

**Health Claims on Dietary Supplements in the US: Regulations,  
Consumer Perceptions and Concerns**

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## **Abstract**

Many US adults use dietary supplements regularly and the number has increased rapidly in the last two decades. This partially can be attributed to the passage of the 1994 Dietary Supplement Health and Education Act (DSHEA). DSHEA allows health claims made on dietary supplements to be treated similarly as that on food. The regulation of health claims of dietary supplements is under the jurisdiction of FDA. Manufacturers need to follow the procedures set by FDA on any health claim petition. No health claim can be used before marketing of dietary supplements without FDA's pre-approval. FDA intends to make health claims very suggestive rather than conclusive. However, many consumers do not have enough knowledge to interpret health claims precisely and misconceptions exist. This may have posed some health risks to consumers. It is suggested that FDA should increase consumer education in this area and trained professionals should be a great resource of help for consumers.

## I. Introduction

Data from National health and Nutrition Examination Survey shows that use of dietary supplements have increased steadily in the last 20 years in the US.<sup>1</sup> The increase in consumption of dietary supplements is seen in both men and women, in all age groups and all ethnic groups<sup>2</sup>. Taking dietary supplements has been well accepted by both the ordinary Joes and health care practitioner.<sup>3</sup> The cause behind the increased use of dietary supplements can be attributed to several factors, but the vast availability of dietary supplements on the markets plays an important role in this. It is estimated that there were about 4000 kinds of dietary supplements on the market in 1994 while the number increased to 75, 000 in 2008.<sup>4</sup> The passage of Dietary Supplement Health and Education Act (DSHEA) in 1994 undoubtedly promoted the increase in manufacturing and sales of dietary supplement in the US. Before 1994, health claims made on dietary supplements were regulated similarly to those made on drugs<sup>5</sup> and the cycle for health claims on dietary supplements to be approved by FDA was time-consuming, which significantly slowed down the process for new products to be marketed. In the post-DSHEA era, FDA's regulatory control over dietary supplements is largely weakened and marketing dietary supplements by manufacturers has become unprecedentedly easy. Congress intentionally lessened the regulation from FDA on dietary supplements as a means to educate consumers on

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<sup>1</sup> Jaime Gahche; Regan Bailey; Vicki Burt.; Jeffery Hughes; Elizabeth Yetley; Johanna Dwyer; Mary Frances Picciano; Margaret McDowell; and Christopher Sempos, "Dietary Supplement Use Among U.S. Adults Has Increased Since NHANES III (1988-1994), *NCHS Data Brief*, 61 (2011): 1

<sup>2</sup> Gahche, 2-3

<sup>3</sup> Annette Dickinson, Nicolas Boyon and Andrew Shao, "Physicians and Nurses Use and Recommend Dietary Supplements: Report of A Survey", *Nutrition Journal* 8 (2009):29

<sup>4</sup> Sanford H Levy, "Dietary supplements---popularity, quality, safety and efficacy". July 17, 2012 (Last updated: Oct. 29, 2012) <<http://www.acsu.buffalo.edu/~shlevy/dietsuppqualitysafetyefficacy.htm>> (Nov. 04, 2012)

<sup>5</sup> Neal Fortin, *Food Regulation: Law, Science, Policy, and Practice*. (New Jersey: John Wiley and Sons, 2007), 325

well-accepted health-related findings, to promote public health and to decrease the dependence on medical care.<sup>6</sup> Although it is believed dietary supplements have helped some sub-population with certain health conditions, there are also concerns with unsupervised usage of dietary supplements.

## II. Statutory Acts that Regulate Health Claims on Dietary Supplements

### 1. What Is A Health Claim?

Health claims are claims made on food or dietary supplements about the relationship between a substance and a disease or a health condition.<sup>7</sup> For example, a statement of “help reduce weight” on a weight management dietary supplement is a health claim. However, health claims do not always have to be in a written format. According to FDA’s regulations, a symbol of heart, an electrical cardiogram tracing, vignettes and even brand names that suggest a relationship between the product and a health condition are considered implicated health claims and are under the same regulation as written health claims. Moreover, health claims are not limited to claims on the actual package. Relevant information in advertising in media for promoting sales of the products can be treated as health claims by FDA too if they meet the definition and be regulated the same way.<sup>8</sup> Health claims on dietary supplements were strictly regulated by FDA under the

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<sup>6</sup> Fortin, 326

<sup>7</sup> 21 CFR §101.14 (a) (1)

<sup>8</sup> Guidance for Industry and FDA Dear Manufacturer Letter Regarding Food Labeling, Jan. 2007 (Last updated: May 24, 2011)  
<<<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053425.htm>> (Nov. 20, 2012)

same regulatory standards for drugs before 1994.<sup>9</sup> Starting 1994 after the pass of DSHEA, regulations of health claims on dietary supplements were regulated similarly to that on food.

## 2. Statutory Acts that Regulate Health Claims on Food and Dietary Supplements

Manufacturers of conventional food can make health claims through three ways.

- 1) The 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to authorize health claims on foods if significant scientific evidence support the claimed relationship between a food ingredient and a health condition.<sup>10</sup> FDA requires the manufacturer to submit enough scientific evidence along with their petition for the health claim. The scientific evidence will be reviewed by FDA's interim review system and a health claim will be authorized if it passes the review. Manufacturers cannot use the health claims on marketed food before FDA's approval.
- 2) Health claims on food can also be made based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Science, based on the 1997 Food and Drug Administration Modernization Act (FDAMA).<sup>11</sup> At least 120 days prior to the use of the health claims, manufacturers are required to submit a notification to FDA about the health claims along with the current, published authoritative statements from "a scientific body of the United States

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<sup>9</sup> Fortin, 325

<sup>10</sup> Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims—Final, January 2009 (Last updated: May 24, 2011)  
<<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm>> (Nov. 22, 2012)

<sup>11</sup> Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on Authoritative Statement of a Scientific Body. June 11, 1998 (Last updated: Dec. 22, 2011)  
<<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm056975.htm>> (Nov. 19, 2012)

with official responsibility for public health protection or research directly related to human nutrition . . . or the National Academy of Sciences (NAS) or any of its subdivisions ".<sup>12</sup> FDA will review the evidence for the health claims and decide whether or not the notification meets the requirement for this kind of health claims under FDAMA. However, manufacturers do not need FDA's approval to market their products with this kind of health claims if FDA do not respond within 120 days.

- 3) The 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims to be made on foods when the quality and strength of the scientific evidence do not meet that required for significant scientific evidence-based health claims to be authorized.<sup>13</sup> Like those health claims based on significant scientific evidence, qualified health claims cannot be used for marketing food until being pre-approved by FDA.

Although dietary supplements are included as food in 21 U.S.C.,<sup>14</sup> they are not regulated exactly the same as conventional food in terms of making health claims. Unlike conventional food, dietary supplement manufacturers cannot make health claims based on authoritative statements from a scientific body of the US government or the National Academy of Science. As a result, health claims made on dietary supplements are made either through meeting the significant scientific agreement or as qualified health claims. In either situation, pre-approval from FDA is needed before marketing the products. There are already health claims approved by FDA under both categories which are covered in details in the

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<sup>12</sup> Notification of a Health Claim

<sup>13</sup> Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. July 2013 (Last updated: June 6, 2011)  
<<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>> (Nov. 16, 2012)

<sup>14</sup> 21 U.S.C. §321 (f)

Guidance for Industry published in October 2009.<sup>15</sup> Manufacturers who wish to make claims that have been approved by FDA for qualified products need to follow the requirements specified in this guidance, including what words can be used and what kind of food or dietary supplement is eligible for making these health claims. For example, health claims regarding calcium and its roles in preventing osteoporosis are approved by FDA.<sup>16</sup> The requirements for making this health claim include that the products are “high in calcium”, the active ingredients are “assimilable” and can “disintegrate and dissolve”; in addition, “potassium content in the products is lower than calcium”. And the wording of the health claims need to make it clear to consumers that “adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis”. If a new health claim is to be made, manufacturers are required to follow the procedures outlined in FDA’s regulations for approval mentioned above.

### **III. From Legislation to Consumers**

#### **1. FDA’s Intension**

In general, FDA has been very cautious in what can be put in the health claims based on the description requirements for the approved health claims given in the Guidance for Industry published in October 2009. The health claims approved are more suggestive than conclusive. There are several reasons for this. First, dietary supplements are supposed to be supplements to diet and should not be in any way suggesting the ability in treating or curing a disease. Second, approved health claims are based on scientific evidence available up to the point of approval. The fact that results from all scientific studies, regardless the scope of the studies, are only findings on a small part of the whole population in some specific situation makes it hard to make

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<sup>15</sup> Guidance for Industry: A Food Label Guide. October 2009 (Last updated: May 23, 2011)  
<<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064919.htm>> (Nov. 15, 2012)

<sup>16</sup> A Food Label Guide

any findings final and conclusive. The view may change as techniques get advanced and more findings become available. Third, health condition of each individual is different and there should not be “one-fits-all” kind of health claims for anything. Therefore, in order not to mislead the consumers, making the statements general and broad rather than very specific is the smart and responsible strategy. FDA has exercised that strategy very well. The message for the consumers here is that health claims on dietary supplements should help them to make a choice, rather than determine what to take.

## **2. Reviewing Process by FDA**

It has been discussed in section II(2) that health claims on dietary supplements need pre-approval from FDA before marketing no matter which statutory acts are followed. Although there is not enough information available for the author to make specific comments on the efficiency of the reviewing process, it seems at least FDA intends to keep the regulation strict based on the Guidance for Industry. Given the fact that health claims on dietary supplements are normally very general, the review process on paper seems to be adequate. At least, it does not seem to be the most concerning part in this matter.

## **3. What Do Health Claims on Dietary Supplements Mean to Consumers?**

Even with all the precautions that FDA takes in approving health claims on dietary supplement, there are several concerns about how consumers think about those claims and what roles health claims play in consumers' choice on dietary supplement usage. In 1994 when Congress passed DSHEA, one goal was to provide the public with more information about nutrition scientific findings by allowing health claims to be made on dietary supplements. The goal was to educate the public so that informed decision could be made in choosing the right dietary supplements for preventive care. Unfortunately, in the current system,

consumers are left alone to make their choice of dietary supplements in most situations. Although this may have helped certain population with specific health conditions, it also creates great health concerns at the same time.

- 1) Pre-market safety and efficacy approval is not required for dietary supplements and this creates a big loophole for adulterated products. The possibility that some manufacturers may rely on making attractive health claims on their adulterated products is a big health and safety concern. A study published in 2001 showed that the majority of the consumers trusted the health claims made on dietary supplements were true.<sup>17</sup> This will put consumers in a vulnerable position when any dietary supplement safety is an issue.
  
- 2) Most consumers seem to make their dietary supplements choice by making “self-diagnosis” based on, at least in part, the health claims on the package. Two studies reported that the majority of the dietary supplement users do not discuss their usage of dietary supplements with their doctors.<sup>18, 19</sup> They generally believe dietary supplements are safe and good for their health. Surprisingly more than two thirds of the surveyed consumers even chose to continue using dietary supplement even if FDA had determined that their choice of dietary supplements were ineffective.<sup>20</sup> Although this irrational trust on the effects of dietary supplements can be attributed to more than one factor, the belief that claims on the labels are true is likely one of them.<sup>21</sup> Even though most dietary supplements are generally believed to be safe, unsupervised use of dietary supplements can be

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<sup>17</sup> Robert J Blendon et al, “American’s View on the Use and Regulation of Dietary Supplement”, *Arch Intern Med* 161 (2001): 808

<sup>18</sup> Blendon, 805

<sup>19</sup> Public Policy Institute (PPI), “Dietary Supplements and Older Consumers”, *PPI Data Digest* 66 (2001): 3

<sup>20</sup> Blendon, 807

<sup>21</sup> Blendon, 808

dangerous to some consumers, especially those with medical conditions. Interference of dietary supplements with some patients' medication is a big concern. Adverse effects associated with taking some dietary supplements have been reported.<sup>22</sup> Depending mainly on the general, suggestive health claims on the labels to make dietary supplement choices is not wise and consumers need to be informed of potential risks associated with dietary supplements usage.

- 3) Most consumers are not aware of the difference between health claims and other claims on the labeling, such as structure and function claims which do not need FDA's approval to appear on the labels.<sup>23</sup> As a consequence, they sometimes treat all the claims labeled on the package as specific health claims for that particular product. This misunderstanding and misconception likely has caused unnecessary consumption of dietary supplements, which in turn can cause health risks in some consumers.<sup>24</sup>

#### IV. Suggestions

In general, the current regulations FDA has on making health claims on dietary supplements seem to be very strict. Adequate evidence is required and health claims are mostly very general. However, it is suggested that FDA should increase its regulation on pre-market safety and efficacy monitoring of dietary supplements. Surveys have shown that the majority of consumers actually get their nutrition information mostly from media, including TV, newspaper and internet, etc.<sup>25</sup>

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<sup>22</sup> Steven Gabardi, Kristin Munz, and Catherine Ulbricht, "A Review of Dietary Supplement-Induced Renal dysfunction", *Clinical Journal of the American Society of Nephrology*, 2 (2007): 757

<sup>23</sup> PPI, 4

<sup>24</sup> Gabardi, 757

<sup>25</sup> Carrie S Swift, "Nutrition Trends: Implications for Diabetes Health Care Professionals", *Diabetes Spectrum* 22 (2009): 24

However, many are confused about the mixed information in the media. FDA should promote and lead a nationwide consumer education campaign. Currently, accredited nutrition information intended for consumer education are published by all different agencies. Little coordination exists. The information is scattered everywhere and buried in information for other purposes. It is very difficult for consumers to track down relevant information. Designated websites, and resource centers of nutrition information that focus on consumer education on dietary supplements are in great need. Trained professionals, including physicians, nurses, dietitians as well as scientists should be encouraged to be actively involved as they are the people who get to actually educate and consult ordinary people.

## **V. Conclusions**

Dietary supplements have played important roles in promoting health and preventing certain medical conditions from occurring in a great proportion of general population. Health claims made on dietary supplements, on one hand, have been very informative to consumers in terms of nutrition information and scientific findings. On the other hand, over-stated health claims along with other unaccredited nutrition information in the media may have exaggerated the effects of dietary supplements, which resulted in unnecessary consumption of dietary supplements. Advert effects of dietary supplements can be attributed to both unsafe products due to a lack of pre-market regulation, and unwise consumption resulted from insufficient nutrition knowledge of the consumers. There is a need for consumer education in dietary supplements about the effects of dietary supplements, the meanings of health claims on dietary supplements, the risks associated with taking dietary supplements, safety issues related to dietary supplement markets, etc. Coordination between different federal agencies and collaboration with trained professional are encouraged in order to outreach consumers and keep them well-informed.