

What's in the Bottle?

Dietary supplements are a class of products that were defined by Congress in the Dietary Supplement Health and Education Act (DSHEA), which became law in 1994. Under DSHEA, a dietary supplement is a product (other than tobacco) taken by mouth that contains a “dietary ingredient” intended to supplement the diet. Dietary ingredients may include vitamins, minerals, herbs (plants and plant parts valued for their therapeutic properties, flavors, and/or scent) and other botanicals, amino acids, and certain other substances. There are also requirements concerning labeling.¹

Herbal and botanical products (herbals and botanicals for short) are among the most popular CAM therapies. However, consumers should be aware that they can have safety and quality issues. “Natural” does not mean “safe,” and “natural” products can have powerful druglike effects. For example, aristolochic

¹Some uses of dietary supplements have been incorporated into conventional medicine. For example, scientists have found that folic acid may reduce the risk of certain birth defects, and a regimen of vitamins and zinc can slow the progression of an eye disease called age-related macular degeneration (AMD).

Seeking Health Information on the Internet

In May 2002, the Pew Internet & American Life Project released “Vital Decisions,” a report on Pew surveys during 2002 of Americans who seek health information online (called “health seekers” for short). Some of its findings include:

- ▶ Sixty-two percent of adults who are Internet users, or 73 million Americans, have sought health information.
- ▶ About 6 million Americans go online for health or medical advice on any given day.
- ▶ Seventy-two percent of women who use the Internet have sought health information, compared with 51 percent of men who use the Internet.
- ▶ Those who are between ages 30 and 64 are more likely to be health seekers than those under 30 or over 65.

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acid, found in certain plants and botanicals and used in some traditional Chinese herbal remedies, has been linked to severe kidney disease. The herb comfrey contains certain chemicals that have been linked to serious, even fatal, liver damage. The U.S. Food and Drug Administration (FDA) has issued warnings about or recalls of dietary supplements because of risks for damaging health effects; contamination with other herbs, pesticides, heavy metals, or prescription drugs; and dangerous interactions with prescription drugs.

Some people wonder whether FDA regulates dietary supplements the way that it regulates prescription drugs. Many supplements look like drugs, are packaged similarly to drugs, and may be marketed with claims of health benefits. However, dietary supplements are considered by FDA to be foods, not drugs. Under DSHEA, FDA is required to regulate dietary supplements differently than drugs. Drugs must undergo premarket testing and review by FDA for safety and effectiveness before they can be sold. Dietary supplement manufacturers do not have to provide FDA with evidence that their product is safe or effective before marketing. (FDA, however, can refuse to allow supplements containing new ingredients to be marketed, or take action to restrict or remove supplements from the marketplace, if it can show that they are not safe. The supplements can also be removed from store shelves if their labels are not accurate, as FDA requires.) In preparing, packing, and storing a product, supplement manufacturers need to follow FDA’s Good Manufacturing Practice regulations (GMPs) for foods; these are different than the GMPs for drugs.



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Despite what's on the label, what's in the bottle of an herbal or botanical is not always predictable. It can depend on many things, such as the species and part(s) of the plant used, when and where the plant ingredients were harvested, where they were processed (different countries, for example, can have different manufacturing standards), and whether they are standardized to any extent. (Standardization is a rigorous manufacturing process used to try to achieve a more consistent product. In the United States, there is no legal definition of or requirement for standardization of dietary supplements.)

Studies have found that dietary supplements can contain little, none, or an excess of what their labels claim. For example, one study, supported by NCCAM, examined 25 commercial ginseng products to determine whether the amount and type of ginseng they contained was consistent with their labeling. The researchers found that the concentrations of ginseng (as determined by chemical analysis) differed widely from what was stated on the product labels. Over half the products contained less than 50 percent of the labeled amount. With regard to the type of ginseng, the researchers found product labeling to be accurate. In another study, researchers reported that when they analyzed 16 DHEA products (DHEA, or dehydroepiandrosterone, is a steroid hormone), 1 product had no DHEA, 2 had trace amounts (i.e., virtually no DHEA), and the other 13 had from 69 to 150 percent of the labeled amount of DHEA.

NCCAM is funding four Centers for Dietary Supplement Research and various individual grants to increase scientific knowledge about herbals and botanicals—including insights and approaches that could lead to the development of purer and more standardized products. The research centers, cofunded with the NIH Office of Dietary Supplements, are at the University of Illinois at Chicago; the University of Arizona; the University of California, Los Angeles; and Purdue University. Botanicals being studied under grants cofunded by NCCAM and the National Institute of Diabetes and Digestive and Kidney Diseases include feverfew, echinacea, and milk thistle.

Complementary and Alternative Medicine at the NIH

is published by the National Center for Complementary and Alternative Medicine (NCCAM), NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475. The newsletter is available by mail, on NCCAM's Web site (nccam.nih.gov), or via e-mail by contacting the NCCAM Clearinghouse.

NCCAM Clearinghouse: For information about NCCAM or any aspect of complementary and alternative medicine, contact the NCCAM Clearinghouse:

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Our mission: The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals.

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Here are some points that may be helpful for consumers of dietary supplements to keep in mind.

- ▶ If you are using or are considering using an herbal or botanical (or any other CAM treatment), talk with your health care provider about it. This is important for your safety and for a comprehensive treatment plan.
- ▶ Become informed about the product and its ingredients (see resources listed below). Find out what is known scientifically. Request information from the product manufacturer or distributor. Read free government brochures written to help you. Resources include:
 - ▶ The NCCAM Web site and Clearinghouse (see box).
 - ▶ Databases of science-based information, such as CAM on PubMed (www.nlm.nih.gov/nccam/camonpubmed.html) and IBIDS (see article, pg. 4).
 - ▶ The Web site of the Office of Dietary Supplements, National Institutes of Health (ods.od.nih.gov).
 - ▶ The FDA Center for Food Safety and Nutrition (toll free 1-888-723-3366, www.cfsan.fda.gov; publications include "Tips for Savvy Supplement Users").
 - ▶ The Federal Trade Commission (toll free 1-877-382-4337, www.ftc.gov/bcp/menu-health.htm; publications include "Miracle' Health Claims: Add a Dose of Skepticism").

Sources for this article include publications for consumers by the Federal agencies listed above and the following journal articles: Harkey, M.R. et al. "Variability in Commercial Ginseng Products: an analysis of 25 preparations," *American Journal of Clinical Nutrition*. 2001. 73: 1101-6. Parasrampur, J., Schwarz, K., and Petesch, R. "Quality Control of Dehydroepiandrosterone Dietary Supplement Products," *Journal of the American Medical Association*. 1998. 280(18): 1565. ■

Seeking Health Information, continued from pg. 1

In a survey of 500 health seekers in 2001, the Project found:

- ▶ Forty-eight percent had looked for information on "alternative or experimental treatments or medicines." Those treated for a serious illness in the past year were more likely to seek this kind of information (62 percent) than those not treated for a serious illness (48 percent).
- ▶ One in 10 health seekers was living with someone who has a disability, handicap, or chronic disease. These caregivers were more likely to research alternative therapies online than people not in this caregiving situation.
- ▶ The topics most often researched were disease information, weight control, and facts about prescription drugs.
- ▶ One-third had looked for information about "a sensitive health topic that is difficult to talk about," a figure that had doubled since the previous year.
- ▶ Thirty-seven percent said they talked to a doctor or other health professional about what they found online.
- ▶ Three-quarters had rejected information from a Web site for various reasons, including because they found the site "too commercial," or they couldn't determine the source of the information or when it was last updated.

The Pew Internet & American Life Project is a nonprofit initiative funded by The Pew Charitable Trusts. The full report is available at www.pewinternet.org. ■

Hong Kong Workshop in October

On October 30–31, 2002, NCCAM will cosponsor a workshop in Hong Kong, “Enhancing the Evidence Base for TCM [Traditional Chinese Medicine] Practice: Methodology and Grantsmanship,” with the University of Maryland and the Health and Welfare Bureau of the Government of Hong Kong Special Administrative Region. The workshop will bring together international experts to address a range of topical issues in research methodologies involving TCM and grantsmanship. For more information on this important event, see www.tcmwksop.org.hk.

First Director of New Office Appointed



Berman, M.D., Ph.D., F.A.A.P.

Jonathan D. Berman, M.D., Ph.D., F.A.A.P., has been appointed Director of NCCAM’s new Office of Clinical and Regulatory Affairs (OCRA), effective July 1, 2002. This new office will help plan, coordinate, and monitor NCCAM’s large clinical trials; serve as a resource for NCCAM’s clinical investigators; and help ensure the safety of clinical trials by overseeing the NCCAM Data Safety Monitoring Board and compliance with all Institutional Review Board and U.S. Food and

Drug Administration regulations. OCRA is located within NCCAM’s Division of Extramural Research and Training. Dr. Berman, a retired colonel in the U.S. Army, came to NCCAM from Walter Reed Army Institute of Research, where he was with the Division of Experimental Therapeutics for over 20 years—most recently as manager of Severe Malaria Drug Development. He also served as an associate professor at the Uniformed Services University of the Health Sciences. Dr. Berman received his Ph.D. in biophysics from Harvard University, his M.D. from the Albert Einstein College of Medicine, and post-graduate training in infectious diseases and pediatrics.

First Intramural Trial Launched

On June 12, 2002, NCCAM announced the launch of the first study by its Division of Intramural Research: a clinical trial of a type of acupuncture called electroacupuncture. Electroacupuncture, which has been in use for decades, involves placing needles at selected points on the body and then pulsing the points with an electric current to stimulate them. NCCAM’s researchers are investigating whether electroacupuncture reduces the delayed nausea experienced by cancer patients following chemotherapy. For more information on this study, consult the NCCAM Web site or Clearinghouse (see box, pg. 2).

Research Funding Opportunities

Visit nccam.nih.gov/research for more information on the following and other NCCAM funding opportunities.

- ▶ Program Announcement (PA–02–124): Basic and Preclinical Research on Complementary and Alternative Medicine. Sponsors: NCCAM, the National Cancer Institute, the National Institute of General Medical Sciences, and the National Institute of Mental Health.
- ▶ Program Announcement (PA–02–094): Ancillary Studies on Control Groups in Clinical Trials. Sponsors: NCCAM and the National Institute of Diabetes and Digestive and Kidney Diseases.
- ▶ Program Announcement (PA–02–072): Methodology and Measurement in the Behavioral and Social Sciences. Sponsors: NCCAM and 15 other NIH Offices, Centers, and Institutes.

NCCAM at Professional Meetings

NCCAM will be exhibiting soon at:

- ▶ American Dietetic Association (www.eatright.org/fnce), October 19–22, Philadelphia, Pennsylvania.
- ▶ Society for Neuroscience (www.sfn.org), November 2–7, Orlando, Florida.

Stop by and see us!

Calendar of Events

This calendar lists meetings on complementary and alternative medicine (CAM) that are sponsored or organized by NCCAM or other components of NIH. Agendas for NCCAM events are posted at nccam.nih.gov. The information line for NCCAM meetings is 301–594–9632.

OCTOBER 2002

“Enhancing the Evidence Base for TCM [Traditional Chinese Medicine] Practice: Methodology and Grantsmanship”: October 30–31, 2002. Location: Hong Kong, China. See related item above.

NOVEMBER 2002

Distinguished Lectures in the Science of Complementary and Alternative Medicine: November 7, 2002. “The Global Transformation of Health Care: Cultural and Ethical Challenges to Medicine.” Speaker: Arthur Kleinman, M.D., Professor of Social Anthropology, Medical Anthropology, and Psychiatry, Harvard University. Location: NIH, Bethesda, Maryland. Call the NCCAM meeting information line (see above) for further details.

Science-Based Information on Dietary Supplements

Are you interested in a one-stop shop for references to science-based information on vitamins, minerals, and selected herbals and botanicals? Try the International Bibliographic Information on Dietary Supplements (IBIDS) database. IBIDS is produced by the NIH Office of Dietary Supplements (ODS) and is maintained by ODS in partnership with the U.S. Department of Agriculture.

IBIDS contains more than 650,000 citations (including author, title, and other publication information) from international scientific literature on dietary supplements. Many citations include abstracts (brief summaries). Currently, the citations are drawn from the National Library of Medicine's PubMed database, two Department of Agriculture databases (AGRIS and AGRICOLA), and CABI (Commonwealth Agricultural Bureau International Publishing). IBIDS also has unique citations that are not found in these sources. IBIDS was developed with a user-friendly approach, including the ability to cut and paste from a master list of keywords for searching.

The inaugural speaker in NCCAM's new Distinguished Lecture Series in the Science of Complementary and Alternative Medicine, Charles E. Rosenberg, Ph.D. (center), meets with audience members after his lecture at the National



Institutes of Health on July 18, 2002. Dr. Rosenberg, Professor of the History of Science and Ernest E. Monrad Professor of Social Sciences at Harvard University, lectured on CAM in the context of medicine as an ever-evolving discipline.

Within IBIDS, there are three subfiles for searching:

- ▶ The IBIDS Consumer Database, which concentrates on information targeted to consumers rather than scientists.
- ▶ The Peer-Reviewed Citations Only Database, drawn from peer-reviewed scientific literature.
- ▶ The Full IBIDS Database, which includes both peer-reviewed and non-peer-reviewed information.

Glucosamine, chondroitin, echinacea, vitamin C, algae, creatine... these are just a few of the thousands of topics available on IBIDS, which is located at ods.od.nih.gov/databases/ibids.html.

New Fact Sheets

New fact sheets are being developed and posted on the NCCAM Web site on an ongoing basis. For copies, go to nccam.nih.gov/health or contact the NCCAM Clearinghouse (see box, pg. 2). Look for the following titles in early fall:

- ▶ Are You Considering Using Complementary and Alternative Medicine?
- ▶ Selecting a Complementary and Alternative Medicine Practitioner
- ▶ Consumer Financial Issues in Complementary and Alternative Medicine
- ▶ General Background Information on Botanicals*
- ▶ Questions and Answers About Black Cohosh and the Symptoms of Menopause*
- ▶ Questions and Answers About Valerian and Sleep Disorders*

*Coproduced by NCCAM and the NIH Office of Dietary Supplements.

A video of "The Science of Complementary and Alternative Medicine," a lecture given at NIH in March 2002 by Stephen E. Straus, M.D., NCCAM Director, is available for viewing on the Web at www.researchchannel.com (customer service phone number 1-877-616-7265).

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