ethnicity did not remain a significant predictor of purchase intentions for green tea in the full regression model(s).

Previous research also demonstrates mixed results for age as a predictor of functional food acceptance with health claims (Contini et al., 2015; Cox et al., 2011; Gilbert, 2000; Pothoulaki & Chryssochoidis, 2009). Age was also initially a strong predictor of green tea purchase intentions with adults aged 55-64 having greater purchase intentions than participants over 65. In the full model, age also did not predict purchase intentions for green tea.

Other research has also indicated that women are more receptive to functional foods and to nutrition information in health claims on product labels (Lahteenmaki, 2012; Pothoulaki & Chryssochoidis, 2009). The current study did not find sex to be a significant predictor of purchase intentions for green tea. Further, no other sociodemographic modifying variables predictive of future behavior with green tea including education, employment, or income.

The intentions to purchase yukichi fruit juice were significantly lower than the intentions to purchase green tea meaning participants considered other information when responding to questions. In addition, existing behavior of green tea consumption and familiarity with the green tea-cancer relationship were both significant predictors of behavioral intentions. These findings are consistent with previous research about acceptance and interest in functional food products with health claims (Dean et al., 2012; Hasler, 2008; Lin, 2008; Pothoulaki & Chryssochoidis, 2009; Reinhardt-Kapsak et al., 2008; Saldanha, 2006; Wills et al., 2012).

We also measured product-specific characteristics regarded as predictors of purchase intentions for functional products with health claims (Wills et al., 2012) including taste and claim language. While there is considerable evidence that taste is a predictor for purchase intentions and behavior with health claims (Nielsen & National Marketing Institute, 2014; Wills et al., 2012) it was not correlated with purchase intentions of green tea with a QHC.

The QHC, however, was predictive of purchase intentions for green tea. While the results of the current study cannot pinpoint the exact language or wording in QHCs that may have led to greater purchase intentions for green tea, the results demonstrated that the Fleminger, Inc. 2004, 2008, and 2010 QHCs produced greater purchase intentions compared with other QHCs. The 2004 Fleminger, Inc. described the evidence for the green tea-cancer relationship as more supportive than it is in actuality; "scientific evidence supporting this health claim although the evidence is not conclusive" (Food and Drug Administration, 2012). Both the 2008 and 2010 Fleminger, Inc. QHCs state the evidence is credible but limited for the green tea-cancer relationship and the 2010 claim goes so far as to specify the FDA, perhaps to increase the trustworthiness of the claim. The 2012 FDA QHC was suggested by the federal court as a compromise between the interests of companies to market the health benefit of green tea and the FDA to prevent consumers from being misled about the scientific certainty for the green tea-cancer relationship (Fleminger, 2012). Compared with other FDA QHCs, consumers had a greater perception of evidence in response to the 2012 FDA QHC when compared with the other three FDA QHCs (Berhaupt-Glickstein & Hallman, In preparationa).

With respect to QHCs, the reported confidence in the green tea-cancer relationship was a very strong predictor of purchase intention. While independently, the perceived cancer risk reduction with the consumption of green tea was associated with purchase intentions, it did not contribute any more predictive value to purchase intentions above and beyond the measure of confidence. Further, since evidence and confidence were associated with the QHC, these results provide more support for the hypothesis that the specific claims differentially affect perceived health benefits.

The overall proportion of variance that can be explained by the independent variables was nearly 40% (Table 6). The HCF and HBM include several additional measures that were not included in the current study and so it is possible that the addition of these measures could lead to even greater predictive models of purchase intentions for green tea in the presence of a QHC. However, both theoretical models apply to the general population. Further, the focus of the HBM is on general health behavior, while the HCF was designed for unqualified health claims that do not describe the degree of scientific support for diet-disease relationships. The current study focused on a specific population (adults 55 years and older), and on a particular product (green tea) and on a specific disease outcome (cancer). Whether additional variables drawn from the HCF or HBM are applicable to such predictions is an empirical question that could be explored in further research.

There is considerable potential for QHCs in the market since most Americans believe that functional foods can reduce the risk of becoming sick with a specific disease (International Food Information Council, 2011) and believe they have some control over their health (International Food Information Council, 2011). We found that participants in

our sample had greater intentions to purchase green tea if in the past year, he or she worried about their health that led them to make a dietary change and took a dietary supplement in the past year. Since Americans perceive cancer as a greater risk than other diseases including heart disease, type 2 diabetes, and stroke (Wang et al., 2009), it seems that there is a considerable marketing opportunity.

It should be noted that the current study examines QHCs for the green tea-cancer relationship, a D-grade claim which meets the lowest level of evidence for a claimed relationship (Food and Drug Administration, 2012). How the level of evidence communicated in QHCs for diet-disease relationships with more scientific support remains unstudied. Such research would provide useful information about existing QHCs and would also contribute to greater understanding of how the results of several lawsuits about claim language may ultimately impact the consumer.

Strengths and Limitations

Few recent studies have examined how consumer perceptions change in response to different QHCs (International Food Information Council, 2013). This study is unique in its contribution to the understanding of the influence of QHCs on purchase intentions. Only one other study has explored purchase intentions with respect to products that bear QHCs and found mixed results (Reinhardt-Kapsak et al., 2008). A major strength of this study is that it included QHCs that were petitioned or used by a green tea company, or were enforced by the FDA.

One potential limitation is that the study did not include a control group of participants who did not view any claim. A control group was not included because the main focus of the study was to evaluate the differences among the various QHCs and to test the assertions made about those claims by the FDA, Fleminger Inc., and the courts.

Testing the differences between no green tea QHC and the currently enforced green tea QHC is a subject for further investigation. Further, a repeated measures study design was considered where participants viewed several QHCs however when tested, it resulted in greater time required to complete the survey and increased participant burden. Moreover, most of the questions that serve as predictor variables could not have been answered by participants in a control group that had not viewed information regarding a relationship between consuming green tea and reductions in the risk of cancer. Participants were asked questions about the level of evidence and confidence in the green tea-cancer relationship as well as perceived cancer risk reduction, based on the QHC statements. However, the inclusion of measures of prior green tea consumption, and of prior familiarity with the green tea diet-disease relationship permits the necessary comparisons. While the measures in this study are single items, the literature shows that they (i.e. purchase intentions, evidence, etc.) have routinely been measured as single items and do not require complex scales. Finally, research in other disciplines has found that self-report and observation data of certain behaviors have low to moderate correlations (Kendall et al., 2004; Price et al., 2008). Since the current study was an online survey, there would likely be a difference between self-report purchase intentions and actual purchases of green tea in the presence of a QHC.

Conclusions

There is a segment of American consumers that positively respond to green tea QHCs. Black and Hispanic consumers between the ages of 55 and 64 who make dietary changes to address their health concerns and consider health claims on dietary supplements important reported greater purchase intentions than others. Consumers who

perceived there to be more evidence for the green tea-cancer relationship also intended to purchase green tea more, as did participants who reported greater confidence in the claimed relationship. Finally, the three claims written by the green tea manufacturer led to greater purchase intentions than the FDA claims and compared with other QHCs, led to greater perceptions of evidence, perceived cancer risk reduction, and confidence in the claimed relationship. The QHCs in this study impacted consumers' perceptions of evidence for a diet-disease relationship which impacted the health perceptions for that product, as well as purchase intentions.

Table 1. Seven qualified health claims that were petitioned, unlawfully used by green tea manufacturers, or prescribed by the US Food and Drug Administration, 2004-2012.

Author	Year	Status	Qualified Health Claim*	*n*
Fleminger, Inc.	2004	Scientifically inaccurate	Daily consumption of 40 ounces of typical green tea containing 170µg/ml of natural (-) epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. **There is scientific evidence supporting this health claim although the evidence is not conclusive.**	185
Fleminger, Inc.	2008	Scientifically inaccurate	Green tea may reduce the risk of cancer of the breast and the prostate. There is **credible evidence** supporting this claim although the evidence is limited.	176
Fleminger, Inc.	2010	Scientifically inaccurate; illegally names FDA	Green tea may reduce the risk of breast and prostate cancers. The **FDA** has concluded that there is **credible evidence** supporting this claim although the evidence is limited.	185
FDA	2005p	Overly technical	**One weak and limited study** does not show that drinking green tea reduces the risk of prostate cancer, but **another weak and limited study** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is **highly unlikely** that green tea reduces the risk of prostate cancer.	211
FDA	2005b	Overly technical	**Two studies** do not show that drinking green tea reduces the risk of breast cancer in women, but **one weaker, more limited study** suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is **highly unlikely** that green tea reduces the risk of breast cancer.	179
FDA	2011	Disclaimer negates green tea-cancer relationship	Drinking green tea may reduce the risk of breast or prostate cancer. **FDA does not agree** that green tea may reduce that risk because there is very little scientific evidence for the claim.	206
Federal Court	2012	Scientifically accurate; technically appropriate	Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.	193

*Highlighted language represents the issues with the description of evidence.

Table 2. Semantic differential scale of evidence separated by grades of evidence for health claims and qualified health claims defined in the 2003 FDA Draft Guidance for Qualified Health Claims.

Semantic differential scale of evidence	**Evidence**												
	None	Minimal			Some						Complete		
	0	1	2	3	4	5	6	7	8	9	10	11	12
Type of Health Claim	N/A	QUALIFIED HEALTH CLAIMS									HEALTH CLAIMS		
Grade of evidence	N/A	D				C			B		A		
Language and description of evidence requirements	N/A	Requires qualifying statement about degree of evidence for the claimed diet-disease relationship.									Requires NO qualifier because the evidence meets *SSA standards.*		
Requirements for use by manufacturers and suppliers of eligible products	N/A	FDA prescribes exact language for the claim.									Allows manufacturers to write a health claim so long as it is truthful and not misleading.		

**A footnote in the 2009 Final Guidance indicated the health claim grading system was no longer in effect* (Food and Drug Administration, 2003b; Food and Drug Administration, 2011). *However, an implicit scale of evidence remains, as it is the fundamental difference between health claims and qualified health claims. For this reason, the 2003 scale of evidence was used for the purpose of exploring consumer perceptions of evidence.*

Table 3. Sociodemographics of study participants

Characteristics	**Green Tea** (n=666)	**Yukichi Fruit Juice** (n=669)	**All Participants** (n=1,335)
Sex*			
Female	323 (46.9)	365 (53.0)	688 (51.5)
Male	343 (53.0)	304 (46.9)	647 (48.5)
Race/Ethnicity			
White	532 (39.9)	528 (39.6)	1,060 (79.4)
Black	65 (4.9)	49 (3.7)	114 (8.5)
Hispanic	39 (3.0)	39 (3.0)	77 (6.0)
Other	20 (1.5)	15 (1.1)	35 (2.6)
2 or more races	26 (1.9)	23 (1.7)	49 (3.7)
Age			
55 to 64 years old	330 (24.7)	328 (24.6)	658 (49.3)
65 to 74 years old	229 (17.2)	236 (17.7)	465 (34.8)
75 or older	107 (8.0)	105 (7.9)	212 (15.9)
Education			
Less than high school	52 (7.8)	50 (7.5)	102 (7.6)
High school	244 (36.6)	209 (31.2)	453 (33.9)
Some college	195 (29.3)	197 (29.4)	392 (29.4)
Bachelor's degree or higher	175 (26.3)	213 (31.8)	388 (29.1)
Household Income			
$0 - $49,999	283 (21.2)	309 (23.1)	592 (44.3)
$50,000 - $99,999	229 (17.2)	207 (15.5)	436 (32.7)
$100,000 - $149,999	98 (7.3)	107 (8.0)	205 (15.4)
$150,000 and above	52 (3.9)	50 (3.7)	102 (7.6)
Health Status			
Cancer (general)	104 (7.8)	99 (7.4)	203 (15.2)
Breast cancer	19 (1.4)	28 (2.1)	47 (3.5)
Prostate cancer	25 (1.9)	20 (1.5)	45 (3.4)
Gastrocoridalis	7 (0.5)	8 (0.6)	15 (1.1)

***** $p < 0.05$

Table 4. Frequencies and percentages [n (%)] of responses to modifying factors and perceived susceptibility measures by condition. Means and standard deviation reported for continuous variables.

	Green Tea n=687		Yukichi Fruit Juice n=644	
	n (%)	M, SD	n (%)	M, SD
Supplement User		4.35, 2.10		4.35, 2.13
Health claims on supplement		3.28, 1.18		3.23, 1.23
Health claims on food		2.92, 1.15		2.82, 1.18
Nutrition Knowledge		3.24, 0.86		3.23, 0.93
Health Status		3.35, 0.89		3.35, 0.90
Health Worry		2.52, 0.98		2.52, 0.97
Health-related worry diet Δ		2.43, 1.07		2.37, 1.02
Cancer Worry		2.26, 1.00		2.15, 0.98
Gastrocoridalis Worry		1.43, 0.79		1.38, 0.76
Cancer Diagnosis	104 (15.7%)		99 (14.9%)	
Gastrocoridalis Diagnosis	7 (1.1%)		8 (1.2%)	

t indicates a statistically significant difference between conditions as determined by independent samples t-test for continuous variables at $p < .05$ level. Chi-square test for independence were used for the categorical variable, cancer diagnosis.

Table 5. Means and standard deviations for perceived risk reduction in cancer and gastrocoridalis, confidence in the claimed relationship, and purchase intentions for green tea and yukichi fruit juice, separated by QHC groups.

	Risk Reduction					Confidence					Purchase Intentions				
	n	Min	Max	M	SD	n	Min	Max	M	SD	n	Min	Max	M	SD
Fleminger, Inc.															
2004	184	1	6	2.42	1.15	184	1	7	2.24	1.19	184	1	7	2.29	1.44
2008	176	1	6	2.30	1.17	176	1	5	2.09	1.11	174	1	6	2.06	1.27
2010	184	1	5	2.31	1.17	183	1	6	2.16	1.21	182	1	7	2.11	1.39
US FDA															
2005p	211	1	5	1.58	0.90	210	1	7	1.45	.086	211	1	7	1.57	1.09
2005b	177	1	6	1.76	0.97	177	1	7	1.62	1.02	175	1	6	1.66	1.11
2011	205	1	5	1.85	0.97	204	1	6	1.65	1.00	204	1	7	1.76	1.25
2012	192	1	5	1.74	0.97	192	1	5	1.64	1.05	192	1	7	1.74	1.19

Scales: Risk reduction: 1-Not at all to 7-Complete reduction [of risk for cancer/gastrocoridalis]
Confidence: 1-Not at all confidence to 7-Absolutely confident [that drinking green tea/yukichi fruit juice will reduce the risk of cancer/gastrocoridalis]. Purchase intentions: 1- Not at all likely to 7-Absolutely certain [to purchase a bottle of green tea/yukichi fruit juice with this statement]

Table 6. Summary of Hierarchical Regression Analysis for Variables Predicting Purchase Intentions for Green Tea

Variable	Model 1					Model 2				
				95% CI Interval					95% CI Interval	
	B	SE_B	*Beta*	*Lower*	*Upper*	*B*	SE_B	*Beta*	*Lower*	*Upper*
Age	-.029	.091	-.014	-.207	.150	.017	.081	.009	-.142	.176
Race or Ethnicity										
Black	.154	.265	.027	-.367	.676	-.002	.236	.000	-.467	.463
Hispanic	.487	.254	.087	-.012	.985	.284	.224	.051	-.155	.723
Other, non-Hispanic	.307	.379	.037	-.437	1.051	.271	.335	.033	-.388	.930
2+, non-Hispanic	.281	.342	.037	-3.90	.953	.258	.302	.034	-.335	.852
Dietary Supplement Use	-.163	.055	-.133**	-.272	-.054	-.121	.049	-.099*	-.218	-.024
Importance of Health Claims										
Food Labels	-.053	.082	-.042	-.215	.109	-.081	.073	-.064	-.224	.062
Dietary Supplement Labels	.169	.077	.138*	.017	.321	.131	.068	.107	-.003	.266
Health Status	.057	.088	.034	-.115	.230	.026	.077	.016	-.126	.179
Worry about Health	-.034	.089	-.022	-.209	.141	-.014	.079	-.010	-.169	.140
Worry about Cancer	.062	.072	.044	-.080	.205	-.024	.064	-.017	-.149	.101
Worry Diet Change	.155	.075	.115*	.008	.301	.142	.065	.106*	.014	.271
Green Tea Consumption	.200	.045	.213**	.111	.288	.171	.040	.182**	.093	.250
Familiarity	.272	.066	.200**	.143	.402	.048	.061	.035	-.072	.168
QHC Group										
QHC 2004	.617	.246	.150*	.133	1.101					
QHC 2008	.609	.250	.140*	.117	1.101					
QHC 2010	.654	.237	.164**	.188	1.121					
QHC 2005b	.126	.2407	.031	-.346	.599					
QHC 2011	.162	.246	.039	-.320	.645					
QHC 2012	.358	.241	.088	-.115	.832					
Evidence						.130	.026	.238**	.079	.181

Confidence			.369	.060	.314**	.250	.487
Adjusted R^2	.202			.372			
F for change in R^2	2.535*			60.891**			

*$p < .05$ **$p < .01$

Reference categories: White is the reference category for race or ethnicity. QHC 2005p is the reference category for QHC Group

Table 7. Means and standard deviations of purchase intentions for green tea by QHC group and whether a person drank green tea or not in the last year.

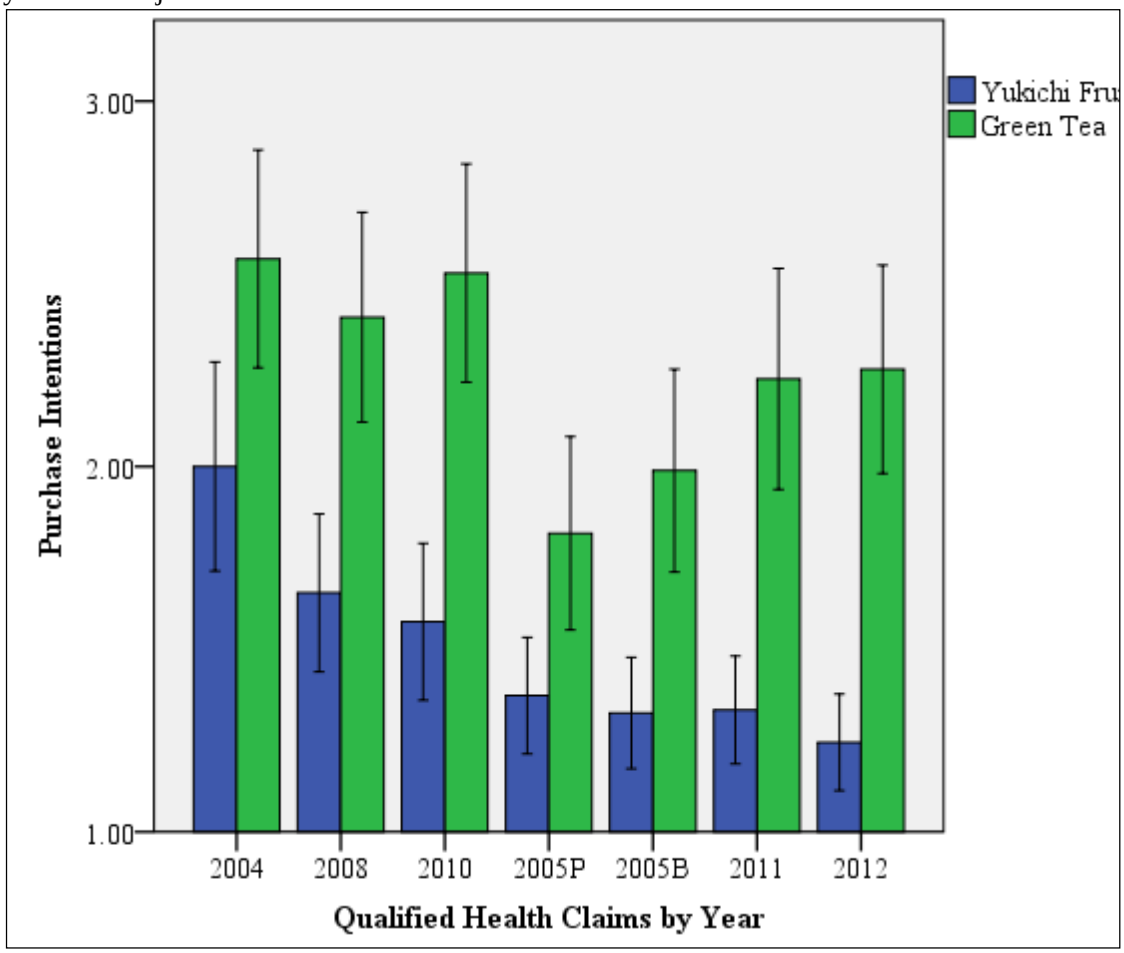
Author	**QHC**	**Drank green tea last year**	***n***	***M***	***SD***
Fleminger, Inc.	2004	No	50	1.92	1.19
		Yes	45	3.29	1.41
		Total	95	2.57	1.46
	2008	No	45	2.11	1.47
		Yes	47	2.72	1.26
		Total	92	2.42	1.39
	2010	No	55	2.10	1.22
		Yes	47	3.04	1.68
		Total	102	2.53	1.52
US FDA	2005P	No	46	1.30	0.59
		Yes	47	2.32	1.56
		Total	93	1.82	1.28
	2005B	No	39	1.38	0.91
		Yes	50	2.46	1.40
		Total	89	1.99	1.32
	2011	No	41	1.59	1.12
		Yes	55	2.73	1.56
		Total	96	2.24	1.49
	2012	No	41	1.78	1.24
		Yes	52	2.63	1.41
		Total	93	2.26	1.40
	Total	No	317	1.76	1.17
		Yes	343	2.73	1.49
		Total	660	2.27	1.43

Familiarity: 1=not at all familiar, 2= somewhat familiar, 3=fairly familiar, 4=very familiar, 5=extremely familiar

Table 8. Group means and standard deviations of ratings for evidence, cancer risk reduction, and confidence in the green tea-cancer relationship by qualified health claim. Correlations (r_s) between group perceptions of evidence, risk reduction, and confidence in the green tea-cancer relationship.

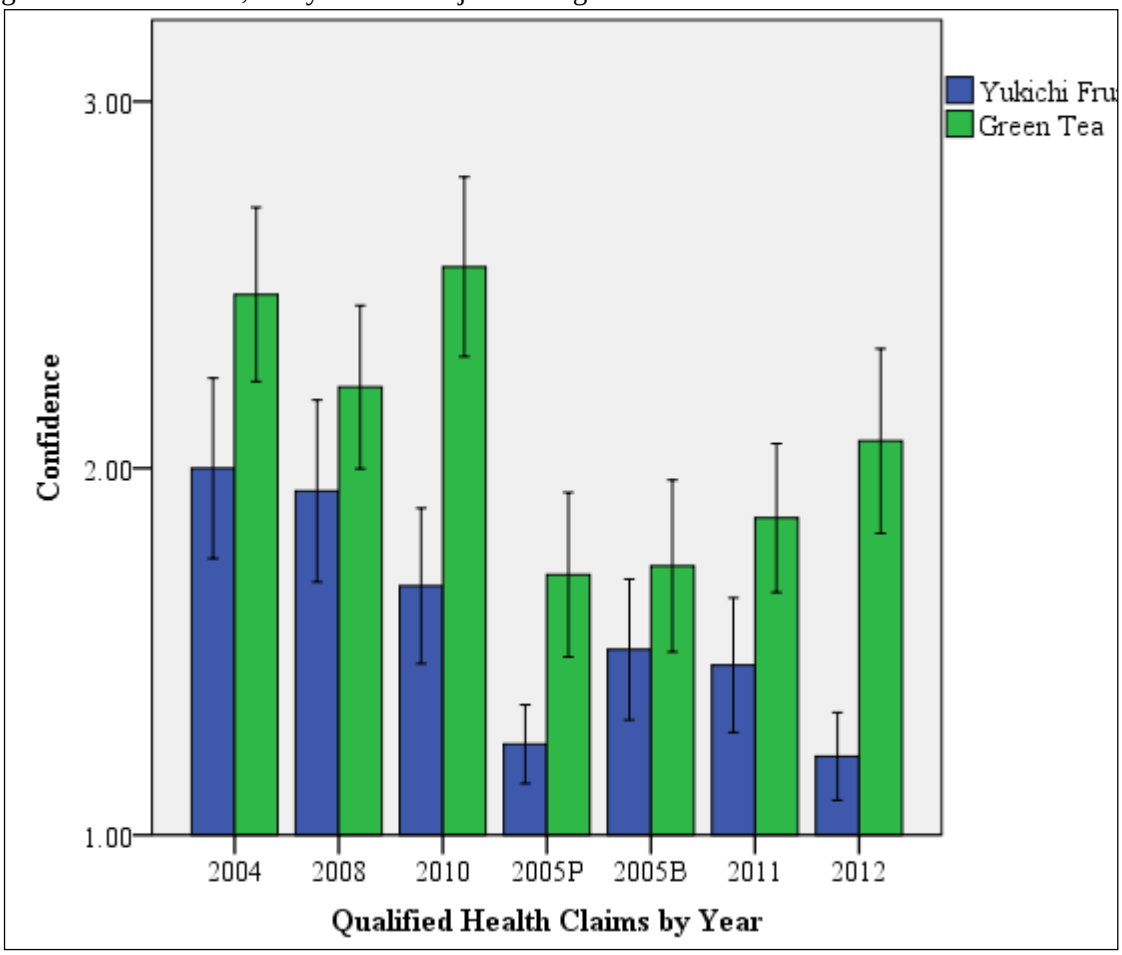
							Risk reduction	Confidence
Measure	**QHC**	***n***	***Min***	***Max***	***M***	***SD***	***r_s, sig***	
Evidence	2004	95	1	10	4.18	2.67	.536, p < .01	.523, p < .01
	2008	93	1	13	3.91	2.69		
	2010	102	1	13	4.70	2.95		
	2005P	92	1	11	2.43	1.98		
	2005B	88	1	12	2.72	2.18		
	2011	96	1	8	2.38	1.77		
	2012	94	1	12	3.23	2.62		
Risk reduction	2004	95	1	5	2.65	1.07		.804, p < .01
	2008	95	1	6	2.35	1.12		
	2010	102	1	5	2.59	1.18		
	2005P	93	1	5	1.81	1.09		
	2005B	90	1	5	1.73	0.88		
	2011	96	1	4	1.98	0.93		
	2012	94	1	5	2.06	1.09		
Confidence	2004	95	1	6	2.47	1.17		
	2008	95	1	5	2.22	1.09		
	2010	102	1	6	2.55	1.25		
	2005P	93	1	7	1.71	1.09		
	2005B	90	1	7	1.73	1.12		
	2011	96	1	5	1.86	1.00		
	2012	94	1	5	2.07	1.23		

Figure 1. Mean and standard error of group responses for purchase intentions for green tea and yukichi fruit juice.



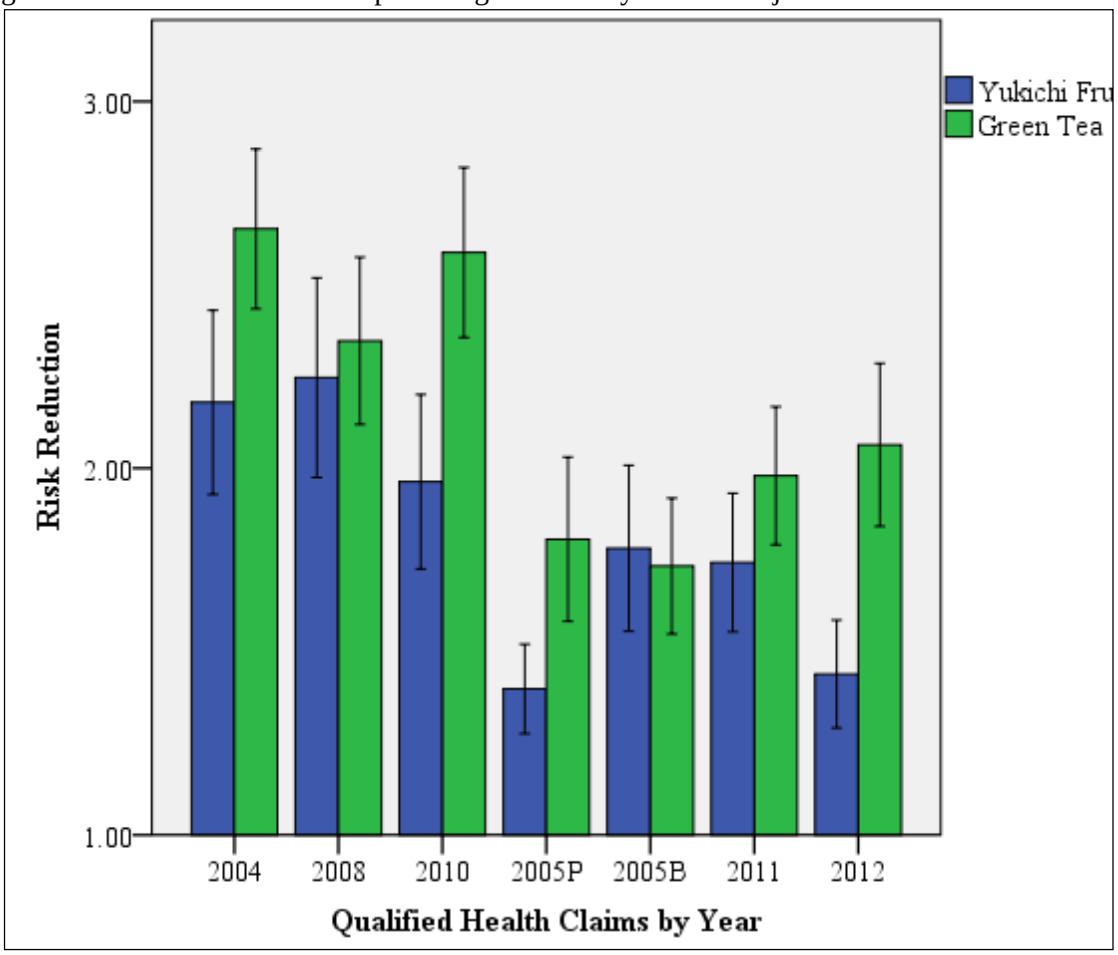
Response scale for purchase intentions: 1-Not at all likely to 7-Absolutely certain

Figure 2. Mean and standard error of group responses for confidence in the relationship between green tea and cancer, and yukichi fruit juice and gastrocoridals.



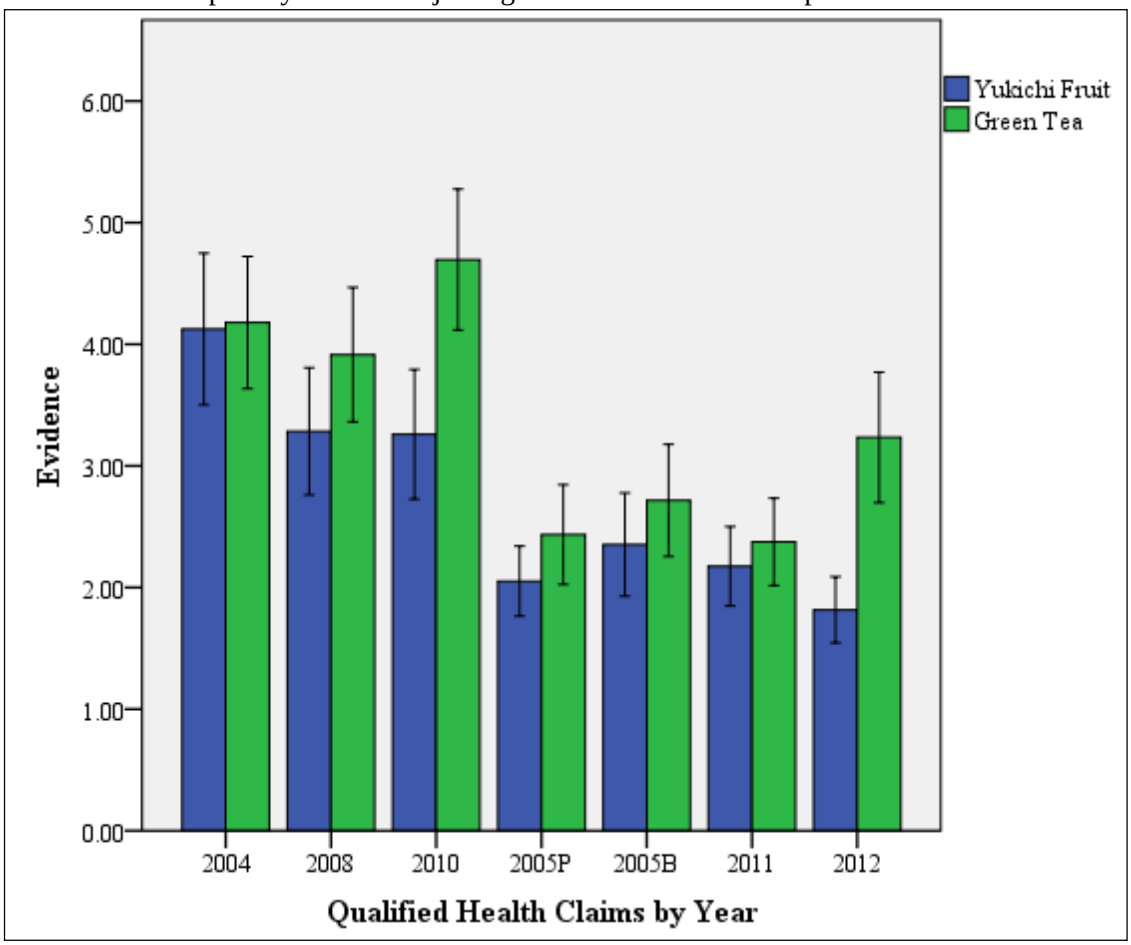
Response scale for confidence: 1-Not at all confident to 7-Absolutely confident

Figure 3. Mean and standard error of group responses for perceived risk reduction for cancer and gastrocoridalis with the consumption of green tea or yukichi fruit juice.



Response scale for risk reduction: 1-Not at all to 7-Complete reduction

Figure 4. Mean and standard error of group responses for evidence ratings for the green tea-cancer relationship and yukichi fruit juice-gastrocoridalis relationship.



Response scale for evidence: 0-No evidence; 1-Minimal; 6-Some; 12-Complete evidence

Table 9. Correlation Matrix.

		SD	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1	Confidence	(1.10)																	
2	Risk Reduction	(1.09)	.79**																
3	Evidence	(2.42)	.54**	.53**															
4	Purchase Intention	(1.27)	.54**	.49**	.45**														
5	Dose	(1.29)	.06	.04	.05	.12**													
6	Past Behavior	(1.54)	.08**	.12**	.03	.20**	.11**												
7	Familiarity	(1.03)	.38**	.37**	.25**	.26**	.09	.24**											
8	General Health	(0.90)	.02	.03	.03	.06	.08*	.18**	.11**										
9	Worry about Health	(0.98)	.06*	.06*	.03	.06*	-.00	-.01	.06	-.42**									
10	Worry that led to Diet Change	(1.05)	.10**	.09**	.02	.14**	.02	.15**	.14**	-.16**	.46**								
11	Informed about Diet-Health	(0.90)	-.01	-.03	-.03	.03	.08*	.23**	.18**	.28**	.01	.18**							
12	Worry about Cancer	(0.99)	.14**	.13**	.05	.11**	-.04	-.03	.03	-.08**	.33**	.30**	-.00						
13	DS Use	(2.11)	-.03	-.01	-.03	.01	.07*	.12**	.11**	.05	.04	.09**	.16**	.07*					
14	Importance of HC on F	(1.17)	.14**	.11**	.04	.16**	.01	.22**	.12**	.04	.16**	.29**	.26**	.12**	.20**				
15	Importance of HC on DS	(1.20)	.11**	.07*	.02	.11**	.06	.11**	.08	.03	.07*	.15**	.18**	.03	.05	.71**			
16	Sex	(0.50)	.00	.03	.00	-.03	.05	.16**	.11**	.06*	-.00	.13**	.17**	.08**	.12**	.14**	.09**		
17	Education	(0.95)	-.08**	-.05	-.02	-.03	.03	.12**	.13**	.21**	-.04	.03	.20**	-.08**	.11**	.00	-.08*	-.05	
18	Age	(0.74)	-.07**	-.06*	-.05	-.09**	-.09*	-.05	-.03	-.01	-.04	-.10**	-.04	-.03	.19**	.00	-.05	.02	-.08**
19	Income	(0.94)	-.05	-.05	-.02	-.03	.05	.06*	.03	.27**	-.06*	.03	.14**	.03	.05*	-.03	-.10**	-.05	.39**
20	Enjoy Taste of Green Tea	(0.49)	.05	.02	.08	.14**	-.03	.18**	.03	-.05	-.08	.00	-.06	-.04	.10*	.02	-.02	-.02	-.02
21	Black, Non-Hispanic	(0.28)	.05	.06*	.01	.09**	-.08*	.08**	-.01	-.02	-.00	.11**	.04	-.04	-.09**	.15**	.14**	.03	-.03
22	Hispanic	(0.23)	.09**	.05*	.02	.06*	-.06	.05	-.02	.01	-.02	.01	-.03	.00	-.03	.02	.01	-.01	-.08**
23	Other, Non-Hispanic	(0.16)	.01	.02	-.01	.04	.03	.09**	.03	.03	-.01	.02	.05*	-.06*	.02	.05	.06	.03	.08**
24	Two + Races, Non-Hispanic	(0.19)	.01	.00	.01	.02	.03	.02	.02	-.03	.02	.01	.02	-.03	.02	.04	.05	-.01	.06*
25	White, Non-Hispanic	(0.40)	-.10**	-.08**	-.02	-.12**	.06	-.13**	-.01	.02	.00	-.09**	-.04	.06*	.06*	-.15**	-.15**	-.02	.01
26	Working	(0.48)	.05	.03	.06*	.07*	.07	.06*	.06	.16**	-.07*	.00	.06*	-.05	-.03	-.01	.02	-.04	.17**

27	Not Working	(0.36)	.05	.06*	.03	.01	-.06	-.03	-.04	-.21**	.15**	.06*	-.04	.03	-.13**	.06*	.05	.03	-.13**
28	Retired	(0.50)	-.08**	-.07**	-.08**	-.07*	-.02	-.04	-.03	-.01	-.05	-.05	-.04	.03	.12**	-.03	-.05	.02	-.07**

Table 9. Correlation Matrix continued…

		SD	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
18	Age																		
19	Income		-.11**																
20	Enjoy Taste of Green Tea		-.01	.04															
21	Black, Non-Hispanic		-.12**	-.11**	.01														
22	Hispanic		-.03	-.05	.08	-.08**													
23	Other, Non-Hispanic		-.04	.06*	.02	-.05	-.04												
24	Two + Races, Non-Hispanic		-.01	-.01	-.03	-.06*	-.05	-.03											
25	White, Non-Hispanic		.12**	.08**	-.05	-.60**	-.49**	-.32**	-.38**										
26	Working		-.43**	.22**	.05	-.00	.00	.04	-.01	-.01									
27	Not Working		-.27**	-.21**	-.04	.07**	.05	.04	.04	-.11**	-.32**								
28	Retired		.61**	-.06*	-.02	-.05	-.04	-.07*	-.02	.09**	-.73**	-.44**							
29	2004 QHC	(0.14)	-.00	.01	.06	-.04	.02	-.01	.01	.01	.01	-.01	-.00						
30	2008 QHC	(0.13)	.00	-.06*	-.00	.02	-.02	-.04	.02	.00	-.03	.01	.02	-.16**					
31	2010 QHC	(0.14)	.02	.02	.06	-.01	.02	.00	.00	-.01	.05*	-.03	-.03	-.16**	-.16**				
32	2005 QHC Prostate Cancer	(0.16)	.00	.03	-.04	.01	.03	.01	-.02	-.01	-.03	-.02	.04	-.17**	-.17**	-.17**			
33	2005 QHC Breast Cancer	(0.13)	-.02	.01	.03	-.02	.04	-.01	.01	-.01	-.01	.07**	-.04	-.16**	-.15**	-.16**	-.17**		
34	2011 QHC	(0.15)	-.03	.01	-.06	.02	-.04	.03	-.03	.01	.03	-.01	-.02	-.17**	-.17**	-.17**	-.19**	-.17**	
35	2012 QHC	(0.14)	.04	-.03	-.05	.02	-.06*	.01	.01	.01	-.02	-.01	.03	-.17**	-.16**	-.17**	-.18**	-.16**	-.18**

* < .05, ** < .01

DS = dietary supplement label; HC = health claim; F = food label; Diet Δ = dietary change

CHAPTER SEVEN
Conclusions and Recommendations

The documented confusion on the part of consumers when faced with QHCs and the apparent reluctance of manufacturers and marketers of products to use the currently enforced QHC's strongly suggests that this system needs to be revised. A more effective QHC system would balance the interests of stakeholders which includes the food and dietary supplement industry, the FDA, and the consumer (Berhaupt-Glickstein & Hallman, 2015).

Qualified health claims are complicated by their two communication objectives. The FDA has attempted several ways to address the challenge of writing QHCs that describe a diet-disease relationship and the partial but credible evidence for the claimed relationship (Derby & Levy, 2005; Food and Drug Administration, 2009). With 36 different approaches to communicate scientific certainty of diet-disease relationships, consumers remain challenged to understand the context for the level of evidence communicated (Berhaupt-Glickstein & Hallman, 2015). The inefficacy of QHCs may be attributed to this implementation, which is not parallel with consumer needs and has limited their use by manufacturers (Fitzgerald Bone & Russo France, 2009).

Our content analysis of 53 QHCs provides baseline data for future research that may evaluate the clarity of currently enforced claims. By understanding the different patterns of language used to communicate scientific evidence in QHCs, researchers can understand which strategies best help consumers understand the level of scientific certainty for a claimed relationship. This information is a first step to ensuring clarity for

consumers and preventing additional lawsuits with the food and dietary supplement industry.

"The fundamental goal for information providers is to present uncertainty in a way that is not overly complicated, yet sufficiently detailed to prompt decision makers to think about the implications of this uncertainty for the decision at hand" (Dieckmann, Peters, Gregory, & Tusler, 2012). Based on the current research, the court-suggested QHC regarding the link between consuming green tea and reductions in the risk of breast and prostate cancers now enforced by FDA appears to achieve this goal (i.e. 2012 FDA QHC). However, while the 2012 FDA green tea QHC is promising, it is a single claim that describes the evidence for the lowest level of scientific support; a D-grade (Berhaupt-Glickstein & Hallman, 2015; Food and Drug Administration, 2009). The greatest challenge with regard to QHCs is communicating one level of evidence within the continuum of scientific certainty in accurate, plain language (Food and Drug Administration, 2009; Hooker & Teratanavat, 2008; Reinhardt-Kapsak, Schmidt, Childs, Meunier, & White, 2008). To inform QHC enforcement, researchers should continue to investigate new strategies to systematically communicate the science to consumers in claims that are also compliant with legal requirements.

In crafting QHCs the FDA must comply with several legal requirements based on case law. The FDA is required to write clear and short claims, with disclaimers (i.e. description of evidence) that do not contradict the claimed relationship, while also providing multiple QHC statements for the same diet–disease relationship so that manufacturers may select that which is most appropriate for their product (Berhaupt-Glickstein, Nucci, Hooker, & Hallman, 2014).

The perceived value of QHCs to these industries is evident by the several federal lawsuits about claim language, and new petitions to FDA to use new QHCs about novel diet-disease relationships. However, even if the clarity of QHCs improves it is unclear whether companies will begin using them on food and dietary supplement product labels. The most recent survey of QHC-eligible products was published in 2009 (Fitzgerald Bone & Russo France, 2009). It is not known if manufacturers have elected to use QHCs that have been revised in response to court rulings on their green tea or other products since that time.

However, perhaps the value of QHCs is not in the claims themselves but rather in the advertising subsequent to FDA's announcement to enforce a QHC for a diet-disease relationship (Fitzgerald Bone & Russo France, 2009). The current research demonstrates that familiarity with the green tea-cancer relationship is predictive of purchase intentions for green tea. This suggests that it may not be necessary to affix a QHC to a label to produce greater sales. Instead, companies may substantially benefit from an increase in the public's awareness of a diet-disease relationship resulting from media coverage, advertising, social media, and word of mouth endorsement of the health benefits of a product triggered by the FDA's enforcement of the QHC. Once aware, the product itself may be an adequate cue to recall a diet-disease relationship.

The importance of seeing health claims on foods was not found to be a predictor of purchase intentions for green tea (Berhaupt-Glickstein, Hooker, & Hallman, In preparation-c), providing further evidence that perhaps awareness of a diet-disease relationship is enough to influence sales. And, there is ample evidence to demonstrate that familiarity with the relationship between the consumption of a dietary substance and

the reduced risk for a disease is a predictor for the purchase of products that contain that substance (Dean et al., 2012; Hasler, 2008; Pothoulaki & Chryssochoidis, 2009; Reinhardt-Kapsak et al., 2008; Saldanha, 2006; Walker Naylor, Droms, & Haws, 2009; Wills, Storcksdieck genannt Bonsmann, Kolka, & Grunert, 2012). Indeed, our research demonstrates that familiarity with the relationship between consumption of green tea and the reduced risk of cancer and past behavior of green tea consumption are strong predictors for future purchase intentions (Berhaupt-Glickstein et al., In preparation-c).

Further, in this study, the group of consumers who already drink green tea had greater intentions to purchase it in the future (Berhaupt-Glickstein et al., In preparation-c). However, there were some similarities and some differences in personal characteristics between older adults who consumed green tea in the past year and those who intend to buy green tea with a QHC in the future (Table 1). Race or ethnicity, a change in diet to address a health concern in the past year, and familiarity with the relationship between green tea and the reduced risk of cancer were relevant predictors in both groups. That is, existing green tea drinkers are more likely to be women who are Black, Hispanic, or from another non-Hispanic racial or ethnic background, who perceive themselves to be informed about diet and health, and are in good health. They are familiar with the green tea-cancer relationship and have made a dietary change in response to a health concern in the past year (Berhaupt-Glickstein & Hallman, In preparation-a). Participants in the study who did not previously drink green tea but reported an intention to purchase a bottle of green tea with a QHC were similarly Black and Hispanic consumers aged 55 to 64 years old, who also made dietary changes to

address their health concerns and consider health claims on dietary supplement labels to be important (Berhaupt-Glickstein et al., In preparation-c).

Different types of consumers have different values with regard to making food decisions and with relation to green tea. The evidence from our study suggests that older adults in our sample rated the evidence correctly, which suggests that the currently enforced QHC from 2012 accurately communicates the level of evidence. And while the claim communicates a low level of evidence, more than half of consumers were slightly likely (or more) to purchase green tea. This represents a potential opportunity for promoters of green tea products to market the added health value of green tea through QHCs.

Knowing the "average consumer" who drinks green tea or intends to purchase green tea (Grunert, Scholderer, & Rogeaux, 2011) (or not) in the presence of a QHC and what influences their decisions provides an opportunity to target specific messages to this population so that they can make informed decisions to reach their health goals. While about half of our sample drank green tea, few drank it to reduce their risk of cancer but rather drank it because they enjoyed the taste. This product-specific attribute was also not associated with future intentions to purchase green tea.

The QHC language does seem to matter in terms of perceptions of evidence and confidence in the green tea-cancer relationship and subsequently, purchase intentions for green tea (Berhaupt-Glickstein et al., In preparation-c). While the exact nature of the claim language that lead to differences in purchase intentions is difficult, if not impossible to pinpoint, the various arguments made by the FDA and the courts about the

language used in different claims seems to hold true. The FDA asserted that the description of evidence in the claims written by the green tea manufacturer, Fleminger, Inc. was inaccurately characterized or was more favorable than the evidence suggested (Fleminger, 2012). In fact, these claims did lead to greater perceptions of evidence, confidence in the claimed relationship, as well as greater purchase intentions (Berhaupt-Glickstein et al., In preparation-c).

The court ruled that the two claims written by the FDA in 2005 about breast cancer and prostate cancer were overly restrictive than necessary since they detailed and characterized the number of studies for each diet-disease relationship (Alliance for Natural Health U.S., 2010). Of the seven QHCs about the green tea-cancer relationship, these two QHCs from 2005 resulted in the lowest ratings of purchase intentions and lowest reported confidence in the claimed relationship (Berhaupt-Glickstein et al., In preparation-c). Further, the currently enforced QHC that was suggested by the federal court appears to be a fair compromise between the interests of the FDA and of the food and supplement industry since it resulted in perceptions of evidence, risk reduction, confidence in the relationship, and purchase intentions that were higher than the other FDA QHCs but also not quite as high as the claims written by Fleminger, Inc. (Berhaupt-Glickstein & Hallman, In preparation-b; Berhaupt-Glickstein et al., In preparation-c). These results highlight the importance of FDA's regulation of QHCs.

Indeed, the language does matter. However, our research did not support some of the other assertions between the FDA and Fleminger, Inc. For example, the inclusion of "FDA" in a QHC did not clearly lead consumers to believe that the government required the claim on a product label which was an assertion made by the FDA in response to an

illegal QHC made by the green tea manufacturer (Berhaupt-Glickstein & Hallman, In preparation-b). However, again, it is not possible to depict the exact claim language that led to participant responses. Further, the tipping point of the debate between FDA and the green tea manufacturer was a claim written by FDA that outright stated the agency did not agree with the claim of the green tea-cancer relationship (Fleminger, 2012). Fleminger, Inc. argued that this statement by the agency directly negated the claim of the relationship between green tea and the reduced risk of cancer. Yet, consumers in the current study understood the opposite meaning, such that the majority thought the claim (i.e. 2011 FDA QHC) suggested that the green tea-cancer relationship was effective (Berhaupt-Glickstein & Hallman, In preparation-b).

The federal lawsuit, Pearson v. Shalala, requires that FDA regulate QHCs on dietary supplement and food labels (Food and Drug Administration, 2011) to prevent consumer confusion about the scientific certainty for diet-disease relationships that are supported by partial but credible evidence (Berhaupt-Glickstein et al., 2014). While there has been considerable effort on the part of the food and dietary supplement industry to push for claim language that is less technical and by the FDA to detail the level of scientific certainty in QHCs, there is a need for further research to create an efficient and efficacious health claims regulatory system.

Our research examines the legal history and the claim language, and the arguments and assertions surrounding the green tea lawsuit, which echo the challenges immediate to the QHC system as a whole. Overall, we found little cohesion in terms of communicating scientific certainty in QHCs but that when presented with a D-grade claim, consumers are able to distinguish the level of evidence and some would consider

purchasing a product with that QHC (Berhaupt-Glickstein et al., In preparation-c). However, the literature demonstrates that QHCs of different levels of scientific certainty lead to confusion among consumers (Derby & Levy, 2005; Hooker & Teratanavat, 2008; Reinhardt-Kapsak et al., 2008). Therefore, research recommendations are offered with the goal of improving the efficiency and efficacy of the health claims system.

Assuming no Congressional action or further adjudication on the issue of qualified health claims, some research recommendations:

- Survey QHC-eligible products for which there have been lawsuits to understand whether the revised claims have encouraged companies to use them on food and dietary supplement labels. An increased use of QHCs would suggest that they benefit the manufacturer in sales and/or competition. The most recent survey of eligible products that use QHCs was published in 2009. Since then, there have two court rulings about QHCs for green tea and selenium that perhaps increased their use by companies.
- Test the currently enforced D-level green tea QHCs with respect to QHCs of different evidence levels with measures of interest for the FDA and for the food and dietary supplement industry, including: perceived level of evidence, perceived health benefit(s), understanding of evidence within the continuum or scale, purchase intentions for products bearing QHCs.
- Similarly, test the 53 currently enforced QHCs with respect to measures of interest for the FDA and for the food and dietary supplement industry, including: perceived level of evidence, perceived health benefit(s), understanding of evidence within the continuum or scale, purchase intentions for products bearing

QHCs. Many of these claims resulted from lawsuits and should be evaluated for their ability to comply with the court rulings. Perhaps determine the best QHC language to communicate scientific certainty and eliminate claims and language that misleads consumers.

- Test the scale of evidence created by the World Cancer Research Fund, used by the World Health Organization, suggested by the industry lawyers, and tested in South Korea: insufficient, possible, probable, convincing. These alternative claims may also be tested with measures of interest for the FDA and for the food and dietary supplement industry, meaning: perceived evidence, perceived health benefit(s), understanding of evidence within the continuum or scale, purchase intentions for products bearing QHCs. Since the Pearson II lawsuit requires that FDA make more than one QHC available for a single diet-disease relationship, this scale may offer an alternative to the existing strategies (Berhaupt-Glickstein et al., 2014).
- Test QHCs that offer a frame of reference or context that there are other levels evidence or the continuum of evidence. Past research did not yield a frame of reference that suited consumers. Since consumers are challenged to understand science-based information without a sufficient educational background (Norman & Skinner, 2006), perhaps a framework or context would improve understanding of the evidence in a QHC.

Table 1. Characteristics that predict the odds of consuming green tea and predict the likelihood of future purchase intentions for green tea.

	Green Tea Consumer	
	Existing	New
Race or ethnicity	Y	Y
Age	N	Y
Sex	Y	N
Health status	Y	N
Perceived nutrition knowledge	Y	N
Diet change for health worry	Y	Y
Familiarity with diet-disease relationship	Y	Y

Note: Existing: consumers who already drink green tea. New: consumers who intend to buy green tea and do not already consume it.

References

Abbatangelo-Gray, J., Byrd-Bredbenner, C., & Byrn Austin, S. (2008). Health and nutrient content claims in food advertisements on hispanic and mainstream prime-time television. *Journal of Nutrition Education and Behavior*, *40*, 348-354.

Academy of Nutrition and Dietetics. (2011). Nutrition and you: Trends 2011
Public opinion on food and nutrition: 20 years of insights. Retrieved from http://www.eatright.org/media/content.aspx?id=7639

Alliance for natural health U.S. v. sebelius, 714 F.supp.2d 48 (2010), 2010).

Alliance for natural health U.S. v. sebelius, 786 F.supp.2d 1 (2011), 2011).

Alster, N. (2004, March 28, 2004). New food labels winning few fans. *New York Times*, pp. Business.

American Cancer Society. (2015a). Cancer facts and figures 2015. Retrieved from http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/index

American Cancer Society. (2015b). Common questions about diet and cancer. Retrieved from http://www.cancer.org/healthy/eathealthygetactive/acsguidelinesonnutritionphysicalactivityforcancerprevention/acs-guidelines-on-nutrition-and-physical-activity-for-cancer-prevention-common-questions

Baglione, S. L., Tucci, L. A., & Stanton, J. L. (2012). Self-reported nutritional knowledge and the acceptance of health-related food benefit claims. *British Food Journal, 114*(4), 453-468.

Balluz, L. S., Kieszak, S. M., Philen, R. M., & Mulinare, J. (2000). Vitamin and mineral supplement use in the united states. results from the third national health and nutrition examination survey. *Archives of Family Medicine*, *9*(3), 258-262.

Barreiro-Hurle, J., Gracia, A., & de-Magistris, T. (2010). Does nutrition information on food products lead to healthier food choices? *Food Policy*, *35*, 221-229.

Bass, S. (Ed.). (2011). *Dietary supplement regulation: A comprehensive guide*. Washington, DC: Food and Drug Law Institute.

Berhaupt-Glickstein, A., & Enrione, E. (2011). Functional foods: Perceptions, attitudes, and practices of registered dietitians. *Topics in Clinical Nutrition, 26*(4), 312-323.

Berhaupt-Glickstein, A., & Hallman, W. K. (2015). Communicating scientific evidence in qualified health claims. *Critical Reviews in Food Science and Nutrition, Forthcoming*

Berhaupt-Glickstein, A., & Hallman, W. K. (In preparation-a). *What are the sociodemographic and psychographic characteristics of older adults who drink green tea?* Unpublished manuscript.

Berhaupt-Glickstein, A., & Hallman, W. K. (In preparation-b). Green tea and cancer: An investigation of contested qualified health claims.

Berhaupt-Glickstein, A., Hooker, N. H., & Hallman, W. K. (In preparation-c). Does the language matter in qualified health claims? A case study of purchase intentions for green tea.

Berhaupt-Glickstein, A., Nucci, M. L., Hooker, N. H., & Hallman, W. K. (2014). The evolution of language complexity in qualified health claims. *Food Policy, 47*, 62-70.

California Walnuts. (2005). An essential food for health. Retrieved from http://www.walnutinfo.com/resources/newsletters/walnuthealth.pdf

Center for Science in the Public Interest. (2007). Congress tells FDA to tighten standards for health claims. Retrieved from http://www.cspinet.org/new/200712203.html

Centers for Disease Control and Prevention, National Center for Health Statistics. (2004). National health and nutrition examination survey questionnaire (or examination protocol, or laboratory protocol). Retrieved from http://appliedresearch.cancer.gov/archive/usualintakes/FFQ.English.June0304.pdf

Centers for Medicare and Medicaid Services. (2012a). Part 2: Using a reader-centered approach to develop and test written material. Retrieved from http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/Downloads/ToolkitPart02.pdf

Centers for Medicare and Medicaid Services. (2012b). Part 7: Using readability formulas: A cautionary note. in: Toolkit for making written material clear and effective. Retrieved from http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/Downloads/ToolkitPart07.pdf

Chena, X., Jahnsa, L., Gittelsohna, J., & Wanga, Y. (2011). Who is missing the message? targeting strategies to increase food label use among US adults. *Public Health Nutrition, 15*(5), 760-772.

Consumers Union. (1986, What has all-bran wrought? *Consumer Reports*, *51*, 638.

Contento, I. R. (2007). *Nutrition education: Linking research, theory, and practice*. Sudbury, Massachusetts: Jones and Bartlett Publishers.

Contini, C., Casini, L., Stefan, V., Romano, C., Jørn Juhl, H., Lähteenmäki, L., . . . Grunert, K. G. (2015). Some like it healthy: Can socio-demographic characteristics

serve as predictors for a healthy food choice? *Food Quality and Preference*, *46*, 103-112.

Council for Responsible Nutrition. (2015). The CRN consumer survey on dietary supplements: 2013. Retrieved from http://www.crnusa.org/consumersurvey/

Cox, D. N., Evans, G., & Lease, H. J. (2011). The influence of product attributes, consumer attitudes and characteristics on the acceptance of: (1) novel bread and milk, and dietary supplements and (2) fish and novel meats as dietary vehicles of long chain omega 3 fatty acids. *Food Quality and Preference*, *22*, 205-212.

Crowell, A., & Schunn, C. (2013). Scientifically literate action: Key barriers and facilitators across context and content. *Public Understanding of Science*, *23*(6), 718-733.

Dean, M., Lampilaa, P., Shepherd, R., Arvola, A., Saba, A., Vassallo, M., & Claupein, E. (2012). Perceived relevance and foods with health-related claims. *Food Quality and Preference*, *24*, 129-135.

Derby, B. M., & Levy, A. (2005). Working paper: Effects of strength of science disclaimers on the communication impacts of health claims (2005). Retrieved from http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf

Pom wonderful pretrial brief: Corrected copy, 2011).

Dieckmann, N. F., Peters, E., Gregory, R., & Tusler, M. (2012). Making sense of uncertainty: Advantages and disadvantages of providing an evaluative structure. *Journal of Risk Research*, *15*(7), 717-735.

Dobrenova, F., & Terlutter, R. (2015). The effect of familiarity on consumer ratings of the scientific support of health claims on food. *Journal of Food Products Marketing, Online*, 1-19.

Dodds, R. L., Tseelon, E., & Weitkamp, E. L. C. (2008). Making sense scientific claims in advertising. A study of scientifically aware consumers. *Public Understanding of Science*, *17*, 211-230.

Elo, S., & Kyngas, H. (2007). The qualitative content analysis process. *Journal of Advanced Nursing*, *62*(1), 107-108-115.

Emord, J. W. (2000). Pearson v. shalala: The beginning of the end for fda speech suppression. *Journal of Public Policy & Marketing*, *19*(1), 139.

Emord, J. W., & Schwitters, B. (2012). Do qualified health claims deceive when they are not misleading? perspectives from the european union and united states. *Food and Drug Policy Forum*, *2*(12), 1.

European Food Information Council. (2015). Can health claims and symbols lead to healthier eating habits? Retrieved from http://www.eufic.org/jpage/en/page/PRESS/fftid/clymbol-healthclaims-symbols/

Federal Trade Commission. (2006). *In the matter of assessing consumer perceptions of health claims.* (Public Meeting; Request for Comments No. Docket No. 2005N-0413).

Ferrer, R. A., Bergman, H. E., & Klein, W. M. P. (2013). Worry as a predictor of nutrition behaviors: Results from a nationally representative survey. *Health Education & Behavior, 40*(1), 88-89-96.

Fitzgerald Bone, P., Kees, J., France, K. R., & Kozup, J. (2012). Consumer confusion: A lose/lose situation [Abstract]. *Marketing and Public Policy Conference Proceedings*, 132-133.

Fitzgerald Bone, P., & Russo France, K. (2009). Qualified health claims on package labels. *Journal of Public Policy & Marketing, 28*(2), 253-258.

Fleminger, inc. v US department of health and human services, 2012).

Food and Drug Administration. (2000a). Letter regarding dietary supplement health claim for fiber with respect to colorectal cancer (docket no. 91N-0098). Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073181.htm

Food and Drug Administration. (2000b). Letter regarding dietary supplement health claim for folic acid with respect to neural tube defects (docket no. 91N-100H). Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealth-Claims/ucm073058.htm

Food and Drug Administration. (2003a). **Claims that can be made for conventional foods and dietary supplements**. Retrieved from http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm

Food and Drug Administration. (2003b). Guidance for industry: Interim procedures for qualified health claims in the labeling of conventional human food and human dietary supplements. Retrieved from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm

Food and Drug Administration. (2003c). Guidance: Interim evidence-based ranking system for scientific data. Retrieved from http://www.fda.gov/ohrms/dockets/dailys/03/Aug03/080103/03n-0069-rpt0001-04-Attachment-b-vol4.pdf

Food and Drug Administration. (2005a). Letter responding to health claim petition dated january 27, 2004: Green tea and reduced risk of cancer health claim (docket number 2004Q-0083). Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm252297.htm

Food and Drug Administration. (2005b). Q&A: QHCs in food labeling – draft report on effects of strength of science disclaimers on the communication impacts of health claims. Retrieved from http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm

Food and Drug Administration. (2009a). Experimental study of qualified health claims: Consumer inferences about monounsaturated fatty acids from olive oil, EPA and DHA omega-3 fatty acids, and green tea. OMB no. 0910-0952. Retrieved from http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207549.htm

Food and Drug Administration. (2009b). Food labeling guide. Retrieved from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm

Food and Drug Administration. (2009c). Qualified health claims: Letters of denial. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072751.htm

Food and Drug Administration. (2009d). Questions and answers: Qualified health claims in food labeling - draft report on effects of strength of science disclaimers on the communication impacts of health claims. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm109470.htm

Food and Drug Administration. (2011a). **Consumer health information for better nutrition initiative: Task force final report**. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/QualifiedHealthClaimsPetitions/ucm096010.htm

Food and Drug Administration. (2011b). Experimental study of health claims on food packages: Preliminary topline frequency report (2007). Retrieved from http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm275985.htm

Food and Drug Administration. (2011c). Guidance for industry: Evidence-based review system for the scientific evaluation of health claims - final. Retrieved from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm

Food and Drug Administration. (2011d). Letter responding to health claim petition dated january 27, 2004: Green tea and reduced risk of cancer health claim (docket number FDA-2004-Q-0427). Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072774.htm

Food and Drug Administration. (2011e). Letter responding to health claim petition dated january 27, 2004: Green tea and reduced risk of cancer health claim (docket number FDA-2004-Q-0427). Retrieved from http://www.fda.gov/Food/ LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072774.htm

Food and Drug Administration. (2011f). PART 101 -- FOOD LABELING: Subpart E--specific requirements for health claims. sec. 101.70 petitions for health claims. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.70

Food and Drug Administration. (2011g). **Summary of qualified health claims subject to enforcement discretion**. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073992.htm#nuts

Food and Drug Administration. (2012a). Alliance for natural health v. sebelius, case no. 09-1546 (D.D.C.). Retrieved from http://www.fda.gov/Food/LabelingNutrition/ LabelClaims/QualifiedHealthClaims/ucm306866.htm

Food and Drug Administration. (2012b). **CFSAN - what we do**
. Retrieved from http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm

Food and Drug Administration. (2012c). **Letter updating the green tea and risk of breast cancer and prostate cancer health claim april 17, 2012**. Retrieved from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm301644.htm

Food and Drug Administration. (2013a). **Consumer health information for better nutrition initiative - attachment D - consumer studies research agenda**. Retrieved from http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm096079.htm

Food and Drug Administration. (2013b). Guidance for industry: A food labeling guide (appendix C: Health claims). Retrieved from http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064919.htm

Food and Drug Administration. (2014). **Guidance for industry: A food labeling guide (8. claims)**. Retrieved from http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064908.htm#health

Food and Drug Administration. (2015). 2002 diet and health survey: Topline frequency report. Retrieved from http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm202786.htm#sectr

Food Marketing Institute. (2013). Shopping for health 2013. Retrieved from http://www.fmi.org/industry-topics/health-wellness/shopping-for-health-2013/2013/06/25/prevention-magazine-and-food-marketing-institute-release-21st-annual-shopping-for-health-survey-results

Food Standards Australia New Zealand: Te Mana Kounga Kai – Ahitereiria me Aotearoa. (2012). *Nutrition, health & related claims.* (No. Review Report - Proposal P 293).

France, K. R., & Fitzgerald Bone, P. (2009). Conveying level of science: Tests of iconic and comparative formats. *Marketing Letters, 20*, 385. doi:10.1007/s11002-009-9081-6

Freimuth, V. S., Hammond, S. L., & Stein, J. A. (1988). **Health advertising: Prevention for profit**. *American Journal of Public Health, 78*(5), 557-561.

Gilbert, L. (2000). Marketing functional foods: How to reach your target audience. *AgBioForum, 3*(1), 20.

Glanz, K., Rimer, B. K., & Viswanath, K. (Eds.). (2008). *Health behavior and health education: Theory, research, and practice* (4th ed.). San Francisco, CA: Jossey-Bass.

Government Accountability Office. (2011). *Food labeling: FDA needs to reassess its approach to protecting consumers from false or misleading claims.* (No. GAO-11-102).

Govindasamy, R., & Italia, J. (1999). *Evaluating consumer usage of nutritional labeling: The influence of socio-economic characteristics.* (No. P-02137-1-99).

Gray, N. (2012). EU project to test how well health claims are understood by consumers. nutra-ingredients. Retrieved from http://www.nutraingredients.com/Research/EU-project-to-test-how-well-health-claims-are-understood-by-consumers?utm_source=copyrightutm_medium=OnSiteutm_campaign=copyright

Gray, S. L., Hanlon, J. T., Fillenbaum, G. G., Wall, W. E.,Jr, & Bales, C. (1996). Predictors of nutritional supplement use by the elderly. *Pharmacotherapy, 16*(4), 715-720.

Grocery Manufacturers Association. (2003). FDA qualified health claim rules could help consumers make more informed food choices. GMA urges agency to reject required language for claims. Retrieved from http://www.thefreelibrary.com/FDA+Qualified+Health+Claim+Rules+Could+Help+Consumers+Make+Informed...-a0105077262

Grunert, K. G., Scholderer, J., & Rogeaux, M. (2011). Determinants of consumer understanding of health claims. *Appetite, 56*, 269-277.

Hasler, C. M. (2008). Health claims in the united states: An aid to the public or a source of confusion? *The Journal of Nutrition, 138*, 1216S-1220S.

Hilgartner, S., & Nelkin, D. (1987). Communication controversies over dietary risks. *Human Values, 12*(3&4), 41-47.

Hooker, N. H., & Teratanavat, R. (2008). Dissecting qualified health claims: Evidence from experimental studies. *Critical Reviews in Food Science and Nutrition, 48*(2), 160-176. doi:10.1080/10408390601177704

Hooker, N. H. (2007). Complex food labels- the move from binary to scale messages [Abstract].

Institute of Medicine of the National Academies. (2010). ***Examination of front-of-package nutrition rating systems and symbols: Phase 1 report***. (Food and Nutrition).

Institute of Medicine of the National Academies. (2011). Child and adult care food program: Aligning dietary guidance for all. chapter 6: Process for developing recommendations for meal requirements., 1-296.

International Food Information Council. (2011). **2011 functional foods/foods for health consumer trending survey**. Retrieved from http://www.foodinsight.org/Resources/Detail.aspx?topic=2011_Functional_Foods_Foods_For_Health_Consumer_Trending_Survey

International Food Information Council. (2013). 2013 food & health survey. Retrieved from http://www.foodinsight.org/LinkClick.aspx?fileticket=34E2C49BOcc%3d&tabid=1480

International Food Information Council. (2015). 2015 what's your health worth? Retrieved from

http://www.foodinsight.org/sites/default/files/2015%20Food%20and%20Health%20Survey%20-%20FINAL.pdf

International Food Information Council, Academy of Nutrition and Dietetics. (2011). A place on the plate for functional foods: Helping consumers achieve optimal health with diet. Retrieved from http://www.foodinsight.org/Content/3842/REVISED%20ADA%20Functional%20Foods%20Webcast%20Deck%207.26.2011%20V2.pdf

Ippolito, P. M., & Mathios, A. D. (1993). New food labeling regulations and the flow of nutrition information to consumers. *Journal of Public Policy & Marketing, 12*(2), 188-205.

Ippolito, P. M. (1999). How government policies shape the food and nutrition information environment. *Food Policy, 24*, 295-306.

Ippolito, P. M., & Mathios, A. D. (1990). Information, advertising and health choices: A study of the cereal market. *The RAND Journal of Economics, 21*(3), 459-480.

Johnson, G. H. (2007). Benefits of health claims to consumers and the industry. *Beneath the Hull: Exploiting the Health-Beneficial Properties of the Rice Grain.* New Orleans, LA.

Kavanaugh, C. J., Trumbo, P. R., & Ellwood, K. C. (2007). The U.S. food and drug administration's evidence-based review for qualified health claims: Tomatoes, lycopene, and cancer. *Journal of the National Cancer Institute, 99*, 1074.

Kiesel, K., McCluskkey, J., & Villas-Boas, S. (2011). Nutritional labeling and consumer choices. *Annual Review of Resource Economics, 3*, 141.

Kim, J. Y., Kang, E. J., Kwon, O., & Kim, G. H. (2010). Korean consumers' perceptions of health/functional food claims according to the strength of scientific evidence. *Nutrition Research and Practice, 4*(5), 428-432. doi:10.4162/nrp.2010.4.5.428

King, D. E., Matheson, E., Chirina, S., Shankar, A., & Broman-Fulks, J. (2013). Research letter: The status of baby boomers' health in the united states: The healthiest generation? *JAMA Internal Medicine*, , E1-E2. doi:10.1001/jamainternmed.2013.2006

Koponen, A., Sandell, M., Salminen, S., & Lenoir-Wijnkoop, I. (2012). Nutrition economics: Towards comprehensive understanding of the benefits of nutrition. *Microbial Ecology in Health and Disease, 23*, 46-50.

Lahteenmaki, L. (2012). Claiming health in food products. *Food Quality and Preference, 27*(2), 196–201.

Lalor, F., & Wall, P. G. (2011). Health claims regulations: Comparison between USA, japan and european union. *British Food Journal, 113*(2), 298-313.

Leatherhead Food Research. (2011). Market report: Future directions for the global functional foods market. Retrieved from http://www.leatherheadfood.com/UserFiles/pdfs/publicationspromopdf/Functional-Directions-for-the-Global-Functional-Foods-Market-2011.pdf

Lepkowska-White, E., & Parsons, A. L. (2001). Comprehension of warnings and resulting attitudes. *The Journal of Consumer Affairs, 35*(2), 278.

Levy, A., & Stokes, R. (1987). Effects of a health promotion advertising campaign on sales of ready-to-eat cereals. *Public Health Reports, 102*(4), 398.

Lin, J. C. (2008). How do consumers interpret health messages on food labels? *Nutrition Today, 43*(6), 267-272.

Lugard, M. (2012). EU health claims regulation. *, CRN's Annual Symposium for the Dietary Supplement Industry. October 4*

Lytton, T. (2010). Banning front-of-package food labels: First amendment constraints on public health policy. *Public Health Nutrition, 14*, 1123-1126.

Mazis, M. B., & Raymond, M. A. (1997). Consumer perceptions of health claims in advertisements and on food labels. *Journal of Consumer Affairs, 31*(1), 10-26.

McColl, D., & Bump, C. (2005, Qualified health claims: Creatures of case law. *Update Magazine, November/December*, 33.

Merriam-Webster. (2015). Negate. Retrieved from http://www.merriam-webster.com/dictionary/negate

Michie, S., & Lester, K. (2005). Words matter: Increasing the implementation of clinical guidelines. *Quality & Safety in Health Care, 14*(5), 367-370. doi:10.1136/qshc.2005.014100

Murphy, J. (2013, P&G pursues qualified health claim for psyllium husk, reduced risk of diabetes. *Food Chemical News, ,* 54.

Naes, T., Kubberod, E., & Sivertsen, H. (2001). Identifying and interpreting market segments using conjoint analysis. *Food Quality and Preference, 12*, 133-143.

Nagler, R. H. (2014). Adverse outcomes associated with media exposure to contradictory nutrition messages. *Journal of Health Communication, 19*, 24-40.

National Archives and Records Administration. (2012). Title 21: Food and drugs: PART 101—Food labeling. Retrieved from http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;rgn=div5;view=text;node=21%3A2.0.1.1.2;idno=21;sid=64fa2cdef4ee54e80414c2f297540271;cc=ecfr

National Cancer Institute. (2015). Questions and answers about green tea. Retrieved from http://www.cancer.gov/about-cancer/treatment/cam/patient/prostate-supplements-pdq/#section/_175

National Research Council (US) Panel on Race, Ethnicity, and Health in Later Life. (2004). 12, racial/ethnic disparities in health behaviors: A challenge to current assumptions.
. In N. Anderson, R. Bulatao & B. Cohen (Eds.), *Critical perspectives on racial and ethnic differences in health in late life.* (). Washington (DC): National Academies Press.

Neiner, R. (2012). Council for responsible nutrition consumer survey on dietary supplements. *, CRN's Annual Symposium for the Dietary Supplement Industry, October 4*

Nestle, M. (2002). In Goldstein D. (Ed.), *Food politics*. Berkeley, California: University of California Press.

Nielsen. (2012). A nielsen report: Battle of the bulge & nutrition labels healthy eating trends around the world. Retrieved from http://no.nielsen.com/site/documents/NielsenGlobalHealthyEatingReportJan2012FINAL.PDF

Nielsen, & National Marketing Institute. (2014). *Health and wellness in america, august 2014.* ().

Nocella, G., & Kennedy, O. (2012). Food health claims – what consumers understand. *Food Policy, 37*, 571.

Norman, C. D., & Skinner, H. A. (2006). eHealth literacy: Essential skills for consumer health in a networked world. *Journal of Medical Internet Research8, 8*(2), Online.

Office of Information and Regulatory Affairs. (2015). Frequently asked questions: Regulations and the rulemaking process. Retrieved from http://www.reginfo.gov/public/jsp/Utilities/faq.jsp

Pearson v. shalala, 130 F.supp.2d 105, 1 2001).

Pearson, D., & Shaw, S. (1998). Pearson vs. shalala, 14 F.supp.2d 10., 1.

Pearson v. shalala, 164 F. 3d 650, 1 1999).

Pothoulaki, M., & Chryssochoidis, G. (2009). Health claims: Consumers' matters. *Journal of Functional Foods, 1*(2), 222-228.

Reinhardt Kapsak, W., Rahavi, E. B., Childs, N. M., & White, C. (2011). Functional foods: Consumer attitudes, perceptions, and behaviors in a growing market. *Journal of the American Dietetic Association, 111*(6), 804-810. doi:10.1016/j.jada.2011.04.003

Reinhardt-Kapsak, W., Schmidt, D., Childs, N. M., Meunier, J., & White, C. (2008). Consumer perceptions of graded, graphic and text label presentations for qualified health claims. *Critical Reviews in Food Science and Nutrition, 48*(3), 248-256. doi:10.1080/10408390701286058

Roe, B., Levy, A., & Derby, B. M. (1999). The impact of health claims on consumer search and evaluation outcomes: Results from FDA experimental data. *Journal of Public Policy & Marketing, 18*(1), 89-105.

Saldanha, L. G. (2006). The qualified health claims quandry. *Nutrition Today, 41*(2), 54-55.

Samavat, H., Dostal, A. M., Wang, R., Bedell, S., Emory, T. H., Ursin, G., . . . Kurzer, M. S. (2015). The minnesota green tea trial (MGTT), a randomized controlled trial of the efficacy of green tea extract on biomarkers of breast cancer risk: Study rationale, design, methods, and participant characteristics. *Cancer Causes Control*, doi:10.1007/s10552-015-0632-2

Sanaullah Khan, R., Grigor, J., Winger, R., & Win, A. (2013). Functional food product development – opportunities and challenges for food manufacturers. trends. *Trends in Food Science and Technology*, *30*, 27–37.

Schneeman, B. (2012). *Evaluating the science behind health claims: U.S. perspective. experimental biology conference 2012: Establishing and evaluating health claims for probiotics.*

Seely, D., Mills, E. J., Wu, P., Verma, S., & Guyatt, G. H. (2005). The effects of green tea consumption on incidence of breast cancer and recurrence of breast cancer: A systematic review and meta-analysis. *Integrative Cancer Therapies, 4*(2), 144-155.

Shiu, E. M. K., Walsh, G., Hassan, L. M., & Shaw, D. (2011). Consumer uncertainty, revisited. *Psychology & Marketing*, *28*(6), 584-585-607.

Singh, B. N., Shankar, S., & Srivastavaa, R. K. (2011). Green tea catechin, epigallocatechin-3-gallate (EGCG): Mechanisms, perspectives and clinical applications. *Biochemical Pharmacology, 82*, 1807–1821.

Slesinski, M. J., Subar, A. F., & Kahle, L. L. (1995). Trends in use of vitamin and mineral supplements in the united state: The 1987 and 1992 national health interview surveys. *Journal of the American Dietetic Association, 95*(8), 921-923.

Sloan, E. A. (2012). Top 10 functional food trends. institute of food technologists. Retrieved from http://www.ift.org/food-technology/past-issues/2012/april/features/top-10- functional-food-trends.aspx?page=viewall

Spring, B., Moller, A. C., & Coons, M. J. (2012). Multiple health behaviors: Overview and implications. *Journal of Public Health, 34*(Supplement 1), i3–i10. doi:10.1093/pubmed/fdr111

Starling, S. (2008). Qualified health claims draw more heat. Retrieved from http://www.nutraingredients-usa.com/news/ng.asp?id=83968

Taylor, M. R. (1995). FDA's public health goals in evaluating health claims. *Critical Reviews in Food Science and Nutrition, 35*(1-2), 1-5.

Taylor, M. R. (2010, How the FDA is picking its food label battles. *The Atlantic,*

Tea Association of the USA, Inc. (2014). Tea fact sheet - 2014. Retrieved from http://www.teausa.com/14655/tea-fact-sheet

Villafranco, J. E., Pippins, R. R. & Wolff, K. L. (2011). Working together: Growing FTC, FDA collaboration. nutritional outlook. Retrieved from http://www.kelleydrye.com/publications/articles/1485/_res/id=Files/index=0/Villafranco_Pippins_Wolff_Working%20Together_Nutritional%20Outlook_%20May%202011.pdf

Walker Naylor, R., Droms, C. M., & Haws, K. L. (2009). Eating with a purpose: Consumer response to functional food health claims in conflicting versus complementary information environments. *Journal of Public Policy & Marketing, 28*(2), 221-233.

Wang, C., O'Neill, S. M., Rothrock, N., Gramling, R., Sen, A., Acheson, L., S., . . . Ruffin IV, Mack T. for the Family Healthware Impact Trial (FHITr) group. (2009). Comparison of risk perceptions and beliefs across common chronic diseases. *Preventive Medicine, 48,* 197-202.

Wansink, B., Sonka, S. T., & Hasler, C. M. (2004). Front-label health claims: When less is more. *Food Policy, 29,* 659.

Watson, E. (2012). ConAgra to FDA: There is 'ample evidence' to support qualified health claim on whole grains and type II diabetes. food navigator-USA. Retrieved from http://www.foodnavigator-usa.com/Regulation/ConAgra-to-FDA-There-is-

ampleevidence-to-support-qualified-health-claim-on-whole-grains-and-type-IIdiabetes

Julian M. whitaker, M.D. v tommy G. thompson, secretary, department of health and human services, 239 F.supp.2d 43, 1 2003).

Williams, P. (2005). Consumer understanding and use of health claims for foods. *Nutrition Reviews, 63*(7), 256-264.

Wills, J. M., Storcksdieck genannt Bonsmann, S., Kolka, M., & Grunert, K. G. (2012). Symposium 2: Nutrition and health claims: Help or hindrance european consumers and health claims: Attitudes, understanding and purchasing behaviour. *Proceedings of the Nutrition Society, 71*, 229.

World Health Organization. (2003). *Diet, nutrition and the prevention of disease of chronic diseases.* (WHO Technical Report Series No. 916). Geneva, Switzerland: WHO Library Cataloguing-in-Publication Data.

Yamada, K., Sato-Mito, N., Nagata, J., & Umegaki, K. (2008). Health claim evidence requirements in japan. *Journal of Nutrition, 138*, 1192S–1198S.