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NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and Alternative Medicine

Focus on Research and Care

in this issue

Complementary and Alternative Medicine: Focus on Research and Care is the newsletter of the National Center for Complementary and Alternative Medicine (NCCAM), a component of the National Institutes of Health, U.S. Department of Health and Human Services.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Survey Sheds New Light on Adults'—and Children's—Use of CAM

Complementary and alternative medicine (CAM) is used frequently in the United States. An updated portrait of this use—including, for the first time, CAM use in children, and trends and changes in overall CAM use since 2002—is now available from a large, national, Federal survey published in December 2008. Among its major findings are that about 38 percent of adult Americans and about 12 percent of American children under age 17 are using CAM.

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Tai Chi

A Collaborative Survey

NCCAM and the National Center for Health Statistics, part of the Centers for Disease Control and Prevention (CDC), developed a detailed set of questions on CAM as part of the 2007 National Health Interview Survey (NHIS). The NHIS is an annual study in which tens of thousands of Americans are interviewed about their health- and illness-related experiences. For the 2007 survey on CAM, researchers interviewed more than 23,300 adults aged 18 years or older. Many respondents also answered questions on CAM use by children in their households (about 9,400 children aged 17 years and under).

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Sorting Claims From Facts About CAM

If you are a health care provider, your patients are likely asking you questions about the use of complementary and alternative medicine. How can you advise them and help them distinguish between CAM therapies that have good-quality research on effectiveness

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If you would like to make a suggestion for a future issue, please write the Editorial Office.

Welcome to Our New Newsletter

We at the National Center for Complementary and Alternative Medicine (NCCAM) have made some significant changes to our newsletter, including a fresh new design and content that is more focused on research and patient care.

The changes you see are based on your comments, including reader surveys, and your expressed preference for information about news focusing on NCCAM—the Center itself, as well as research and clinical care information emerging from its activities and functions.

As we mark our 10th anniversary, we plan to offer you a publication with a new mix of feature stories and other information, which we hope will be useful, lively, and quick and easy to read and use.

Forty-eight percent of our readers are health care providers, making them our largest audience segment. Thus, eight pages of the newsletter have a focus on news for clinicians, whether they are in conventional medicine, CAM, or integrative medicine. Patients, their families and friends, and the general public make up about 30 percent of our audience, and each issue will have an insert containing features targeted to them. We hope, however, that all NCCAM's stakeholders will find evidence-based information throughout each issue that they can use.

As you read the first few issues in 2009, we invite you to let us know how our new format is working and suggest what you would like to see in future issues. There will be a reader survey in our September 2009 issue.

As before, you will also find news and information on NCCAM's Web site, through our Clearinghouse, and in *NCCAM Update*, our electronic news bulletin. Thank you for your interest in NCCAM and its outreach activities.

Upcoming Talks by the Director

This column lists selected upcoming talks by Josephine P. Briggs, M.D., Director of NCCAM.

February 19, New York City:
Integrative Healthcare Symposium

February 26, Washington, D.C.:
Summit on Integrative Medicine and the Health of the Public

March 6, Fort Worth:
Research Appreciation Day, Texas College of Osteopathic Medicine

March 14, Washington, D.C.:
Annual Meeting, American Academy of Allergy, Asthma & Immunology

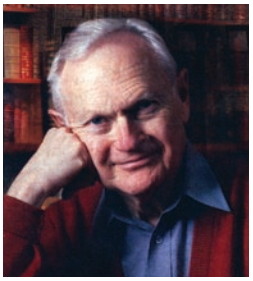
April 18, Portland, Oregon:
Symposium for Portland Area Research on Complementary & Alternative Medicine

Join Us As We Celebrate 10 Years

February 2009 marks NCCAM's 10th anniversary as one of NIH's institutes and centers. Since the U.S. Congress established NCCAM in 1999, the Center has funded more than 2,200 research projects, helping to fulfill its mission of supporting rigorous research on CAM, building CAM research capacity, and sharing authoritative information.

Among the many activities we are planning to mark this milestone, we will feature:

■ Inauguration of a new lecture series at NIH, the Stephen E. Straus Distinguished Lecture in the Science of CAM. The lecture series is named in honor of NCCAM's first Director and supported by the Foundation for the National Institutes of Health with generous funding from the Bernard Osher Foundation. On March 10, 2009, NCCAM will welcome Sherwin B. Nuland, M.D., who will speak on "Chinese Medicine, Western Science, and Acupuncture." Dr. Nuland is clinical professor of surgery at the Yale School of Medicine and a research affiliate of Yale's Institution for Social and Policy Studies and its Program in the History of Science and Medicine. His many books include *How We Die*, *The Art of Aging*, and his new book in 2009, *The Soul of Medicine*. The lecture will be videocast and archived for future Web viewing at videocast.nih.gov.


Sherwin Nuland, M.D.

■ A scientific symposium at NIH on December 8, 2009, that will highlight major scientific advances and research opportunities in CAM research.

■ A special section on CAM in the Winter 2009 issue of *NIH MedlinePlus* magazine.

For the latest information on 10th anniversary activities, go to nccam.nih.gov/news/anniversary.htm. For more on NIH MedlinePlus *magazine (subscriptions are free), go to www.nlm.nih.gov/medlineplus/magazine.html.*

From the Director

I extend my best wishes for 2009 to all readers of NCCAM's newsletter, a newly refocused and redesigned publication. This is an important year for NCCAM. Not only are we celebrating the Center's 10th anniversary, we are also embarking on our next phase of strategic planning. In that context, I would like to offer a few thoughts and invite your participation.

Recently, we saw the release of findings from the latest National Health Interview Survey on complementary and alternative medicine, discussed on pg. 1. They continue to show that a large number of Americans are using CAM for purposes of health and wellness. It is also clear that there is an enormous public desire for information about CAM. As I scan news on the Internet, open the newspaper, or turn on the TV or radio, I am struck by how often CAM topics are in the news. If you are a health care provider, you almost certainly hear about CAM from your patients. The high levels of interest in and use of CAM underscore the importance of NCCAM's mission to support rigorous research, build CAM research capacity, and share authoritative, evidence-based information.

Since I was appointed NCCAM's Director last year, I have engaged in a "listening tour." This has given me the opportunity to meet and learn from an enormously diverse group of practitioners, scientists, and members of the public. The insights gained from those meetings are helping to craft the Center's research priorities and inform our next strategic plan for the coming years.

As in previous strategic planning processes, we invite suggestions and comments from all of our stakeholders. We want to hear your thoughts and ideas in terms of future directions for research, training, and information dissemination.

I look forward to meeting and hearing from more of you in the course of this special year for NCCAM.

Josephine P. Briggs, M.D.
Director

Calendar of Events

This calendar lists CAM events in which NCCAM or other components of NIH are sponsors or participants, and that especially may be of interest to clinicians. It includes information available at press time and Web sites for more information.

MARCH 2009

The Stephen E. Straus Distinguished Lecture: March 10. Sherwin Nuland, M.D., Yale University (see pg. 3). *Location:* Masur Auditorium, Building 10, NIH, Bethesda, Maryland. See nccam.nih.gov/news/.

MAY 2009

North American Research Conference on Complementary & Integrative Medicine: Collaboration to Promote Scientific Discovery and Health: May 12-15. *Location:* Minneapolis. See www.imconsortium-conference.org.

next issue

Ginkgo Studied for Prevention of Dementia

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Ginkgo biloba

The herb ginkgo *(Ginkgo biloba)* comes from one of the oldest types of trees in the world and has been part of traditional Chinese medicine for thousands of years. Today, many people who use ginkgo do so with the intent to improve their memory or prevent dementia.

Results are in from the largest clinical trial ever conducted on ginkgo, the Ginkgo Evaluation of Memory (GEM) study. The researchers found that ginkgo had no significant effect in reducing the development of dementia or Alzheimer's disease in older people. On the safety side, there were no significant adverse effects or increased risk of bleeding in people taking ginkgo.

The multicenter study was led by Steven T. DeKosky, M.D., vice president of the School of Medicine at the University of Virginia in Charlottesville, formerly of the University of Pittsburgh. It was funded by five NIH components: NCCAM; the National Institute on Aging; the National Heart, Lung, and Blood Institute; the National Institute of Neurological Disorders and Stroke; and the Office of Dietary Supplements.

The GEM study focused on whether ginkgo decreased the incidence of all types of dementia and if it had any effect on overall cognitive decline. Functional disability, occurrence of cardiovascular disease, and mortality were also measured.

The 8-year, placebo-controlled trial enrolled over 3,000 participants age 75 or older who were diagnosed with either normal cognition or mild cognitive impairment (volunteers with prevalent dementia were excluded). The active-treatment group received 120 milligrams of ginkgo extract twice daily; the placebo group, an identical-appearing extract. The study's endpoint was the diagnosis of dementia, as determined from standard criteria. Patients with this diagnosis underwent magnetic resonance imaging to identify the type of dementia.

Among future benefits from GEM will be knowledge about how many participants are needed to obtain clinically significant outcome measures and possible insights on subgroups who may be at greater risk for developing dementia. The study also showed that large clinical trials on dementia prevention can be conducted successfully in older adults.

"If older patients are considering using ginkgo for preventing dementia," said Dr. DeKosky, "I urge them to speak with their health care providers about the results of this study and work together to create the best treatment plan. Our results confirm the importance of randomized trials in the development of new therapies for dementia and Alzheimer's disease and in determining therapeutic benefit not only for conventional therapies but also complementary therapies like ginkgo."

For more information, visit nccam.nih.gov/news/2008/111808.htm. An interview with Dr. DeKosky appears at right.

Reference

DeKosky ST, Williamson JD, Fitzpatrick AL, et al. Ginkgo biloba for prevention of dementia. *Journal of the American Medical Association*. 2008;300(19):2253-2262.

Cognitive Disorders in Later Life

An Interview with Steven T. DeKosky, M.D.

Steven T. DeKosky, M.D., principal investigator and lead author of the Ginkgo Evaluation of Memory study (see pg. 4), is vice president and dean of the University of Virginia School of Medicine. He was formerly professor and chairman of the department of neurology and director of the Alzheimer's Disease Research Center at the University of Pittsburgh. Dr. DeKosky's research has progressively focused on the science and clinical care of Alzheimer's disease. Among his other commitments, he has served as a board member for the Alzheimer's Association USA and Alzheimer's Disease International.

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Why do some older Americans turn to CAM to try to prevent or treat cognitive issues? How do you advise your patients in this situation?

Older individuals notice the normal age-related changes in memory and cognitive function. This can serve as a stimulus to try things that may be helpful in preserving their thinking function, including many preparations that may have a biological rationale [i.e., a theory as to how it may work], such as anti-inflammatory or anti-oxidant activity. We know that there is mild inflammation and oxidative stress in the brain (and other parts of the body) associated with normal aging.

In general, if a CAM medication that a patient wishes to try is not harmful and is not expensive to the point of causing family hardship, I will work to incorporate its use along with FDA-approved medications, as will many physicians. The major problems are if side effects emerge or if it interacts, or could interact, with a prescription medicine. Thus, it is very important for patients to tell their doctors about all medications—both over-the-counter and prescription—that they are taking.

I also tell patients that it is helpful if there is a biological rationale for a CAM treatment, but it does not prove the treatment works. If there are clinical trials evaluating the treatment, I urge the patient and family to participate, both for the careful evaluation and follow-up that is provided and to help science to determine whether or not the treatment truly is effective.

You have also researched depression in later life. Is this a common problem, and can it be connected to cognitive disorders?

Depression is quite common in late life. It is quite capable of causing both loss of interest in everyday activities and impairment of memory, thinking functions, and speed of cognitive processing. It should always be a consideration in the differential diagnosis of cognitive impairment in late life. The literature is still unsettled as to whether having depression is a risk factor for Alzheimer's disease or whether some of the early brain changes in Alzheimer's cause depression. In either case, looking for depression and treating it aggressively is extremely important.

There are other disorders as well that interact with Alzheimer's and other cognitive losses in late life; perhaps the most frequent is cerebrovascular disease. Vascular disease and large and small strokes can in themselves cause vascular dementia. Also, it appears that the presence of Alzheimer's pathology and cerebrovascular disease interact. Many experts think that clinical dementia symptoms emerge sooner if you have both diseases present.

> "Depression is quite common in late life... [it] should always be a consideration in the differential diagnosis of cognitive impairment." — Dr. DeKosky

As an expert in Alzheimer's disease, what do you think are some promising and/or exciting directions in that field?

The initial medications developed for Alzheimer's emerged because we understood some of the losses of specific neurotransmitters, the chemicals that allow nerve cells to communicate with each other. Boosting or enhancing neurotransmission was intended to give some short-term symptomatic improvement. That strategy worked, but was not directed at trying to slow progression of the disease.

Over the last decade, research has increasingly shown us the fundamental mechanisms that appear to result in loss of brain cells and their connections and to affect and alter proteins. An immense amount of research is

continued on back page

Research Award for CAM Practitioners

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The Bernard Osher Foundation/ NCCAM CAM Practitioner Research Career Development Award was established in 2006 to help diminish barriers for CAM clinicians who desire to pursue a career in CAM research. Awards provide support for a sustained period of "protected time" of intensive career development research and training under the guidance of an experienced mentor.

In late 2008, NIH announced that eligibility guidelines have been expanded. They now include candidates with:

- A CAM health-professional doctoral degree (i.e., a CAM clinical doctorate); those who also hold a conventional biomedical or behavioral research or clinical doctoral degree (e.g., Ph.D. or M.D.) are no longer excluded.
- A conventional biomedical or behavioral research or clinical doctoral degree (Ph.D. or M.D.) and a state license to practice a CAM profession.

For more information, visit grants.nih.gov/grants/guide/notice-files/not-at-08-005.html.

New Research Centers Announced

In October 2008, NCCAM added four new Centers of Excellence for Research on Complementary and Alternative Medicine (CERCs) to its research centers program. In each CERC, highly accomplished researchers across a variety of disciplines apply cutting-edge technology to projects in CAM.

Wisconsin Center for the Neuroscience and Psychophysiology of Meditation

Principal Investigator: Richard J. Davidson, Ph.D.
Institution: University of Wisconsin, Madison
Dr. Davidson's team will examine the impact of two forms of meditation—loving-kindness/compassion meditation and mindfulness meditation—on the brain and body, focusing on the regulation of emotion and on emotional reactivity. Potential applications in health include biological and behavioral processes linked with emotions and/or stress, such as recurrent depression.

CAM as Countermeasures Against Infectious and Inflammatory Disease

Principal Investigator: Mark A. Jutila, Ph.D.
Institution: Montana State University, Bozeman
This center will study biologically based CAM therapies and their effects on immune system function in infectious and inflammatory diseases. One project focuses on effects of botanical extracts—from apple polyphenols, which are concentrated in apple skins, and from yamoa, which comes from the bark of an African gum tree—on white blood cells, using models of infection and inflammation of the intestinal mucosa. A second project examines two compounds in licorice root—glycyrrhizin and 18-glyrrhetinic acid—for their potential antiviral effects in models of influenza and stomach virus. A third project will focus on bacterial products to see how they treat autoimmune diseases, like arthritis, which may also help build understanding of probiotics' action.

Metabolic and Immunologic Effects of Meditation

Principal Investigator: Frederick M. Hecht, M.D.
Institution: University of California, San Francisco
Dr. Hecht and his colleagues will study a program combining mindfulness meditation, mindful eating (a practice of awareness and attentiveness in the present moment while eating), and a diet and exercise program, for use in obesity and metabolic syndrome. They will test whether this program helps alter participants' hormonal responses to stress and helps enhance and maintain weight loss. Metabolic syndrome involves a cluster of abnormalities—including increased cholesterol, high blood pressure, and insulin resistance—that increases one's risk for developing diabetes and cardiovascular diseases.

Center for Herbal Research on Colorectal Cancer

Principal Investigator:
Chun-Su Yuan, M.D., Ph.D.
Institution: University of Chicago
Colorectal cancer is the third most common cancer and the third leading cause of cancer-related death. Dr. Yuan and his colleagues will examine the antitumor effects of different preparations of the herbs American ginseng (*Panax quinquefolius*) and notoginseng (*Panax notoginseng*). They will seek to learn more, through laboratory and animal studies, about how these herbs act upon cellular and molecular pathways of the mechanisms of cancer inhibition.

For more about NCCAM's research centers, go to nccam.nih.gov/training/centers/.

Get the Facts

Information for Consumers

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Children and Complementary and Alternative Medicine

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A wide range of complementary and alternative medicine (CAM) therapies are used in children, including herbs and dietary supplements, massage, acupuncture, chiropractic care, naturopathy, and homeopathy. This fact sheet from the National Center for Complementary and Alternative Medicine (NCCAM) offers information for parents who are thinking about using a CAM therapy for their child.

Patterns of CAM Use in Children

The 2007 National Health Interview Survey gathered information on CAM use among more than 9,000 children aged 17 and under. Nearly 12 percent of the children had used some form of CAM during the past 12 months. CAM use was much more likely among children whose parents also used CAM. Adolescents aged 12-17, children with multiple health conditions, and those whose families delayed or did not use conventional medical care because of cost were also more likely to use CAM. The accompanying figures show survey findings on CAM use by children, including top therapies and diseases/conditions.

In addition, a 2001 survey of 745 members of the American Academy of Pediatrics found that 87 percent of pediatricians had been asked about CAM therapies by a patient or a parent in the 3 months prior to the survey. The pediatricians were asked most often about herbs and dietary supplements.

Safety of Childhood CAM Use

Few high-quality studies have examined how CAM therapies may affect young people, and results from studies in adults do not necessarily apply to children. Children are not small adults. Their immune and central nervous systems are not fully developed, which can make them respond to treatments differently from adults. This is especially true for infants and young children.

Herbs and other dietary supplements may interact with medicines or other supplements, or they may cause problems during surgery, such as bleeding-related complications. In addition, "natural" does not necessarily mean "safe." CAM therapies can have side effects, and these may be different in children than in adults.

Parents should seek information from scientific studies about how safe and effective a specific CAM therapy is in children. However, since few, if any, rigorous studies in young people exist, additional scientific studies are needed. Anecdotes and testimonials (personal stories) about CAM therapies are common and can be compelling, but they are not evidence.

Discussing CAM With Your Pediatrician

Parents often do not tell pediatricians or other health care providers that their child is receiving CAM. It is important, however, that families speak with their child's health care provider about any CAM therapy being used or considered. Providing a full picture of what is being done to

For tips about talking with your health care provider about CAM, see NCCAM's Time to Talk campaign at nccam.nih.gov/timetotalk/.

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manage your child's health will help ensure coordinated and safe care.

If seeking care from a CAM practitioner, it is important to ask about the practitioner's:

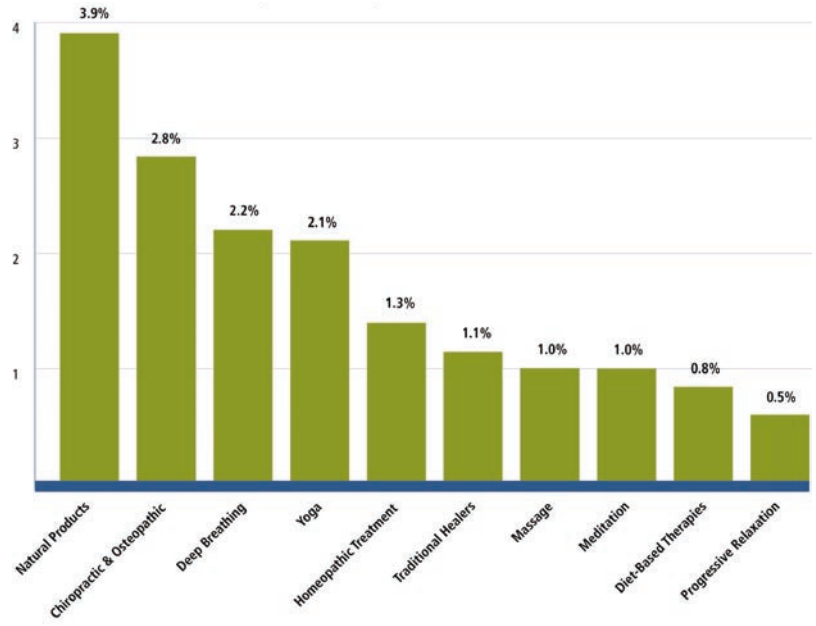
- Education and training
- Experience in delivering care to children
- Experience working with other providers, including physicians, to ensure coordinated care
- Licensing (some states have licensing requirements for certain CAM practitioners, such as chiropractors, naturopathic doctors, massage therapists, and acupuncturists).

Additional Points To Consider

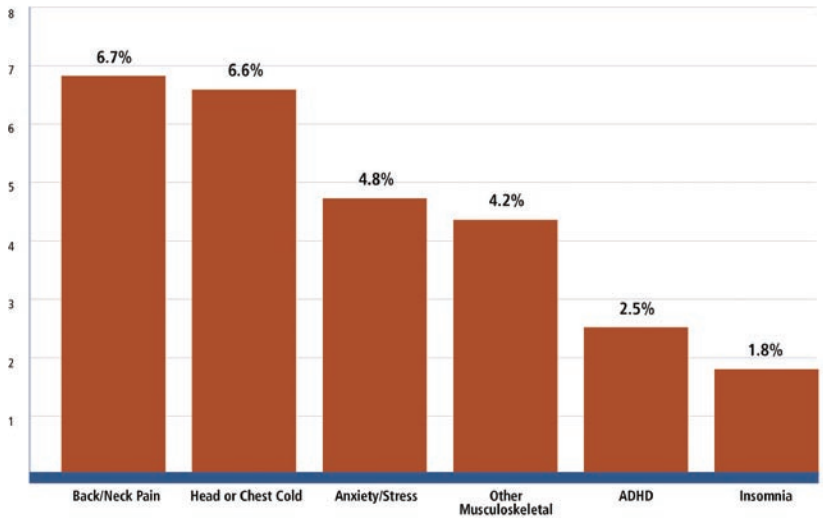
In addition to asking your child's physician what is known about whether a therapy works and is safe for children, consider these points when making decisions about using CAM in children:

- Ensure that your child has received an accurate diagnosis from a licensed health care provider and that CAM use does not replace or delay conventional medical care.
- If you decide to use CAM for your child, do not increase the dose or length of treatment beyond what is recommended. More is not necessarily better.
- If your child experiences an effect from a CAM therapy that concerns you, contact your child's health care provider.
- Store herbal and other dietary supplements out of the sight and reach of children.
- If you are a woman who is pregnant or breastfeeding, remember that some CAM therapies may affect your fetus or nursing infant.

10 Most Common Therapies Among Children—2007



Diseases/Conditions for Which CAM Is Most Frequently Used Among Children—2007



For More Information

You can learn more about CAM through the NCCAM Clearinghouse. The Clearinghouse provides a wide range of resources, including:

- Fact sheets with important tips for making decisions about CAM use
- Information on specific types of CAM
- Additional findings from the 2007 NHIS survey on CAM use by adults and children
- Access to other resources, such as online databases where you can search for scientific evidence about CAM therapies you may be considering for your child.

NCCAM Clearinghouse

Web site: nccam.nih.gov
Toll-free in the U.S.: 1-888-644-6226
TTY (for deaf and hard-of-hearing callers): 1-866-464-3615
E-mail: info@nccam.nih.gov

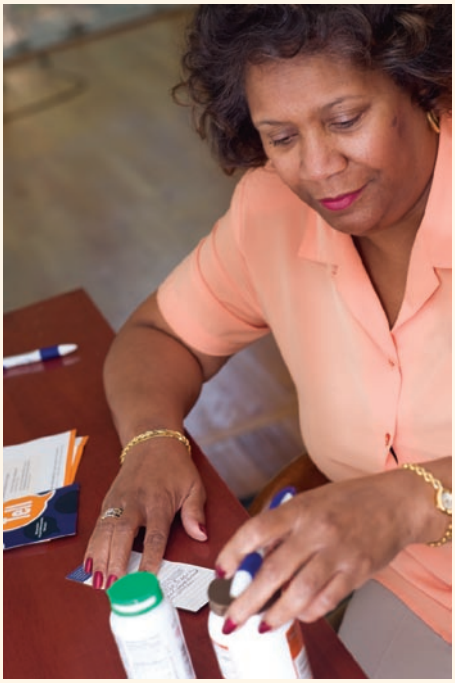
Please note that NCCAM does not provide medical advice, treatment recommendations, or referrals to practitioners.

Get the Facts

Information for Consumers

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Using Dietary Supplements Wisely



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Many people take dietary supplements in an effort to be well and stay healthy. With so many dietary supplements available and so many claims made about their health benefits, how can a consumer decide what's safe and effective?

About Dietary Supplements

Dietary supplements were defined in a law passed by Congress in 1994 called the Dietary Supplement Health and Education Act (DSHEA). According to DSHEA, a dietary supplement is a product that:

- Is intended to supplement the diet
- Contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and certain other substances) or their constituents
- Is intended to be taken by mouth, in forms such as tablet, capsule, powder, softgel, gelcap, or liquid
- Is labeled as being a dietary supplement.

Research has shown that some uses of dietary supplements are effective in preventing or treating diseases. For example, scientists have found that folic acid (a vitamin) prevents certain birth defects, and a regimen of vitamins and zinc can slow the progression of the age-related eye disease macular degeneration. Also, calcium and vitamin D supplements can be helpful in preventing and treating bone loss and osteoporosis (thinning of bone tissue).

Research has also produced some promising results suggesting that other dietary supplements may be helpful for other health conditions (e.g., omega-3 fatty acids for coronary disease), but in most cases, additional research is needed before firm conclusions can be drawn.

Federal Regulation of Dietary Supplements

The Federal Government regulates dietary supplements through the U.S. Food and Drug Administration (FDA). The regulations for dietary supplements are not the same as those for prescription or over-the-counter drugs. In general, the regulations for dietary supplements are less strict.

- A manufacturer does not have to prove the safety and effectiveness of a dietary supplement before it is marketed. A manufacturer is permitted to say that a dietary supplement addresses a nutrient deficiency, supports health, or is linked to a particular body function (e.g., immunity), if there is research to support the claim. Such a claim must be followed by the words "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- Manufacturers are expected to follow certain "good manufacturing practices" (GMPs) to ensure that dietary supplements are processed consistently and meet quality standards. Requirements for GMPs went into effect in 2008 for large manufacturers and are being phased in for small manufacturers through 2010.
- Once a dietary supplement is on the market, the FDA monitors safety. If

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it finds a product to be unsafe, it can take action against the manufacturer and/or distributor, and may issue a warning or require that the product be removed from the marketplace.

Also, once a dietary supplement is on the market, the FDA monitors product information, such as label claims and package inserts. The Federal Trade Commission (FTC) is responsible for regulating product advertising; it requires that all information be truthful and not misleading.

Sources of Science-Based Information

It's important to look for reliable sources of information on dietary supplements so you can evaluate the claims that are made about them. The most reliable information on dietary supplements is based on the results of rigorous scientific testing.

To get reliable information on a particular dietary supplement:

- Ask your health care providers. Even if they do not know about a specific dietary supplement, they may be able to access the latest medical guidance about its uses and risks.
- Look for scientific research findings on the dietary supplement. NCCAM and the Office of Dietary Supplements, both a part of the National Institutes of Health (NIH), as well as other Federal agencies, have free publications, clearinghouses, and information on their Web sites.

Safety Considerations

If you are thinking about or are using a dietary supplement, here are some points to keep in mind.

Tell your health care providers about any complementary and alternative practices you use, including dietary supplements (see nccam.nih.gov/timetotalk/). It is especially important to talk to your health care provider if you are

- Thinking about replacing your regular medication with one or more dietary supplements.
- Taking any medications (whether prescription or over-the-counter), as some dietary supplements have been found to interact with medications.
- Planning to have surgery. Certain dietary supplements may increase the risk of bleeding or affect the response to anesthesia.
- Pregnant or nursing a baby, or are considering giving a child a dietary supplement. Most dietary supplements have not been tested in pregnant women, nursing mothers, or children.

If you are taking a dietary supplement, **read the label instructions**. Talk to your health care provider if you have any questions, particularly about the best dosage for you to take. If you experience any side effects that concern you, stop taking the dietary supplement, and contact your health care provider. You can also report your experience to the FDA's MedWatch program. Consumer safety reports on dietary supplements are an important source of information for the FDA.

Keep in mind that although many dietary supplements (and some prescription drugs) come from natural sources, **"natural" does not always mean "safe."** For example, the herbs comfrey and kava can cause serious harm to the liver. Also, a manufacturer's use of the term "standardized" (or "verified" or "certified") does not necessarily guarantee product quality or consistency.

Be aware that **an herbal supplement may contain dozens of compounds** and that its active ingredients may not be known. Researchers are studying many of these products in an effort to identify active ingredients and understand their effects in the body. Also consider the possibility that what's on the label may not be what's in the bottle. Analyses of dietary supplements sometimes find differences between labeled and actual ingredients. For example:

- An herbal supplement may not contain the correct plant species.
- The amount of the active ingredient may be higher or lower than the label states. That means you may be taking less—or more—of the dietary supplement than you realize.
- The dietary supplement may be contaminated with other herbs, pesticides, or metals, or even adulterated with unlabeled ingredients such as prescription drugs.

For current information from the Federal Government on the safety of particular dietary supplements, check the "Dietary Supplements: Warnings and Safety Information" section of the FDA Web site at www.cfsan.fda.gov/~dms/ds-warn.html.

For More Information

You can learn more about dietary supplements from NCCAM by viewing the expanded version of this fact sheet at nccam.nih.gov/health/supplements/wiseuse.htm or ordering a printed version from the NCCAM Clearinghouse. The expanded fact sheet includes selected references and additional resources.

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Web site: nccam.nih.gov
Toll-free in the U.S.: 1-888-644-6226
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Please note that NCCAM does not provide medical advice, treatment recommendations, or referrals to practitioners.

Glucosamine and Chondroitin for Cartilage Loss

A recent study of the dietary supplements glucosamine and chondroitin sulfate (CS), alone and in combination, for treating cartilage loss in knee osteoarthritis has found that the active-treatment group did not fare better than the placebo group. Interpreting these results is complicated, however, by the placebo group having lost a smaller amount of cartilage than was expected, based on prior research.

The findings, released in September 2008, are from an ancillary (secondary) study in the Glucosamine/chondroitin Arthritis Intervention Trial, or GAIT. This is a large, prospective, randomized clinical trial supported by NCCAM and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and led at the University of Utah School of Medicine, Salt Lake City.

Previous GAIT results, reported in 2006, centered on pain in osteoarthritis. In that study, overall, glucosamine and CS did not provide significant pain relief for all participants. However, when combined, these supplements may have provided relief for a small subgroup with moderate-to-severe pain.

The 2008 results are from a 2-year study of a subset of GAIT participants. Five randomized groups received either 500 milligrams (mg) of glucosamine three times daily, 400 mg of CS three times daily, glucosamine plus CS, 200 mg of celecoxib daily, or placebo. Using an x-ray protocol, the researchers measured loss of cartilage, represented by loss of joint space width, upon entrance to the study and at 1- and 2-year benchmarks.

Allen Sawitzke, M.D., associate professor of internal medicine at the University of Utah, led the ancillary study, and *Complementary and Alternative Medicine* asked him to comment to clinicians. He said, "We have found these agents to be generally safe and well tolerated. To date, the evidence supporting relief of pain is stronger than that for slowing of cartilage loss. Hence, a short trial for relief of pain can help each patient make his own decision."

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Daniel Clegg, M.D., principal investigator for GAIT and professor of medicine and chief of rheumatology at the University of Utah, noted that despite limitations in the ancillary study, it has yielded new insights on the progression of osteoarthritis, techniques for reliably measuring structural damage from the disease, the effects of these supplements, and predictors for who may respond best in future studies.

To read more, go to www.nih.gov/news/health/sep2008/nccam-29.htm.

Reference

Sawitzke AD, Shi H, Finco MF, et al. The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: a report from the glucosamine/chondroitin arthritis intervention trial. *Arthritis & Rheumatism.* 2008;58(10):3183-3191.

Dr. Killen Named Deputy Director

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John (Jack) Killen, Jr., M.D., was recently appointed Deputy Director of NCCAM. Dr. Killen joined the Center in 2003 as Director of the Office of International Health Research, where he has fostered international research collaborations studying complementary, alternative, and traditional medicine. He has also served as NCCAM's Acting Deputy Director, Acting Director of the Division of Extramural Research, and Acting Director of the Office of Policy, Planning, and Evaluation.

In his 27-year NIH career, Dr. Killen has served in a number of other senior positions as well, including Head of the Office of Biodefense Research, Associate Director of Research Ethics, and Director of the Division of AIDS at the National Institute of Allergy and Infectious Diseases. He was also Head of the International Research Section of the Department of Clinical Bioethics at the NIH Clinical Center, and he has worked with multicenter clinical trials and drug development at the National Cancer Institute.

Dr. Killen received his M.D. degree from Tufts University in 1975. He is board certified in internal medicine and medical oncology and has pursued additional training in end-of-life care and mind-body medicine. His awards include the NIH Merit Award, the NIH Director's Award, the U.S. Public Health Service (PHS) Special Recognition Award, and the PHS Superior Service Award.

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"These new findings provide the most current, comprehensive, and reliable information on Americans' use of CAM," said Josephine P. Briggs, M.D., Director of NCCAM. "As in 2002, they confirm that CAM practices are a frequently used component of Americans' health care regimens. They also reinforce the need for rigorous research on the safety and effectiveness of these therapies and for open discussion between patients and providers about CAM use."

The 2007 survey, compared with the 2002 NHIS supplement on CAM:

- Asked about more types of CAM—36 therapies, up from 27 in 2002. These include 10 provider-based therapies such as acupuncture and chiropractic, and 26 therapies that do not require a provider, such as herbal supplements and special diets. The 2007 survey also included new questions focusing on traditional healers and movement therapies.
- Assessed more diseases and conditions.
- Surveyed CAM use in children for the first time.

CAM Use Among Adults

Richard L. Nahin, Ph.D., M.P.H., is a coauthor of the study. He serves as NCCAM's Acting Director of the Division of Extramural Research and Senior Advisor for Scientific Coordination and Outreach. Dr. Nahin noted some other points of comparison with the 2002 data as follows:

- The 2007 figure of 38 percent of adults using CAM is essentially unchanged from the 2002 figure of 36 percent. Dr. Nahin commented that "it appears that the rate of CAM use in the United States has probably stabilized."
- There were changes in 2007, however, in the rate of use of some CAM therapies—including increases in several mind-body therapies (deep breathing exercises, meditation, and yoga) and in acupuncture, massage therapy, and naturopathy (see Figure 1). Rate of use decreased significantly for some therapies, including several special diets (the Atkins, Zone, and Macrobiotic diets) and tai chi.
- The most commonly used CAM modality was various nonvitamin, nonmineral, natural products (17.7 percent) such as herbal medicines and other dietary supplements. In this category, the most commonly used products were fish oil/omega 3/DHA, glucosamine, echinacea, flaxseed oil or pills, and ginseng (Figure 2).
- After natural products, the next most popular CAM therapies were deep breathing exercises (12.7 percent); meditation (9.4 percent); chiropractic or osteopathic manipulation (8.6 percent); and massage (8.3 percent) (Figure 1).
- Adult use of CAM in 2007 was greater in groups that had one or more of the following characteristics (most of which were also found in 2002):
  - ☐ Female
  - ☐ A higher level of education
  - ☐ A race/ethnicity of American Indian/Alaska native, followed by the categories of White, Asian, Black, and Hispanic
  - ☐ Residence in the Western United States
  - ☐ A higher income level
  - ☐ A higher number of health problems (diseases and/or conditions)
  - ☐ A higher number of doctor visits in the prior 12 months
  - ☐ History of hospitalization in the year prior to the survey
  - ☐ Having delayed or not received conventional care in the previous year because of cost issues
  - ☐ Former smokers.

The highest rates of CAM use were in adults aged 40 to 60. The highest **increase** in the rate of CAM use was seen in adults aged 60 to 85-plus.

- Americans used CAM most often for conditions involving chronic pain, a trend that was also seen in 2002. The top four diseases/conditions for which people used CAM in 2007 were back pain or other back problems, neck pain or other neck problems, joint pain or stiffness or other joint condition, and arthritis (Figure 3). Next in line were anxiety, cholesterol control, and head or chest cold.

Figure 1. 10 Most Common CAM Therapies Among Adults—2007

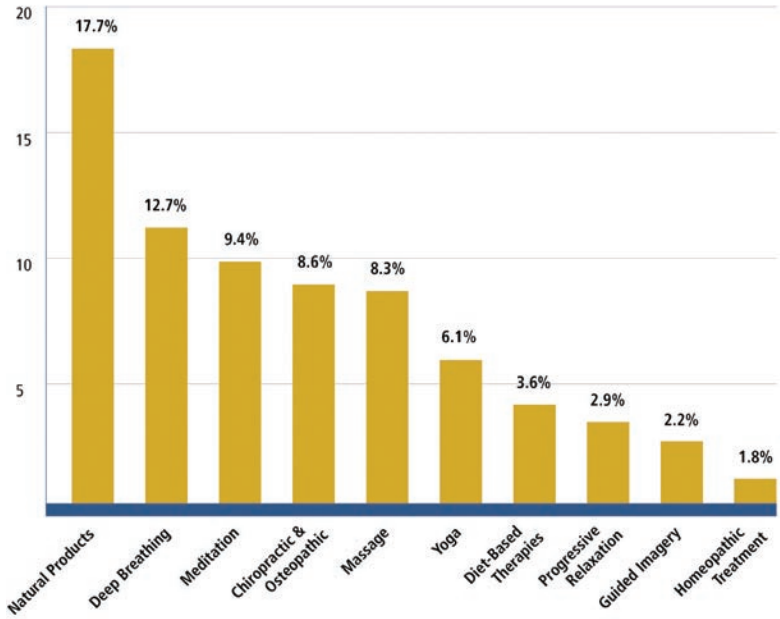
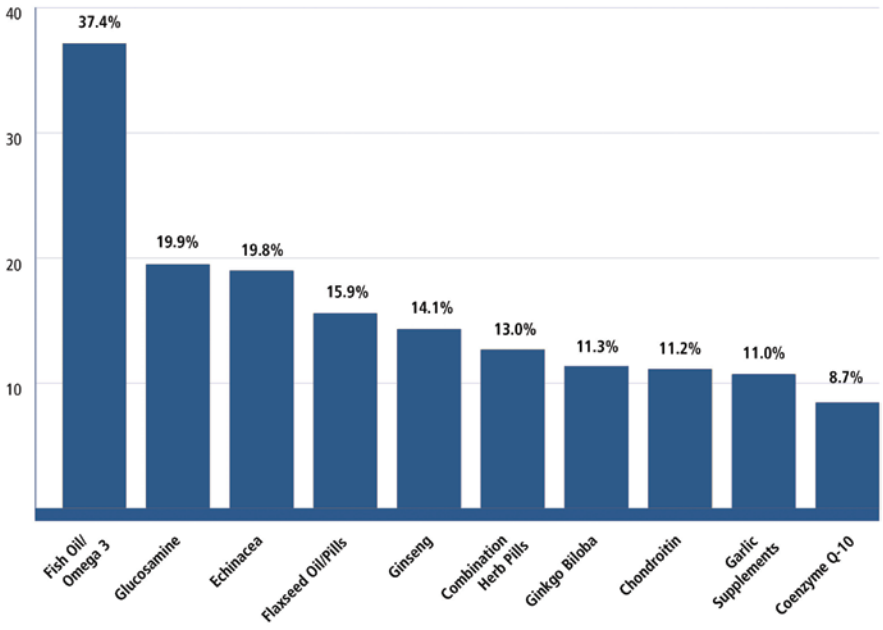


Figure 2. 10 Most Common Natural Products Among Adults—2007



CAM Use in Children

■ Almost one in nine children (about 12 percent) in the survey had used CAM. The authors note that the estimates of CAM use by children may actually be on the low side, because some adolescents may not reveal CAM use to parents or other adults in their household.

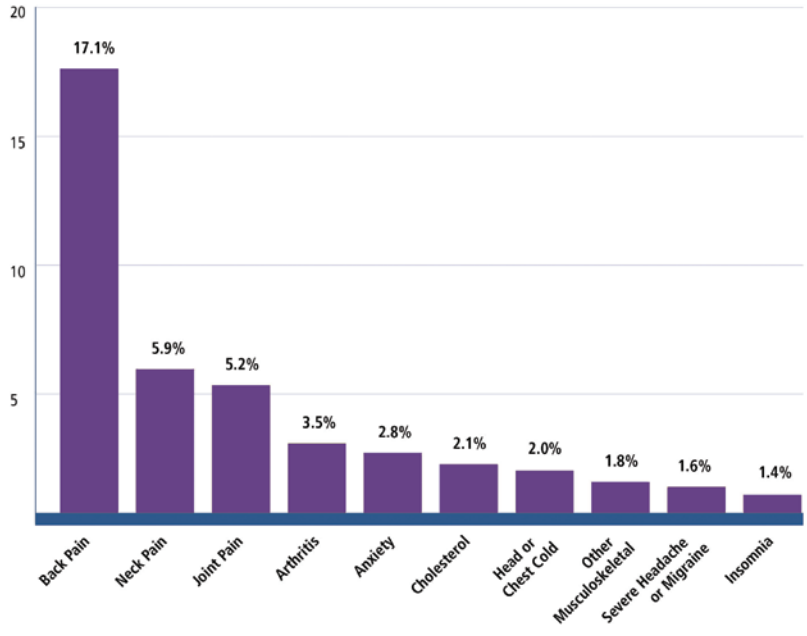
■ The most commonly used CAM therapies in children were nonvitamin, nonmineral, natural products; chiropractic or osteopathic manipulation; deep breathing exercises; yoga; and homeopathic treatment (for figures on children, see nccam.nih.gov/news/camstats/2007).

■ Most often, CAM therapies were used in children for back or neck pain, colds, anxiety or stress, other musculoskeletal problems, and attention deficit/hyperactivity disorder (ADD/ADHD).

■ Children whose parents used CAM were almost five times more likely to use CAM than children whose parents did not use CAM.

■ Child CAM users were similar to adult CAM users when it came to population factors like socioeconomic status and region of residence.

Figure 3. Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults—2007



In addition to NCCAM, six other components of NIH supported the 2007 NHIS CAM supplement: the National Heart, Lung, and Blood Institute; the National Institute of Allergy and Infectious Diseases; the National Institute of Mental Health; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the NIH Office of Dietary Supplements; and the NIH Office of Behavioral and Social Sciences Research.

The full report on the 2007 CAM supplement is available through the NCCAM Web site at nccam.nih.gov/news/camstats/2007/. The survey data are also publicly available for additional analysis from the CDC Web site at www.cdc.gov/nchs.

References

Barnes PM, Bloom B, Nahin R. Complementary and alternative medicine use among adults and children: United States, 2007. *CDC National Health Statistics Report #12*. 2008.

Barnes PM, Powell-Griner E, McFann K, Nahin RL. Complementary and alternative medicine use among adults: United States, 2002. *CDC Advance Data Report #343*. 2004.

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and safety, and those with claims that may be attractive but are not evidence-based? What should you consider when you counsel patients about CAM? In this article we discuss CAM and cancer, but the information resources apply to many other conditions.

Case in Point: Cancer and CAM

CAM use for cancer is substantial, although estimates vary widely. A large 2002 national survey on CAM found that about 40 percent of the respondents with a cancer diagnosis reported using CAM.* The National Cancer Institute (NCI) and NCCAM both support large programs of research intended to build an evidence base that will inform this use. Two ways health care providers can be most helpful to their patients are to encourage open communication about CAM therapies and to find out where to turn for reliable, evidence-based information.

Encouraging Open Communication

"It is very important for health care providers to create an environment, as well as a relationship with their patients, in which they can talk freely about all treatment options, whether CAM or conventional," says Josephine P. Briggs, M.D., Director of NCCAM. "I also believe that health care providers need to convey their understanding of the evidence and advise patients accordingly, even if they are not always in agreement."

* References: (1) Saydah SH, Eberhardt MS. Use of complementary and alternative medicine among adults with chronic diseases: United States 2002. *Journal of Alternative and Complementary Medicine*. 2006; 12(8):805-812. (2) Mao JJ, Farrar JT, Xie SX, et al. Use of complementary and alternative medicine and prayer among a national sample of cancer survivors compared to other populations without cancer. *Complementary Therapies in Medicine*. 2007;15(1):21-29.

"It is very important for health care providers to create an environment, as well as a relationship with their patients, in which they can talk freely about all treatment options." — Dr. Josephine P. Briggs

Questions To Consider

Patrick J. Mansky, M.D., who is trained both in medical and pediatric oncology and in selected CAM therapies, was the first Director of NCCAM's Complementary and Integrative Medicine Consult Service at the NIH Clinical Center before he joined the Cancer Team at Bellin Health in February 2009.

When he has a patient who is interested in CAM therapies, Dr. Mansky asks the following questions:

- What does the therapy consist of?
- Why is the patient interested in trying a CAM therapy? Does she think that her current care is adequate?

Resource Tip

"About Herbs, Botanicals, and Other Products" is an evidence-based, searchable database of the Memorial Sloan-Kettering Cancer Center Integrative Medicine Service, at www.mskcc.org/mskcc/html/11570.cfm. NCCAM's Center for Botanical Immunomodulators, a research center, is located at this institution. Partnering institutions on the center are Memorial Sloan-Kettering, Weill Medical College of Cornell University, The Rockefeller University, and the Institute of Chinese Medicine at the Chinese University of Hong Kong.

Dr. Mansky examines a patient at the NIH Clinical Center

Does she want to add a treatment or make a switch? Is it an issue of side effects?

- Where did the patient hear about the therapy—on the Internet, for example, or from another health care practitioner, a family member or friend, an advocacy organization, etc.?
- Has there been any research published on it? If there are study results, who sponsored the study or studies, are the results freely available, and where were they published (in a peer-reviewed journal or not)?

Is There Evidence?

"No health care provider can be knowledgeable about every CAM therapy and claim out there," Dr. Mansky says. "Sometimes my answer to patients is that I need to do some research and get back to them. For cancer patients, I turn first to NIH Web sites—including those of NCCAM, the National Cancer Institute, the Office of Dietary Supplements, and the National Library of Medicine's PubMed database. There are also large cancer centers that are affiliated with teaching hospitals [e.g., see box at left] and have developed and posted information.

"Many or even most CAM treatments that people hear about or get excited about, however, have not yet been studied for effectiveness and safety," he continues. "Even if there is only a preliminary study or two, it might be at least somewhat helpful. In these cases I offer an honest assessment of the evidence and make the best recommendation I can, making sure that I provide the very best evidence-based care available and keeping the patient's safety a top priority."

Considering Safety

Herbal and other dietary supplements are an area in which safety needs to be looked at carefully. "While many beneficial drugs have been made from plants," Dr. Mansky says, "there are other plants or plant parts that are poisonous or potentially harmful. Many botanicals are pharmacologically active and can interact with conventional drugs or each other. 'Natural' does not equal 'safe.' "

Another major concern is about the use of CAM delaying or interfering with proven, beneficial treatments. For example, some herbs can enhance the blood-thinning effects of drugs such as aspirin or Coumadin. That could increase the risk of bleeding in a patient who is undergoing surgery or receiving chemotherapy that reduces platelet count. High doses of vitamins can significantly interact with chemotherapy and radiation.

Herbal and other dietary supplements are an area in which safety needs to be looked at carefully.

The bottom line, Dr. Mansky says, is that "when I am consulted about CAM, I try to make sure that my patients know that they can talk with me about it. I will do my best to put what is known about the therapy into perspective, help my patients to understand whether the claims are founded, and advise on whether I think it is in their best interests to use it."

FDA and FTC Act on Unsupported Claims

There are many reasons to be concerned about unsupported or even fraudulent therapeutic claims in the field of cancer. The U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have major initiatives to address these concerns.

In September 2008, the FDA announced that it had issued warning letters to 28 U.S. companies and 2 foreign individuals to stop them from selling what it calls "fake cancer 'cures.'" It also warned consumers to stop using them. The 187 products listed include tablets, teas, tonics, black salves (a type of corrosive ointment), and creams that have been sold under various names on the Internet. Because they have not been shown to be safe and effective for their labeled use to cure, treat, mitigate, or prevent disease, the FDA says, they are being marketed as unapproved new drugs and thus are violating the law.

Also in September, the FTC announced an initiative called "Operation False Cures." The agency pursued 11 law enforcement actions against companies, some of which it said were also falsely claiming clinical or scientific proof for their product(s) marketed to treat cancer. These consisted of some Essiac teas and other herbal mixtures, laetrile, black salves, and some mushroom extracts.

For More Information

NCCAM
- *Thinking About Complementary and Alternative Medicine: A Guide for People with Cancer* (coproduced with the National Cancer Institute): www.cancer.gov/cancertopics/thinking-about-CAM
- *Time to Talk* educational campaign (free toolkits available): nccam.nih.gov/timetotalk/
- Toll-free: 1-888-644-6226

National Cancer Institute
- Home page on CAM: www.cancer.gov/cancertopics/pdq/cam/cam-cancer-treatment
- PDQ® treatment summaries: www.cancer.gov/cancertopics/treatment/cam
- Toll-free: 1-800-422-6237

National Library of Medicine
- PubMed: www.ncbi.nlm.nih.gov/sites/entrez

Food and Drug Administration
- "Beware of Online Cancer Fraud": www.fda.gov/consumer/updates/cancerfraud061708.html
- Toll-free: 1-888-463-6332

Federal Trade Commission
- "CURE-ious? Ask.": www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt079.shtm
- Toll-free: 1-877-382-4357

NIH Office of Dietary Supplements
- Health information site: http://dietary-supplements.info.nih.gov/Health_Information/Health_Information.aspx

Clinicaltrials.gov
- An online registry of clinical trials: www.clinicaltrials.gov

Complementary and Alternative Medicine:
Focus on Research and Care
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Center for Complementary and Alternative Medicine
31 Center Drive MSC 2182
Building 31, Room 2B-11
Bethesda, MD 20892-2182

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being directed toward trying to stop the changes in specific proteins and actually modify the course of the disease process. Several of these new medications are in clinical trials now. Recent, spectacular improvements in neuroimaging will not only improve our diagnostic capability but will allow us to measure brain structure or function over time to see whether the brain is shrinking less and its function is maintained. This will make our trials much more efficient and hopefully shorter, and put less stress on our patients.

When medications have been shown to help people who have symptomatic Alzheimer's disease, they will likely go into trials in older people who are cognitively normal or have only very mild cognitive impairment, to see if they can prevent symptoms from ever emerging or delay them for so long that they never become a factor in someone's normal lifespan. That is our ultimate goal.

New Resources From NCCAM

Chinese herbal medicine

The following new NCCAM publications are available on the Web and from the NCCAM Clearinghouse (see pg. 2):

- *CAM and Hepatitis C: A Focus on Herbal Supplements* (nccam.nih.gov/health/hepatitisc/)
- *Tips for Talking With Your Health Care Providers About CAM* (nccam.nih.gov/health/decisions/talkingaboutcam.htm); also in Spanish (nccam.nih.gov/health/espanol/consejos/)

In addition, NCCAM's *Herbs at a Glance: A Quick Guide to Herbal Supplements* booklet is being reprinted—see nccaminfo.org/herbs/herbs.asp or contact the Clearinghouse.

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