

Dietary Supplements

Introduction

Dietary supplements in the United States are defined under the Dietary Supplement Health and Education Act of 1994 as diet alternatives that can provide or replace nutrients such as vitamins, minerals, or amino acids. Dietary Supplements are not supposed to be taken as a replacement for meals or nutrients. I wanted to research the facts about dietary supplements because every morning I take vitamins and my coaches are always encouraging that we take some dietary supplements such as Iron and Omega 3. However, they always warn us to take ones that are safe and contain only good things. I wanted to research these supplements so that I would be able to tell which supplements contain more good things than bad, and take the right ones. In my research I found that there is some controversy surrounding the subject of dietary supplements especially regarding the regulations of labels and ingredients of the supplements.

Section 1: Background and Problem Statement

- **Web site #1 Name:** U.S. Food and Drug Administration (Healthy People 2010 did not directly address my topic)
- **Web address:** <http://www.fda.gov/Food/DietarySupplements/default.htm>
- **Background Information:**

Healthy People 2010 does not address dietary supplements on their Web site however, the U.S. Food and Drug Administration does dedicate an entire section to the regulations applied to dietary supplements. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements. This means that the FDA does not necessarily need to "step-in" and

have any regulations on the dietary supplement until after it is sold and something goes wrong with the product. Manufacturers must make sure that product label information is truthful and not misleading. Manufacturers must also make sure that the product does not claim to “treat” or “cure” any ailments or health concerns as dietary supplements are not regarded as medications.

- **Web site #2 Name:** Science-Based Medicine
- **Web address:** <http://www.sciencebasedmedicine.org/?p=3772>
- **Background Information:**

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements.* Manufacturers must make sure that product label information is truthful and not misleading. In other words, when a supplement is marketed it's more or less the honor system. No registration with the FDA is required. After all, supplements are food, not medicine! In effect, the government can't really do anything unless problems are reported after the supplement is marketed.

- **Web site #3 Name:** The Food and Drug Administration
- **Web address:** <http://www.fda.gov/Food/DietarySupplements/default.htm>
- **Background Information:**

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. (FDA <http://www.fda.gov/Food/DietarySupplements/default.htm>) Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or

selling dietary supplements.* Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

Section 2: Research

- **Web site #1 Name:** U.S. Nation Library of Medicine
- **Web address:** <http://www.ncbi.nlm.nih.gov/pubmed/20218027>
- **Summary of the research:**

Many natural health products and dietary supplements are purchased in pharmacies and it has been argued that pharmacists are in the best position to provide patients with evidence-based information about them. This study was designed to identify how the pharmacist's role with respect to natural health products and dietary supplements is portrayed in the literature. A systematic search was conducted in a variety of health databases to identify all literature that pertained to both pharmacy and natural health products and dietary supplements. Of the 786 articles identified, 665 were broad-coded and 259 were subjected to in-depth qualitative content analysis for emergent themes. **KEY FINDINGS:** Overwhelmingly, support for the sale of natural health products and dietary supplements in pharmacies is strong.

- **Web site #2 Name:** International Bibliographic Information on Dietary Supplements
- **Web address:** http://grande.nal.usda.gov/ibids/index.php?term1=H327K1329&limit=20&mode2=detail&session=473304971&throw=889100&origin=ibids_references_outcomes
- **Summary of the research:**

A experiment was conducted to see if omega-3, a dietary supplement composed of eicosapentaenoic acid and docosahexaenoic acid decreases the

occurrence of cardiovascular events over a wide spectrum of patients. After supplements were administered to 39,044 patients for one year, eleven studies were conducted using patients with different health histories ranging from prior heart surgeries to peripheral vascular disease. The conclusion is that Dietary supplementation with omega-3 fatty acids should be considered in the secondary prevention of cardiovascular events.

- **Web site #3 Name:** East Tennessee State University
- **Web address:** <http://www.etsu.edu/etsu/news/20010340.htm>
- **Summary of the research:**

A study published last year by an East Tennessee State University scientist has been listed as one of the top 25 major scientific advances in dietary supplement research for the year 2000. The study was led by Dr. Craig Broeder, director of ETSU's Human Performance Laboratory, who published an article in a November 2000 issue of the American Medical Association's Archives of Internal Medicine that identified a number of potential health risks associated with use of the supplement androstenedione. According to Broeder, andro became widely known when it was reported that baseball star Mark McGwire used the supplement. Many men have begun taking andro to help combat aging, build muscle, and improve sexual performance. While andro does raise the level of testosterone within the first month, Broeder found that it eventually returned to normal within 12 weeks. This extra amount of "free testosterone" resulted in harmful effects on the body's hormone and cholesterol levels. When this extra testosterone, the body will convert it to estrogen and dihydrotestosterone. The estrogen can cause breast tissue to grow in men and increases the risk for breast cancer. Dihydrotestosterone has been shown to cause the prostate to enlarge. Furthermore, men using andro in the study experienced a decrease in the levels of the beneficial form of cholesterol known as HDL, which helps fight the buildup of artery-clogging plaque

Section 3: Statistics

- **Web site #1 Name:** CDC Center for Diseases Control and Prevention

- **Web address:** <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5438a4.htm>
- **Summary of the statistics:**

The Gallup survey has been conducted since 1995 using a random-digit--dialed telephone interview of a proportionate stratified sample. Response rate for the 2005 survey was 32%, with 2,647 women aged 18--45 years responding; response rates for previous surveys ranged from 24% to 52%. Statistical estimates were weighted to reflect the total population of women aged 18--45 years in the contiguous United States who resided in households with telephones. The margin of error for estimates based on the total sample was +2%. To assess awareness of folic acid, respondents were asked, "Have you ever heard, read, or seen anything about folic acid?" To assess knowledge about folic acid, respondents were asked, "What have you heard, read, or seen about folic acid?" In addition, the survey asked questions regarding motivating factors and barriers to taking folic acid. In the 2005 survey, 33% of women of childbearing age reported taking folic acid daily, compared with 40% in 2004. This decrease was consistent across most demographic characteristics, with non-white, young, less educated, and lower-income women the least likely to report taking folic acid daily. The percentage of women reporting awareness of folic acid increased from 78% in 2004 to 84% in 2005, an all-time high for the survey. However, the percentage of women knowing that folic acid prevents birth defects remained unchanged at 25%, and the percentage of women knowing that folic acid should be taken before pregnancy decreased from 12% in 2004 to 7% in 2005, the lowest percentage since 1997.

TABLE 1. Percentage of women aged 18–45 years who reported taking folic acid daily, by selected sociodemographic characteristics — United States, 2003–2005*

Characteristic	2003 %	2004 %	2005 %
Race			
White	34	43	36
Nonwhite	28	31	23
Ethnicity			
Hispanic	29	38	27
Non-Hispanic	33	40	34
Age group (yrs)			
18–24	25	31	24
25–34	34	39	36
35–45	35	46	37
Education			
Less than high school	21	19	20
High school	28	32	31
College (any)	37	48	35
Annual household income			
<\$25,000	24	30	27
\$25,000–\$39,999	31	40	28
\$40,000–\$49,999	39	48	37
≥\$50,000	38	46	38
Pregnancy status			
Pregnant	82	81	90
Not pregnant	30	37	31
Total	32	40	33

* Estimates weighted to reflect the total population of women aged 18–45 years in the contiguous United States who resided in households with telephones.

- **Web site #2 Name:** Healthy People 2010

- **Web address:**

http://www.cdc.gov/nchs/ppt/hp2010/focus_areas/fa19_2_ppt/fa19_nutrition2_ppt.htm

- **Summary of the statistics:**

The contribution of dietary supplements to total calcium intake varied by age and gender, with the greatest contribution for women 51 and older. The percent of calcium intake by females aged 51+ that is from food (66%), from supplements (32%) and from antacids (2%). The percent of calcium intake by males aged 51+ that is from food (83%), from supplements (15%) and from antacids (3%). The substantial contribution of dietary supplements to total calcium intake for older women illustrates the importance of

collecting data on nutrient intake from all sources including dietary supplements. For these older women and men, only a small amount of calcium came from antacids.

- **Web site #3:** Consumer Healthcare Products Association
- **Web address:** http://www.chpa-info.org/pressroom/ds_factsfigures.aspx
- **Summary of the statistics:**

The most prevalent reason consumers use dietary supplements is to improve overall health and general well being. In 2004, 18.9 percent of Americans reported that they had taken one or more dietary supplements in the past year.

Section 4: Consumer Information

Web site #1 Name: Medline Plus

- **Web address:** <http://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v%3Aproject=medlineplus&query=Dietary+Supplements&x=0&y=0>
- **Summary of the information:**

Dietary supplements are vitamins, minerals, herbs and other substances meant to improve your diet. They can come as pills, capsules, powders and liquids. Supplements do not have to go through the testing that drugs do. Some supplements can play an important role in health. For example, pregnant women can take the vitamin folic acid to prevent certain birth defects in their babies. Taking supplements can also be a type of complementary or alternative medicine (CAM) which are medical products and practices that are not part of standard care.

- **Web site #2 Name:** MayoClinic.com
- **Web address:**
<http://www.mayoclinic.com/print/supplements/NU00198/METHOD=print>
- **Summary of the information:**

Dietary supplements are not intended to replace or supplement a meal or nutrients in their entirety. Whole foods are always the best option for obtaining all of the nutrients and vitamins a body needs to function properly however some people are

advised to take dietary supplements. Dietary supplements may be considered appropriate if a person consumes less than 1,600 calories a day, is a vegetarian and doesn't substitute or complement their diet appropriately, is pregnant, trying to get pregnant or breast-feeding is a woman who experiences heavy bleeding during your menstrual period, is a postmenopausal woman, has a medical condition that affects how their body absorbs, uses or excretes nutrients, such as chronic diarrhea, food allergies, food intolerance or a disease of the liver, gallbladder, intestines or pancreas, and if they have had surgery on their digestive tract and are not able to digest and absorb nutrients properly.

- **Web site #3 Name:** Consumer Healthcare Products Association

- **Web address:**

<http://www.mayoclinic.com/print/supplements/NU00198/METHOD=print>

- **Summary of the information:**

Most misunderstandings regarding dietary supplements occur when people confuse dietary supplements with drugs and expect them to be regulated in the same manner. Dietary supplements are meant to supplement the diet; accordingly, the Dietary Supplement Health and Education Act of 1994 (DSHEA) defines them as a subset of foods, and they are regulated as such. Under DSHEA, the U.S. Food and Drug Administration (FDA) has several post-marketing responsibilities to ensure the safety of dietary supplements. Among those is enforcement of the final rule on dietary supplement Good Manufacturing Practices (GMPs), released on June 25, 2007. This rule establishes uniform standards needed to ensure quality throughout the manufacturing, packaging, labeling, and holding of dietary supplement products. FDA also oversees mandatory adverse event reporting by dietary supplement manufacturers. In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act, requiring that dietary supplement manufacturers promptly communicate serious adverse events to FDA. This requirement went into effect December 22, 2007.

Section 5: Solutions to the Problem (or Issue)

- **Web site #1 Name:** U.S. Senator John McCain

- **Web address:**

http://mccain.senate.gov/public/index.cfm?FuseAction=PressOffice.Speeches&ContentRecord_id=952dda07-b71c-4034-4f34-c38974978f7d

- **Summary of the information:**

"This legislation would require dietary supplement manufacturers to register with the FDA and fully disclose the ingredients contained in the supplement. Surveys have found that a majority of dietary supplement users believe the FDA approves the safety of dietary supplements prior to market introduction. However, that is not the case. In fact, dietary supplement manufacturers' advertised claims of safety and effectiveness are not reviewed or approved by the FDA." This act will ensure the safety of dietary supplements and banish some of the mystery behind regulating and labeling of dietary supplements that still remain after the Dietary Supplements Health and Education Act of 1994.

- **Web site #2 Name:** U.S. Pharmacopeia

- **Web address:**

<http://www.usp.org/pdf/EN/USPVerified/dietarySupplementRegulation.pdf>

- **Summary of the information:**

The U.S. Food and Drug Administration regulates dietary supplements through their Center for Food Safety and Applied Nutrition. The Food Drug and Cosmetic Act as amended to the Dietary Supplement Health and Education Act of 1994 is the law that regulates dietary supplements.

- **Web site #3 Name:** U.S. Food and Drug Administration

- **Web address:**

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIIIProhibitedActsandPenalties/ucm086300.htm>

- **Summary of the information:**

The Federal Food Drug and Cosmetic Act has amended several laws regarding the regulation and labeling of dietary supplements that were not part of the Dietary Supplement Health and Education Act of 1994. Such as the regulation of faulty claims as to the results of using a specific supplement.

Conclusions:

Dietary supplements can be any vitamin, mineral or herb that is intended to better your wellness, diet or health. However, the regulations of dietary supplements are sometimes difficult to understand and may create some gray areas for consumers. The FDA is not responsible for the regulation and labeling of dietary supplements in the same way that it regulates other drugs. Each manufacturer is responsible for the accurate claims made about their product and ensure that all ingredients are listed on the label. The U.S. Food and Drug Administration will not “step in” and regulate, unfortunately, until an issue is apparent, which is usually not until someone is injured or their health is negatively affected by the supplement.

Back to Betty C. Jung’s Web site	http://www.bettycjung.net
Back to Fact Sheet Directory	http://www.bettycjung.net/Pch202fs.htm