

# Assessing Claims of Functional Foods and Nutritional Supplements

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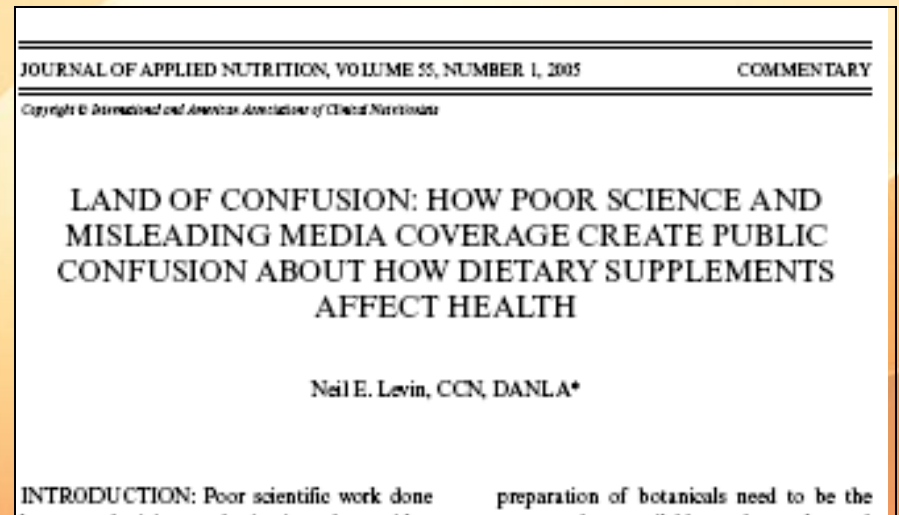
***Health Journalism 2010***

# Dietary Supplement Topics

- Are Dietary Supplements Safe?
- Are Supplements Adequately Regulated?
- What Claims can be Legally Made?
- How Can Journalists Present Balanced Information?
- Resources

# Dietary Supplement Controversies

- Lots of Confusion in Nutritional Science
  - Poor Training, Misinformation
  - PR Campaigns Promote Sensational Reports
- Journalists May Lack Resources to Fact Check Reports
- Scientific Journals Not Be Accurate/Unbiased



# Dietary Supplement Controversies

Reader's Digest April 2010

## 5 Vitamin Truths and Lies

Are you still relying on vitamins to keep you healthy? Learn the truth about which supplements help and which ones you can toss. Plus, find out the [25 foods that you can eat to get your vitamins](#).

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By Christie Aschwanden From [Reader's Digest](#)

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Once upon a time, you believed in the tooth fairy. You counted on the stability of housing prices and depended on bankers to be, well, dependable. And you figured that taking vitamins was good for you. Oh, it's painful when another myth gets shattered. Recent research suggests that a daily multi is a waste of money for most people—and there's growing evidence that some other old standbys may even hurt your health. Here's what you need to know.

**Myth: A multivitamin can make up for a bad diet**

An insurance policy in a pill? If only it were so.

Last year, researchers published new findings from the Women's Health Initiative, a long-term study of more than 160,000 midlife women. The data showed that multivitamin-takers are no healthier than those who don't pop the pills, at least when it comes to the big diseases—cancer, heart disease, stroke. "Even women with poor diets weren't helped by taking a multivitamin," says study author Marian Neuhouser, PhD, in the cancer prevention program at the Fred Hutchinson Cancer Research Center, in Seattle.

Vitamin supplements came into vogue in the early 1900s, when it was difficult or impossible for most people to get a wide variety of fresh fruits and vegetables year-round. Back then,

# Are Dietary Supplements Regulated?

The New York Times  
nytimes.com

September 19, 1998

## Unregulated Dietary Supplements

There is mounting evidence that Congress should revisit its ill-advised decision in 1994 to insulate pills and powders sold as "dietary supplements" from Federal regulation. The latest warning appears in the New England Journal of Medicine, which on Thursday published six reports of people who had become ill after treating their ailments with remedies from health-food stores.

The reports follow a monthlong controversy generated by the baseball player Mark McGwire's admission that androstenedione, an over-the-counter compound that is thought to elevate testosterone levels and build muscle experts asserted that the compound gave McGwire an unfair competitive edge. Others were not sure. But nearly agreed that because so little is known about androstenedione's long-term effects on the body, it would be wise from drugstore shelves pending rigorous tests.

Journal of Pediatric Gastroenterology and Nutrition:  
October 2001 - Volume 33 - Issue 4 - pp 439-441  
Editorials

## Unregulated Dietary Supplements: Bitter Medicine for Children

Baker, Susan S.



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EDITORIAL

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Volume 339:839-841

September 17, 1998

Number 12

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Alternative Medicine — The Risks of Untested and Unregulated Remedies

FDA Can't Protect Americans from  
Dangerous Dietary Supplements, GAO  
Says

In response to the lobbying efforts of the multibillion-dollar "dietary supplement" industry, Congress in 1994 exempted their products from FDA regulation.

# Straight Facts About Dietary Supplements Regulation



U.S. Department of Health & Human Services

www.hhs.gov

**FDA** U.S. Food and Drug Administration

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## Food

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### Dietary Supplements

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## 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.\* Manufacturers must make sure that product label information is truthful and not misleading.

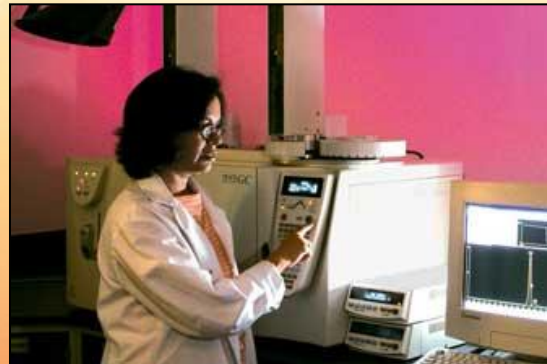
FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

\*Domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register their facility with the FDA. For more information, see [Registration of Food Facilities](#).

# Straight Facts About Dietary Supplements

## The Dietary Supplement Health and Education Act of 1994 (**DSHEA**)

- Requires manufacturers to follow Good Manufacturing Practices (GMP) set by the FDA
- Continues to define dietary supplements as “Foods”
- Regulates label claims



# Straight Facts About Dietary Supplements

## DSHEA

Approves pre-existing dietary ingredients

- Common vitamins, minerals, herbs



Requires pre-market submission of all  
**New Dietary Ingredients** to the FDA

# Straight Facts About Dietary Supplements

## The Food, Drug and Cosmetic Act of 1938

“Under the **1938 grandfather clause** a drug product that was on the market prior to passage of the 1938 Act and which contained in its labeling the same representations concerning the conditions of use as it did prior to passage of that Act was not considered a *new drug* and therefore was exempt from the requirement of having an approved new drug application.”

# Straight Facts About Dietary Supplements

## The Food, Drug and Cosmetic Act of 1938

(amended in 1962)

“Under the **1962 grandfather clause**, the Act exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the Act at that time, and (c) not covered by an effective application.”

# Straight Facts About Dietary Supplements

## Dietary Supplement Safety

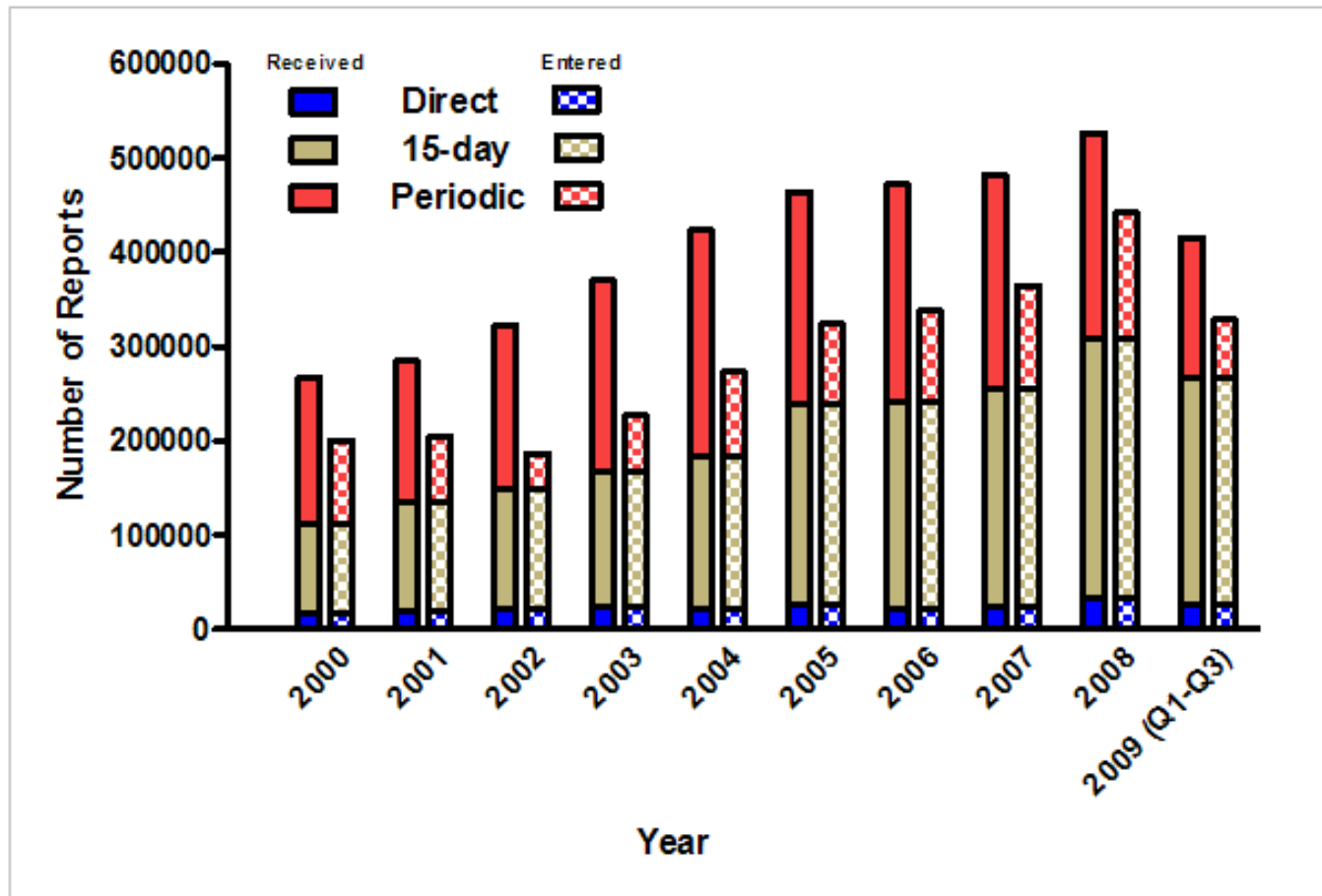
### Food-Related Illness and Death in the United States

Paul S. Mead, Laurence Slutsker, Vance Dietz, Linda F. McCaig, Joseph S. Bresee, Craig Shapiro, Patricia M. Griffin, and Robert V. Tauxe - Centers for Disease Control and Prevention, Atlanta, Georgia, USA

To better quantify the impact of foodborne diseases on health in the United States, we compiled and analyzed information from multiple surveillance systems and other sources. **We estimate that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.**

# Drug Safety

Figure 1. This figure illustrates the number of reports received (solid bars) and entered (checkered bars) into AERS by type of report since the year 2000 until the end of the third quarter of 2009.



This table represents the number of reports received by FDA and entered into AERS by type of report since the year 2000 until the end the third quarter of 2009.

# Straight Facts About Dietary Supplements

## Dietary Supplement Safety



### Dietary supplements cause 600 'adverse events'

Updated 9/22/2008 5:06 PM

By A.J. Perez, USA TODAY



Photo illustration by Sean Dougherty, USA TODAY

The FDA didn't name the supplements that caused the deaths and hospitalizations.

Serious side effects from the use of food supplements resulted in 604 "adverse-event" reports

“If the trend continues, there will be fewer than the **960** adverse-event reports the FDA had estimated it would receive each year.”

“Adverse-event reporting has been required for prescription and some non-prescription drugs for years. The FDA took in **482,154** adverse-event reports for prescription drugs last year.”

# Straight Facts About Dietary Supplements

CLINICAL RESEARCH STUDY

THE AMERICAN  
JOURNAL of  
MEDICINE®

## Potential for Interactions Between Dietary Supplements and Prescription Medications

Amit Sood, MD, MSc,<sup>a</sup> Richa Sood, MD,<sup>a</sup> Francis J. Brinker, ND,<sup>b</sup> Ravneet Mann, MBBS,<sup>c</sup> Laura L. Loehrer,<sup>a</sup>  
Dietlind L. Wahner-Roedler, MD, MSc<sup>a</sup>

<sup>a</sup>Division of General Internal Medicine, Mayo Clinic, Rochester, Minn; <sup>b</sup>Program in Integrative Medicine, University of Arizona College of Medicine, Tucson; <sup>c</sup>Christian Medical College, Ludhiana, Punjab, India.

**No patient was harmed seriously from any interaction.**

(Survey of 1795 patients at Mayo Clinic)

Conclusions: A small number of prescription medications [(antithrombotic medications, sedatives, antidepressant agents, and antidiabetic agents] and dietary supplements [garlic, valerian, kava, ginkgo, and St. John's Wort] accounted for most of the interactions. **The actual potential for harm was low.**

# Straight Facts About Dietary Supplements

## Dietary Supplement Safety

*Clinical Toxicology* (2009) 47, 911–1084

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ISSN: 1556-3650 print / 1556-9519 online

DOI: 10.3109/15563650903438566

AAPCC 2008 ANNUAL REPORT OF THE NPDS

### 2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 26th Annual Report

ALVIN C. BRONSTEIN, M.D., DANIEL A. SPYKER, PH.D., M.D., LOUIS R. CANTILENA, JR, M.D., PH.D.,  
JODY L. GREEN, PH.D., BARRY H. RUMACK, M.D., and SANDRA L. GIFFIN, RN, BSN, MS

**ZERO accidental deaths reported from dietary  
supplement use in 2008**

# Straight Facts About Dietary Supplements

## Dietary Supplement Safety

Journal of Medical Toxicology – Volume 4, Number 2 – June 2008

Toxicology Investigations

### Dietary Supplement Adverse Events: Report of a One-Year Poison Center Surveillance Project

*Christine A. Haller, MD<sup>a</sup>, Tom Kearney, PharmD<sup>b</sup>, Stephen Bent, MD<sup>c</sup>, Richard Ko, PharmD, PhD<sup>d</sup>, Neal L. Benowitz, MD<sup>e</sup>, Kent Olson, MD<sup>b</sup>*

**Conclusion:** Most supplement-related adverse events were minor. Clinically significant toxic effects were most frequently reported with caffeine and yohimbe-containing products.

# Straight Facts About Dietary Supplements

## Dietary Supplement Safety

### Conclusion:

These data are consistent with the hypothesis that increased pharmaceutical advertising is associated with publishing fewer articles about DS and publishing more articles with conclusions that DS are unsafe.

### **BMC Complementary and Alternative Medicine**



Correspondence

**Open Access**

### **Does pharmaceutical advertising affect journal publication about dietary supplements?**

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\* Corresponding author

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# FDA Regulated Health Claims

**Is it legal to market a dietary supplement product as a treatment or cure for a specific disease or condition?**

“No, a product sold as a dietary supplement and promoted on its label or in labeling\* as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved--and thus illegal--drug.”

\*Labeling includes accompanying promotional material

# FDA Regulated Label Claims

By law, manufacturers may make three types of claims for their dietary supplement products:

- **Health claims**
- **Structure/function claims**
- **Nutrient content claims**

# FDA Regulated Health Claims

The 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions

# FDA Regulated Health Claims

## The 1997 Food and Drug Administration Modernization Act (FDAMA)

- Provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences
- Such claims may be used after submission of a health claim notification to FDA

# FDA Regulated Health Claims

The 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation.

- Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers.

# FDA Regulated Health Claims

## Qualified Health Claims allowed for Foods:

### *Healthy Fats and Heart Disease/Cancer*

- Corn Oil and Reduced Risk of Heart Disease
- Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease
- Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease
- Walnuts & Heart Disease
- Nuts & Heart Disease
- Dietary Lipids (Fat) and Cancer

# FDA Regulated Health Claims

## Approved Health Claims allowed for Foods:

### *Fiber and Sugar Alcohols*

- Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
- Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries
- Fiber-containing Grain Products, Fruits and Vegetables and Cancer
- Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble fiber, and Risk of Coronary Heart Disease

# FDA Regulated Health Claims

## FDA Qualified health claims for supplements

Examples:

- Calcium for Colon/Rectal Cancer & Polyps
- Green Tea for Cancer
- Antioxidants (Vitamins E and/or C, Selenium) for Cancer
- Omega-3 Fatty Acids for CHD
- Vitamins B<sub>6</sub>, B<sub>12</sub>, and/or Folate for Vascular Disease
- Folic Acid & Neural Tube Birth Defects

# FDA Regulated Health Claims

## Approved Health Claims for Supplements:

- Calcium, Vitamin D, and Osteoporosis
- Soy Protein and Risk of Coronary Heart Disease
- Stanols/Sterols and Risk of Coronary Heart Disease

# FDA Nutrient Content Claims

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food.

- Using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*.

# FDA Structure/Function Claims

- Have historically appeared on the labels of conventional foods and dietary supplements as well as drugs
- DSHEA established special regulatory procedures for S/F claims for dietary supplement labels

# FDA Structure/Function Claims

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans

Example:

“Calcium builds strong bones”

# FDA Structure/Function Claims

S/F claims may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function or may describe general well-being from consumption of a nutrient or dietary ingredient

Example:

“Fiber maintains bowel regularity”

“Antioxidants maintain cell integrity”

# FDA Structure/Function Claims

If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

# FDA Claims Enforcement

FDA's Electronic Reading Room - Warning Letters

Diagnostic Ultrasound Equipment, Leaks + Remarket Approval/Misbranded  
Diagnostic X-ray Equipment  
Diagnostic X-ray Equipment (Performance Standards)  
Diapro, Inc. (dba Diapro USA Inc), San Francisco District Office, Natural PentosePl  
Dietary Supplement Contract Manufacturing Facility/Adulterated/Misbranded  
Dietary Supplement Labeling Regulations/Misbranded  
Dietary Supplement Labeling/False & Misleading Claims/Misbranded  
Dietary Supplement Regulations/Misbranded  
Dietary Supplement/Adulterated  
Dietary Supplement/Labeling False and Misleading/Misbranded  
Dietary Supplement/Labeling/Adulterated  
Dietary Supplement/Labeling/False & Misleading Claims/Misbranded  
Dietary Supplement/Labeling/Misbranded  
Dietary Supplement/Plantain  
Dietary Supplement/Promotional Claims False & Misleading/Adulterated/Misbranded  
Dietary Supplements  
Dietary Supplements/Adulterated/Misbranded  
Dietary Supplements/Adulterated/Misbranded/Labeling  
Dietary Supplements/Food Labeling/Misbranded  
Dietary Supplements/Food/New Drug/Adulterated/Misbranded  
Dietary Supplements/Labeling/Misbranded

# FDA Claims Enforcement

U.S. Department of Health & Human Services [www.hhs.gov](http://www.hhs.gov)

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## Pom Wonderful



Department of Health

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### CERTIFIED MAIL RETURN RECEIPT REQUESTED

Matt Tupper, President  
POM Wonderful  
11444 West Olympic Blvd.  
Los Angeles, California 90047  
Re: CFSAN-OC-10-20  
Dear Mr. Tupper:  
The Food and Drug Administration

**Inspections, Compliance, Enforcement, and Criminal Investigations**

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## Nature'S Gift Inc 2/16/10

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WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
WASHINGTON, D.C. 20740

TO: [marge@naturesgift.com](mailto:marge@naturesgift.com)  
[www.naturesgift.com](http://www.naturesgift.com)  
316 Old Hickory Blvd. East  
Madison, TN 37115

FROM: The Food and Drug Administration and the Federal Trade Commission

RE: Unapproved/Uncleared/Unauthorized Products Related to the H1N1 Flu Virus; and  
Notice of Potential Illegal Marketing of Products to Prevent, Treat or Cure the H1N1 Virus

# Straight Facts About Dietary Supplements

- The Safety of Dietary Supplements is Well Established
- Supplements Are Adequately Regulated
  - But enforcement can be improved
- Illegal Claims Being Addressed by FDA & FTC
- Journalists Need Fair & Balanced Resources
  - Scientific & Medical interests are not necessarily accurate and unimpeachable sources

# Straight Facts About Dietary Supplements

- Total 2008 U.S. consumer sales of \$101.8 billion
- 79% of American physicians and 82% of nurses recommend dietary supplements to their patients
- 85% of American adults surveyed indicated that they believe vitamin and mineral supplements are safe
- 64% of American adults classify themselves as supplement users



Sources: Nutrition Business Journal (June/July 2009) and 2008 Council for Responsible Nutrition Consumer Survey on Dietary Supplements, conducted August 20-25, 2008 by Ipsos Public Affairs and funded by CRN. The survey was weighted to reflect the actual U.S. adult population with an estimated margin of error of +/- 2.2 percentage points.

# Independent Resources

- American Nutrition Association  
[www.americannutritionassociation.org](http://www.americannutritionassociation.org)
- American Botanical Council  
[www.herbalgram.org](http://www.herbalgram.org)
- American Herbal Pharmacopoeia  
[www.herbal-ahp.org](http://www.herbal-ahp.org)
- The Natural Health Research Institute  
[www.naturalhealthresearch.org](http://www.naturalhealthresearch.org)

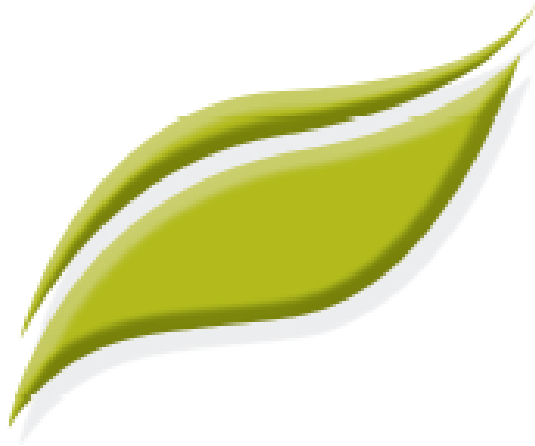
# Industry Resources

- Natural Products Association  
[www.npainfo.org](http://www.npainfo.org)
- American Herbal Products Association  
[www.ahpa.org](http://www.ahpa.org)
- United Natural Products Alliance  
[www.unpa.com](http://www.unpa.com)
- Council for Responsible Nutrition  
[www.crnusa.org](http://www.crnusa.org)

# Thank You!

American  
Nutrition  
Association

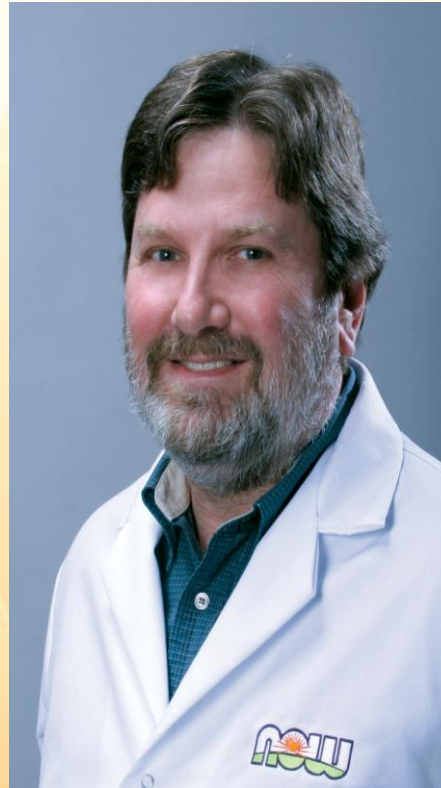
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Improving Lives Through  
Nutrition & Wellness Education

[AmericanNutritionAssociation.org](http://AmericanNutritionAssociation.org)

708.246.FOOD (3663)



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