

## **Library Research Award**

My research explored the world of dietary supplements and the regulation behind it. Initially, I feared that too narrow of a topic would prove burdensome when finding substantial information. However, I contend that the dietary supplement industry is rapidly gaining recognition as more people are using it in conjunction with prescription and over-the-counter medicine. Through deductive reasoning, I carefully considered all of the questions that needed to be answered: What is the nature and scope of the problem? How problematic is it? Who are the stakeholders involved? What are policy options that are available or have been used in the past? What are politics around dietary supplements and how is it resolved? My objective was to take this broad spectrum of questions and through investigative research, prioritize the topics according to the amount of information that is available.

While most student researchers turn to the search engines on the Internet as their first step, I was careful to consider where I would obtain my data. I looked to the library resources to facilitate secondary research. I began the search by combing through the library catalog to identify books and government documents related to dietary supplements, herbal supplements and alternative and complementary medicine. This resulted in a gamut of information. However, the irony of books is that it is a tangible resource that can endure wear and tear, but its information may be outdated. Scanning through the titles I selected a few to leaf through and obtained a general idea of what issues are involved from both sides of the government and consumer point of view. From there, I looked at the references listed to serve as a springboard to other important topics, and titles of articles and books.

My organization skills improved tremendously as well. For every webpage that provided insightful information, I utilized the online bookmarking tool, del.icio.us. It was a great way to keep track of everything I read and write quick annotations. This method allowed me to easily synthesize information, observe overall trends in the dietary supplement industry and cross-check facts.

Through this research project, I have discovered my new favorite resource to search for items not found in the Fondren library collection. The Inter-Library Loan service has made my research pursuits much easier to accomplish. After experiencing first-hand success with the accuracy and the timeliness of this service I have transformed into an avid fan and a major proponent of the system by recommending and directing my friends to this link online. While Fondren library has an elaborate library catalog of volumes, it has room to grow, especially in the medical policy area. Though the bulk of my research was from online academic journal articles, I also referred to the references listed in each article to cross-check information and search for the original sources of the information. If the item is not in the Fondren library catalog, I can always find the item I need through the Rice ILLiad system. This showed me that my research is not limited to the geographic locations of libraries, but only to limitations of the mind. If I wanted to read more about the use and regulation of dietary supplements in other countries like Canada or Australia, I could obtain an article from the *British Medical Journal* or the *Journal of Australian Association of Nurse Practitioners*. By exploring medical journals from around the world, I could begin a comparative study of the use of dietary supplements. This certainly put the subject into perspective and allowed me to examine how other nations view medicine under an entirely different cultural lens.

Before completing this research project, I was only aware of only two medically related academic journals and began my initial search there, taking advantage of the Fondren Library subscription to these online journals. Though I obtained most of my material via the *Journal of the American Medical Association* or the *New England Journal of Medicine*, I knew that the specificity of my topic were limited even in these two acclaimed publications. Browsing through the topic categories of the Academic Journal Index on the Fondren website, I was able to view other academic journals related to the topic of dietary supplements such as the *American Journal of Clinical Nutrition*. I eventually found

all the information I needed by exploring other journals and conducting an initial search for “dietary supplements” and “regulation”.

To bring the topic of dietary supplements closer to home, I wanted to introduce an example associated with the university. I remember reading an article from the *Thresher* earlier on in the year that mentioned a Rice football player’s fatal reaction with use of dietary supplements. In my search for back issues of the *Thresher*, I discovered the library’s extensive archives of various newspapers from local and international media sources. Not only did I find the correct issue of the *Thresher*, I even leafed through a few of the other periodicals from around the world that were sitting on the shelves nearby. In case I need to refer to older editions of the *Thresher*, I know that I can find them all at Woodson Research Center, the archival home to the *Thresher* since 1965.

Not only did the library serve as a gateway to online resources and links to tangible books, but it also served as the ideal location to muse over the information I collected and gather my thoughts. I completed a majority of my writing in the tranquil ambience of Fondren Library. Sitting by the large floor windows or inside the safety of a study room, I was better able to assess the material with the comfort of having instant online access to academic journals or the help of trained individuals at the circulation desk nearby. To include the diagrams and tables in the appendices, I utilized the scanning equipment in the Digital Media Center, a lesser known but just as ideal location to study. The DMC is home to some of the most advanced technology on campus and has helped me envision future multimedia projects that utilize audio recordings, video clips and digital artwork to showcase my projects.

Though this was my first time utilizing so many aspects of the library, it is definitely not my last. The resources I have used in this research project have helped me realize the possibilities of research are never limited – there are always ways to circumvent and explore other sources of information. The library will help propel my research to the next level of academic caliber.

# Dietary Supplement Industry and the Lack of Regulation

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## ABSTRACT

One of the fastest growing industries within alternative and complementary medicine is dietary supplements. As biologically active products that highly resemble conventional drugs, dietary supplements do not go through the same review and scrutiny as their drug counterparts. Legislation such as the Drug Supplement Health and Education Act of 1994 allows supplement industries to be responsible for proving the safety and efficacy of its products without conducting clinical trials or receiving approval from the regulatory agency, FDA. In this policy brief, I will look at legislation that deregulated the industry and the unintended consequences that followed. The potential for drug/herb/supplement interaction and variation in the labeling and quantity and quality of the product could lead to serious adverse effects. The lack of industry regulation could pose a safety and health problem for the general population who can easily obtain supplements without physician approval.

With a greater breadth of healthcare options available, consumers everywhere can choose a combination of conventional medicine and prescription drugs to alternative and complementary medicine and dietary supplements. Gaining more public recognition is the rapidly growing dietary supplement industry, which topped \$22.1 billion in U.S. sales in 2006 (Nutrition Business Journal 2008). Virtually all cultures use a variety of herbal medications, vitamins, minerals, sports supplements, meal supplements and weight loss products. These products are readily available on the market in pharmacies, grocery stores, health food stores and over the Internet, without a prescription, leaving the decision to take these products at the sole discretion of the consumer. Though their physical appearance may often times resemble their drug counterparts, it would be sensible to think these products have undergone formal review and scrutiny for its safety and efficacy before reaching the public. Yet, the facts indicate that dietary supplements are largely unregulated and have no set industry standards, which may pose a risk to the health and welfare of the public.

### **Pervasive Usage**

Targeted to the general population, dietary supplements include “vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites” (U.S. Food and Drug Administration 2001), and are recommended for a variety of health problems and groups including pregnant women, nursing mothers, strict vegetarians, people with food allergies, senior citizens and those with cancer, kidney, and cardiovascular disease (Zelman 2007). According to a nation-wide survey, 14% of the U.S. population takes herbal medications and supplements, with use of vitamins higher amongst middle-aged people and among women more so than men (Kaufman et al. 2002). The study also concluded that the people most likely to use alternative forms of health care include those with

more education, poor health status, and who are dissatisfied with conventional medicine. By far, the most common reason why people take dietary supplements is because of the purported belief of it being healthy or “good for you” (Kaufman et al. 2002). However, the common belief that what is “natural” is therefore safer is not necessarily true since some herbal medications have levels of toxicity and adverse side effects (Spinella 2001). Unlike synthetic drugs, some supplements, especially herbs, have multiple active and inactive ingredients that are hard to identify or isolate. On the other hand, synthetic drugs can omit extraneous components, leaving a purified and more potent single active ingredient. The public may not be aware of the potential risks involved in a seemingly benign product.

### **Policy through the Ages**

Dietary supplements are vaulted in a separate category from over-the-counter and prescription drugs. One particular piece of legislation changed the fate of the dietary supplement industry and highlighted the growing concern of how supplements are viewed by the U.S. regulatory agency, the Food and Drug Administration (FDA). Intended to streamline the entry process of lower-risk products and to empower consumers to make their own choices, the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) has left consumers and the industry alike with unintended consequences (Ashar 2008).

Most notably, this act classified dietary supplements as a food, subject to the same regulations as other conventional foods, instead of a drug. Previously, the Federal Food, Drug and Cosmetic Act of 1938 allowed supplements to fall under either food or drug depending on its intended usage (Harris 2000). Since the FDA defines drugs as any article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” no other substances can make such claims (U.S. Food and Drug Administration 2008:1) (See APPENDIX A). In order to be

sold on the market, all drugs must undergo review by the FDA for approval and pass scientific-based clinical trials. Classified as a food, however, dietary supplements are not subject to this review process and can, as intended, easily enter the market with few restrictions. Manufacturers of dietary supplements are not required to provide evidence of safety or efficacy to the FDA prior to marketing, nor are they required to register or obtain FDA approval for their products (DeAngelis & Fontanarosa 2003). Without clinical trials, it may be impossible to ensure the safety and efficacy of the product (Angell 2004). Dietary supplements are therefore marketed without any clear evidence of their proven effectiveness or substantiated benefits. However, from the industry's perspective, clinical trials and research on supplements may not be the most cost-effective option considering some substances, such as herbs, are not patentable. With the cost of clinical trials for pharmaceutical companies ranging between \$100-500 million for a single drug, manufacturers of dietary supplements, who are generally smaller firms, see little incentive to perform clinical trials if it is voluntary (Taylor 1996).

Perhaps the less stringent regulations have allowed the dietary supplement industry to explode in growth since the passage of DSHEA. In 1994, before DSHEA was enacted, about 4,000 dietary supplements were available. Eight years after DSHEA, there were over 29,000 supplements on the market with new products churning out at a rate of about 1,000 per year (Marwick 2002). However, these unregulated pharmacologically active products have the potential to cause a ripple of health and safety problems for the consumer.

According to DSHEA, the manufacturers of the products are responsible for ensuring the safety and efficacy of its products, not the FDA. The regulatory agency's role is to provide post-marketing oversight and remove harmful products only after it presents "an unreasonable risk of illness or injury" (McNamara 2005:92). This innocent until proven guilty approach has

consequences in and of itself. Companies that want to promote their product might find it difficult to give an impartial evaluation, considering negative findings would dampen their image and sales. Companies also self-regulate to make sure their claims are not false or misleading (U.S. Food and Drug Administration 2001). Based on this evidence, I recommend dietary supplements be reviewed by an impartial third-party to verify the safety, efficacy, quality and quantity of the product, especially since Angell (2004:135) aptly said, “As in all businesses, there is an inherent conflict of interest between selling products and assessing them.”

Therefore, it is especially crucial that post-marketing surveillance is implemented and enforced since routine monitoring of dietary supplements is among the lower priorities of the FDA, below public health emergencies and fraudulent claims (Food and Drug Administration 2001). However, the means by which the FDA monitors these products is not always effective. In order for the FDA to be aware of harmful effects from dietary supplements, the incidents need to be reported. Right after DSHEA was approved there was no federal mandate for manufacturers to report adverse events. It was purely on a voluntary basis. According to a report from the Office of Inspector General, the FDA receives less than 1% of all adverse events associated with dietary supplements (Fontanarosa et al. 2003). This is an industry enshrouded in mystery. Since manufacturers do not have to register their product prior to marketing them, the FDA does not keep a list of all the manufacturers, distributors or types of supplements in the market (U.S. Food and Drug Administration 2001). This information asymmetry makes it difficult for the FDA to properly oversee post-market trends of supplements.

Due to limited information and the burden of proving a product is harmful, the FDA was criticized for being slow to respond to the number of adverse events associated with ephedra (Hampton 2005). Ephedra, a desert plant, has been sold in the United States to stimulate weight



loss and increase athletic performance. However, a RAND study concluded that the substance had minimal short term effects and unknown long term effects on weight loss (Schulman 2003). The substance is notoriously linked to adverse events such as heart attacks, seizures, stroke, palpitations, anxiety and even death. While adverse event reports on ephedra mounted to 2,277 reports between February 1993 and July 2003, the FDA did not act immediately to ban the product (Schulman 2003). The U.S. General Accountability Office said there was not enough scientific evidence linking exposure to ephedra with these adverse events and FDA would have to conduct further investigation (Herbal Gram 1999). The debate between association versus causation may have delayed federal action to remove these products. Ephedra was not banned until 2004, almost a decade after FDA first proposed a warning label on products containing ephedra in 1997 (U.S. Food and Drug Administration 2004). Though it is clear that dietary supplements are associated with adverse events, it not easy to prove they caused them.

The question of association versus causation is more complex when other factors play in. One survey finds that 16% of prescription drug users also reported use of one or more dietary supplements (Kaufman et al 2002). Known as polypharmacy, the act of taking multiple drugs and supplements at once may lead to serious side effects and a higher probability for complications, making it difficult to isolate the causal factor (Angell 2004). Though not as potent as conventional drugs, dietary supplements do contain bioactive properties and potential toxicities. The severity of adverse effects depends on the type of supplement/herb/drug interaction, genetic predisposition, diet, etc. (Matthews 1999). A combination of factors can be lethal. For example, two years ago a Rice University freshman died during a football practice. His parents contend that a “combination of performance-enhancing supplements containing creatine and rigorous practices caused a fatal reaction due to his underlying sickle-cell anemia”

(Bratic 2008:1). Whether doctors knew about the potential interaction between the supplement and sickle-cell anemia condition is unknown. Studies have shown that dietary supplements are severely underreported. Commonly self-prescribed, consumers often fail to mention the use of dietary supplements to their doctors or pharmacists (Bell 1999). A British survey concluded that people are less likely to report minor adverse reactions from conventional prescription and over-the-counter drugs to their physician, and even less inclined to do so if the adverse effect is from an herbal remedy (Barnes 1998). Even without experiencing adverse effects, 69% of users generally do not tell their family practitioners they use supplements (Pereira et al. 2008). On the other hand, the responsibility is not only on the consumer. A study of Texas pharmacists revealed that 35.9% never asked their patients if they were using alternative therapies (Kwan et al. 2006). With the potential to interact negatively with the human body, dietary supplements do not carry the same level of concern among consumers and health care professions as drugs do.

This series of adverse events with dietary supplements has spurred legislative change. The passage of the Dietary Supplement and Non-Prescription Consumer Protection Act in 2006 made it mandatory for manufacturers and distributors of dietary supplements to report serious adverse events through the FDA's MedWatch program within 15 days. This includes reports of death, a life-threatening experience, hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect (U.S. Food and Drug Administration 2006).

However, perhaps some of these adverse events can be prevented through standardization and proper labeling. Encompassing an array of formats, dietary supplements include capsules, teas, pills, tinctures and extracts. Currently, there are no rules limiting the dosage or amount of active ingredient in any supplements (U.S. Food and Drug Administration 2001). This increases the variability between different supplement brands and within the individual company itself.

Consumers may not be receiving the highest quality or the correct amount of ingredients as claimed on the product label, and risk receiving adulterated products. Therefore, the FDA has issued a final rule on current good manufacturing practice requirements (cGMPs) to ensure manufacturers evaluate the identity, purity, strength and composition of their dietary supplements (U.S. Food and Drug Administration 2007). First proposed in 1997, the final rule was finally established in 2007, allowing for a decade of variability within the industry. Before this, some manufacturers voluntarily followed good manufacturing practices devised from their trade groups. The United States Pharmacopeia and The National Formulary, which is the official compendium on standards for dietary supplements, have established a certification program that allows manufacturers who meet a certain criteria to place a Dietary Supplement Verification Program mark on their products. This label certifies the manufacturer has confirmed the contents of its dietary supplement products, been evaluated for its manufacturing processes, and is in compliance with purity standards (Young 2002).

Several other trade associations have followed suit and have devised their own criteria and seal of approval. I recommend that standardization among trade associations should apply to all manufacturers to decrease discrepancies. Since there is so much variability among different brands and formats of supplements, a more detailed product label complete with recommended dosage, warnings of known adverse chemical reactions will inform users how to obtain the optimal results. Both supplier and customer will benefit since standardized methods within the industry increase the companies' credibility and reputation, leaving consumers confident about the consistency of the products (Taylor 2004).

Benign enough to not be classified as a drug, yet powerful enough to promote health benefits, dietary supplements receive unique treatment regarding the content on their labels.

According to FDA regulations, labels on dietary supplements must include a descriptive name of the product that clearly identifies it as a supplement, the name and location of the manufacturer, a complete list of ingredients in a “supplement facts” panel, and the net contents of the product (U.S. Food and Drug Administration 2001). Classified as a food and not as a drug, dietary supplements cannot be marketed “to diagnose, treat, cure, or prevent any disease” (U.S. Food and Drug Administration 2001:6). However, it can make three types of claims including: health claims, nutrient content, and role of nutrients affecting the structure or function of the body (Morris 2003) (See APPENDIX B). These claims are merely a correlation with health benefits and have not been substantiated with scientific evidence; otherwise dietary supplements would be promoted as a drug. The FDA has room to improve on its policy considering its attempt to deny certain health claims on four dietary supplement products was overruled in the *Pearson v. Shalala* case. The court ruled that the FDA did not specify what “significant scientific agreement” was necessary in order for dietary supplement products to carry health claims on their labels (Hasler 2005:92). Albeit FDA’s goal of making companies provide substantiated scientific evidence before health claims can be made is a step toward the right direction, the vague language and criteria surrounding this policy makes FDA’s attempts seem futile.

Advertisements promoting these claims are scrutinized by an entirely different regulatory agency, the Federal Trade Commission, which require “truth in advertising” to make sure any claims are not false or misleading (DeAngelis 2003:1520). Though discrepancies in the daily operations between the FDA and FTC may arise, the two regulatory agencies are working to create a more cohesive taskforce through the joint Dietary Supplement Enforcement Group (Hampton 2005). In this capacity, the FTC can levy hefty punishments to companies that violate labeling standards, as it did in the case *FTC v. Kevin Trudeau, Robert Barefood, Shop America*

(USA), LLC, and Deonna Enterprises. The FTC contended that claims of the calcium supplement Coral Calcium Supreme, which is used to treat or cure cancer and other diseases such as multiple sclerosis, lupus, and chronic hypertension, were unsubstantiated and false (Federal Trade Commission 2004). As a result, the supplement company paid restitution to consumers, had frozen assets, and were prohibited from making the same health claims that were challenged in court. This level of punishment is much more effective than the number of warning letters the FDA and FTC previously sent to violators (DeAngelis 2003).

### **Other Recommendations**

Though dietary supplements continue to be used pervasively and without a prescription, there needs to be more measures that ensure the safety and awareness of consumers. Variability within the industry, especially when it comes to labeling and content of the product, could be solved through establishment of industry-wide standards. Currently, there is still no rule requiring recommended dosage or black box warnings for potential adverse interaction on labels or information inserts. In fact, the lax regulation of dietary supplements is similar to that of the tobacco industry. Structure or function claims for supplements must accompany a disclaimer that the product has not been evaluated by the FDA. Tobacco products have their own disclaimer in the form of the surgeon general's warning (Morris 2003). While the tobacco industry has worked to make the warning label as small as possible, the dietary supplement industry is in favor of limiting the disclaimers on health claims to just three sentences (GovTrack 2008a). However, both industries are not regulated for the content of its products even though it can physiologically alter the human body and may be linked to adverse events.

As biologically active products that look strikingly similar to conventional drugs, dietary supplements do not go through nearly enough review and scrutiny as their drug counterparts do.

This double-standard has some people advocating for the FDA to regard dietary supplements with purported health claims as they would to over-the-counter drugs (Fontanarosa et al. 2003). To this end, clinical trial testing should be required for products that claim a health benefit on their labels. This would benefit both the public and the regulatory agency since these trials would be the basis for the supplement companies' substantiated claims.

Additionally, a move toward mandating clinical trials would accomplish some of the goals outlined in the Dietary Supplement Strategy, a ten-year strategic plan that calls for a more science-based approach (U.S. Food and Drug Administration 2000). However, any notion to mandate trials has met with resistance from the supplement industry. As described earlier, manufacturers are discouraged by the high cost of clinical trials and the fact that some natural supplements are not patentable.

Nevertheless, with more clinical trials and research the FDA can establish a proper database of possible herb/supplement interaction, similar to the German Commission E monographs which document known herbal interactions, to equip consumers and health professionals with the knowledge to prevent adverse effects from the use of these products (Taylor 1996). Unfortunately for the supplement industry, the current system only focuses on reporting negative, adverse effects of drugs and dietary supplements to the FDA via the MedWatch program. There is not a system in place to report the positive effects (Taylor 1996).

However, a provision of DSHEA established the Office of Dietary Supplements (ODS) under the National Health Institute has already made efforts to research the benefits of dietary supplements (Ashar 2008). The government sponsored ODS along with the National Center for Complementary and Alternative Medicine and National Center for Toxicology Research can work to improve the knowledge of health care professionals regarding the toxicities of certain

herbs and verify the correlation between certain supplements and health benefits (Taylor 2004). If the bill is approved, the DSHEA Full Implementation and Enforcement Act of 2007 will provide more funding to ODS to expand research initiatives and direct the Secretary of Health and Human Services to report to Congress on the implementation and enforcement of DSHEA (Gov Track 2008b). Holding the regulatory agency accountable and not just the industry would provide better oversight of dietary supplements.

**Box 1. Criteria by Which the Food and Drug Administration Considers Claims to Diagnose, Mitigate, Treat, Cure, or Prevent Disease\***

1. Has an effect on a specific disease or class of diseases
2. Has an effect, using scientific or lay terms, on 1 or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different diseases
3. Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm
4. Has an effect on disease through 1 or more of these factors:
  - Name of the product
  - Statement about the formulation of the product, including a claim that the product contains an ingredient that has been regulated by the Food and Drug Administration as a drug and is well-known to consumers for its use in preventing or treating disease
  - Citation of a publication or reference, if the citation refers to a disease use
  - Use of the term *disease* or *diseased*
  - Use of pictures, vignettes, symbols, or other means
5. Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease
6. Is a substitute for a product that is a therapy for a disease
7. Augments a particular therapy or drug action
8. Has a role in the body's response to a disease or to a vector of disease
9. Treats, prevents, or mitigates adverse events associated with a therapy for a disease and if the adverse events constitute diseases
10. Otherwise suggests an effect on a disease or diseases

\*Source: *Federal Register*.<sup>20</sup>



APPENDIX B (Morris 2003:1506)

**Table 1.** Types of Dietary Supplement Claims Recognized and Permitted by the Food and Drug Administration<sup>5,6</sup>

Type of Claim	Definition	FDA Preapproval Required	Acceptable Examples
Health	Approved claims of relationships between a nutrient and a disease or condition, provided certain other components to the claim are included	Yes	"A diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life" <sup>7</sup> "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect" <sup>8</sup>
Nutrient content	Descriptions of the relative amounts of a nutrient in a product, as per specific FDA regulations	Yes	Low in sodium, fat free
Structure or function	Role of a nutrient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient acts to maintain such structure, provided that such statements are not disease claims	No	Saw palmetto supports prostate function Echinacea helps to maintain immune function

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