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

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LAND OF CONFUSION: HOW POOR SCIENCE AND MISLEADING MEDIA COVERAGE CREATE PUBLIC CONFUSION ABOUT HOW DIETARY SUPPLEMENTS AFFECT HEALTH

Neil E. Levin, CCN, DANLA

INTRODUCTION: Poor scientific work done preparation of botanicals need to be the

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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.

By Christie Aschwanden    From Reader's Digest

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?

In response to the lobbying efforts of the multibillion-dollar "dietary supplement" industry, Congress in 1994 exempted their products from FDA regulation.
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.”
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.”
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 of the third quarter of 2009.
“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.”
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.

The American Journal of Medicine (2008) 121, 207-211
ZERO accidental deaths reported from dietary supplement use in 2008
Conclusion: Most supplement-related adverse events were minor. Clinically significant toxic effects were most frequently reported with caffeine and yohimbe-containing products.
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
Does pharmaceutical advertising affect journal publication about dietary supplements?
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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
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.
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
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

Source: US FDA
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

Source: US FDA
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 B₆, B₁₂, and/or Folate for Vascular Disease
• Folic Acid & Neural Tube Birth Defects

Source: US FDA
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

Source: US FDA
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"
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"
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.
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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
- American Botanical Council
  www.herbalgram.org
- American Herbal Pharmacopoeia
  www.herbal-ahp.org
- The Natural Health Research Institute
  www.naturalhealthresearch.org
Industry Resources

- Natural Products Association
  www.npainfo.org
- American Herbal Products Association
  www.ahpa.org
- United Natural Products Alliance
  www.unpa.com
- Council for Responsible Nutrition
  www.crnusa.org
Thank You!

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