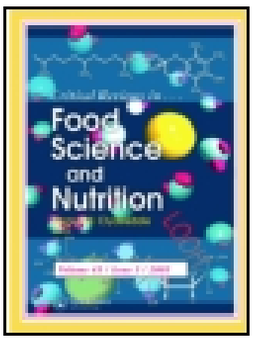

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Amanda Berhaupt-Glickstein & William K Hallman

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Communicating Scientific Evidence in Qualified Health Claims

Amanda Berhaupt-Glickstein[a], William K Hallman[b]

Rutgers University, New Brunswick, United States

[a]Corresponding author Email: amanda.berhaupt@gmail.com

[b]Corresponding author Email: hallman@rci.rutgers.edu

Abstract

Qualified health claims (QHCs) are found on food and dietary supplement labels and aim to communicate the quality and strength of scientific evidence for a diet-disease relationship. Since the evidence varies for diet-disease relationships, the language to describe the evidence also varies. However, research indicates that consumers misinterpret QHCs as a whole product evaluation. The FDA is reviewing the evidence ranking system for QHCs and the current study aims to inform future consumer research. A content analysis examined the language used to convey scientific evidence in 53 QHCs and organized them into an intrinsic scale of evidence. Results revealed 36 formats to present the evidence in 53 QHCs. seventy-seven percent (n=41) demonstrate a reading level above 9th grade. Most claims describe the quality of evidence (n=51, 96%) ("very weak") and/or reference its consistency (n=41, 77%), while a quarter (n=13) also quantify the evidence ("two studies"). Twenty-five claims (47%) present the evidence before stating the diet-disease relationship. There is an absence of a systematic description of evidence among QHCs that may contribute to the misleading, albeit unintentional, nature of these claims. Policymakers might consider reforming QHC regulations so that a hierarchy of evidence for diet-disease relationships is clearly communicated to consumers.

Keywords

functional food

Food and Drug Administration

marketing

regulation

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), a significant burden is placed on the FDA 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 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 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. >12th grade). The average F-K score for all QHCs is 12th 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. ≥ 10th grades), nine (17%) as average (i.e. 7th-9th grades), and only three (< 1%) as easy (4th-6th 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.

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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	Some scientific evidence suggests

		first, followed by the diet-disease relationship	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	F	17.12	---	Embedded	Qualitative	C, R

	nutrition information for fat content.]						
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	F	19.78	---	Embedded	Qualitative	C, R

	information for fat [and calorie] content.						
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	F, DS	11.47	---	Embedded	Qualitative	C, R

	nutrition information for total fat, saturated fat, and cholesterol content.]						
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	F	22.17	✓	Point-counterpoint	Qualitative	Q, C, R

	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.						
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	DS	9.95	✓	Point-counterpoint	Qualitative	Q, C, R

	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.						
C	**Selenium** may produce anticarcinogenic effects in the body. Some scientific evidence	DS	14.25	✓	Point-counterpoint	Qualitative	Q, C, R

	suggests that consumption of selenium may produce **anticarcinogenic effects** in the body. However, FDA has determined that this evidence is limited and not conclusive.						
C	Some scientific evidence suggests that consumption of **antioxidant vitamins** may reduce the risk of certain forms of **cancer**.	DS	11.89	✓	Embedded	Qualitative	Q, C, R

	However, FDA has determined that this evidence is limited and not conclusive.						
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	DS	11.58	✓	Embedded	Qualitative	Q, C, R

	conclusive.						
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,	DS	16.93	✓	Point-counterpoint	Qualitative	

	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.						
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	F	13.64	---	Embedded	Qualitative	Q, C, R

	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.						
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	F	13.95	---	Embedded	Qualitative	Q, C, R

	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 calories you eat in a day. One serving of this product contains [x] grams of canola oil.						
D	Two weak studies and one	DS	11.86	✓	Embedded	Mixed model	Q, C, R

	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.						
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	DS	11.96	✓	Point-counterpoint	Qualitative	Q, C, R

	concluded that there is very little scientific evidence for this claim.						
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**.	DS	8.88	✓	Embedded	Mixed model	Q, C, R

	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.						
D	**Vitamin E** may reduce the risk of **bladder cancer** although the FDA has concluded that there is very	DS	11.96	✓	Point-counterpoint	Qualitative	Q, C, R

	little scientific evidence for this claim.						
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**	DS	11.70	✓	Embedded	Mixed model	Q, C, R

	cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer.						
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	DS	6.94	✓	Point-	Qualitativ	Q, C, R

	reduce the risk of **gastric cancer**. FDA has concluded that there is very little scientific evidence for this claim.				counterpoint	e	
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,	DS	9.89	✓	Embedded	Mixed model	Q, C, R

	FDA concludes that it is highly uncertain that selenium supplements reduce the risk of bladder cancer in women.						
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	DS	9.60	✓	Embedded	Mixed model	Q, C, R

	risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.						
D	**Selenium** may reduce the risk of **prostate cancer**. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA	DS	8.48	✓	Point-counterpoint	Qualitative	C, R

	does not agree that selenium may reduce the risk of prostate cancer.						
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**.	DS	8.76	✓	Point-counterpoint	Qualitative	C, R

	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.						
D	**Selenium** may reduce the risk of **colon cancer**. Scientific evidence concerning this claim is inconclusive.	DS	8.23	✓	Point-counterpoint	Qualitative	C, R

	Based on its review, FDA does not agree that selenium may reduce the risk of colon.						
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	DS	12.21	✓	Embedded	**Qualitative**	Q, C, R

	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.						
D	Very little scientific evidence suggests that, for healthy infants who are not exclusively	F	30.30	---	Embedded	Qualitative	Q, C, R

	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.						
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	F	23.08	✓	Point-counterpoint	Qualitative	Q, C, R

	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.						
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	F	12.31	✓	Embedded	Qualitative	Q, C, R

	supporting this claim.						
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	F	14.61	✓	Embedded	Quantitative	Q, R

	uncertain that tomato sauce reduces the risk of ovarian cancer.						
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	F	11.18	✓	Embedded	Quantitative	Q, C, R

	the risk of gastric cancer.						
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	F	14.41	✓	Embedded	Mixed model	Q, C, R

	tomatoes reduce the risk of pancreatic cancer.						
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	F, DS	5.81	✓	Point-counterpoint	Qualitative	Q, C, R

	that there is very little scientific evidence for this claim.						
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	F	11.58	✓	Embedded	Qualitative	Q, C, R

	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.						
D	Consumption of **phosphatidylserine** may reduce	DS	12.76	✓	Point-counterpoint	Qualitative	Q, C, R

	the risk of **dementia** in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim.						
D	Consumption of **phosphatidylse**	DS	13.60	✓	Point-counterpo	Qualitative	Q, C, R

	rine 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.				int		

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	DS	15.88	✓	Embedded	Mixed model	Q, R

	type 2 diabetes is highly uncertain.						
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	DS	13.79	✓	Embedded	**Mixed model**	Q, C, R

	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.						
D	Three studies, including a large clinical trial, do not show that **calcium** supplements reduce the risk of	DS	11.63	✓	Embedded	**Mixed model**	Q, C, R

	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.						
D	**0.8 mg folic acid** in a dietary supplement is	DS	11.88	✓	Point-counterpoint	Qualitative	R

	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.						
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	F	6.85	✓	Point-counterpoint	Qualitative	Q, C, R

	evidence for this claim.						

† 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

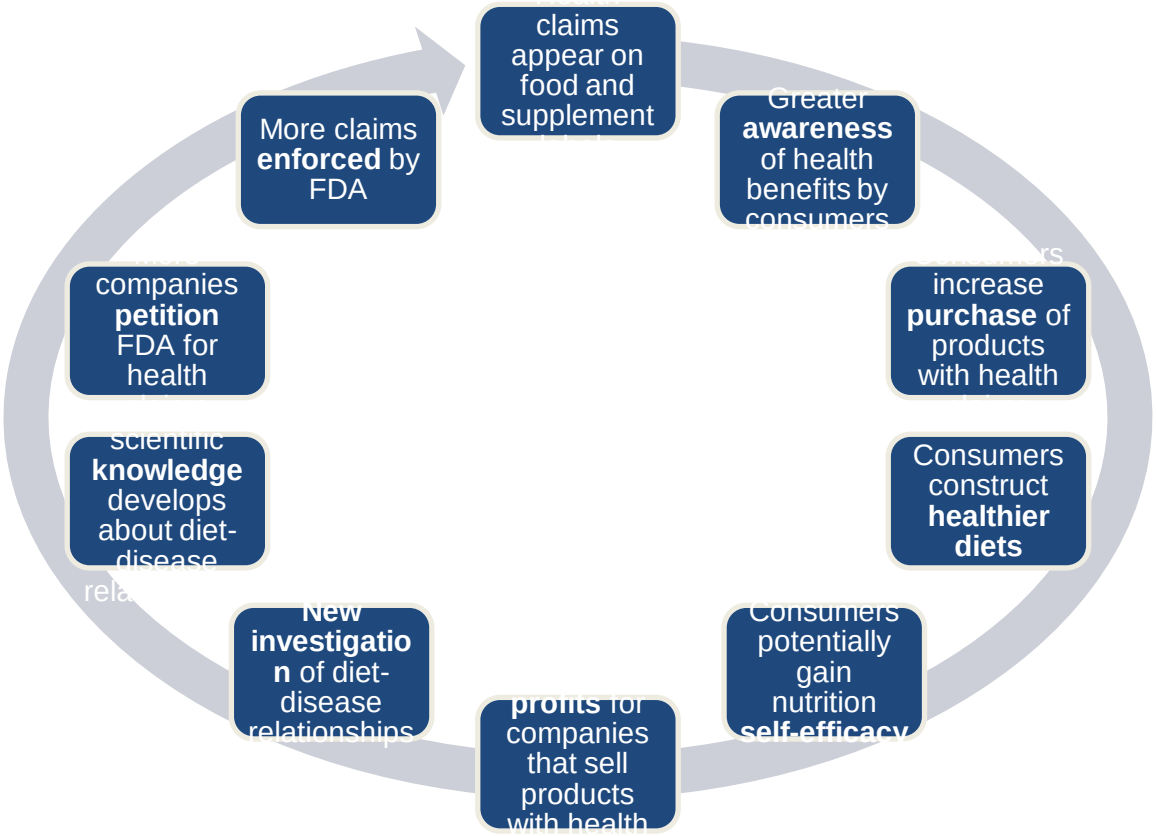

Figure 1. Virtuous cycle of health claims

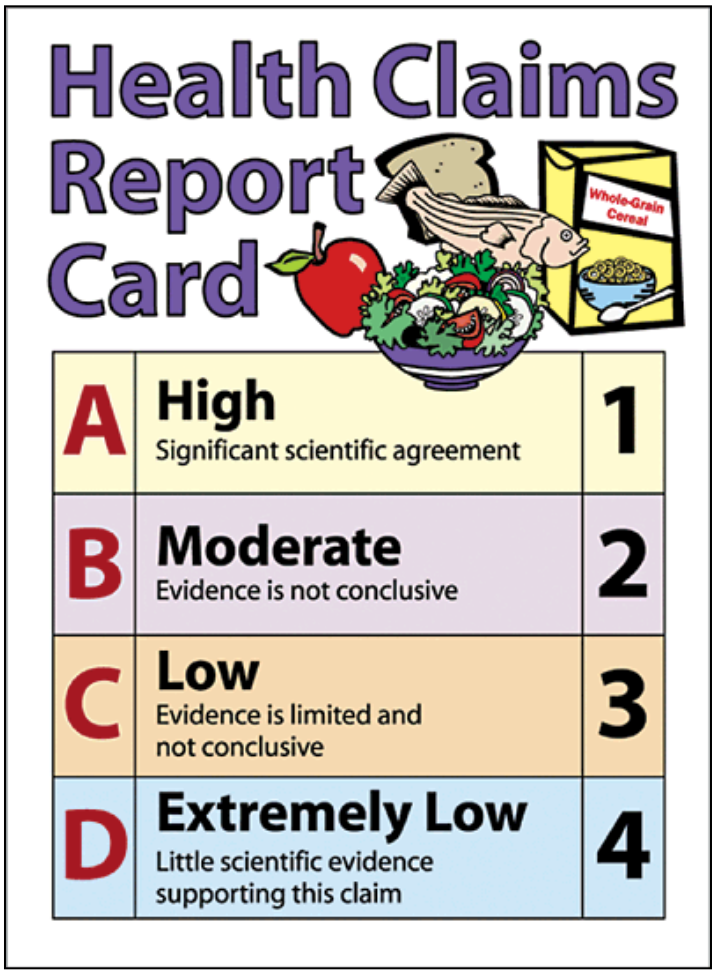

Figure 2. Health Claims Report Card