

# CAM AT THE NIH

FOCUS ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

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## In Memoriam: Stephen E. Straus, M.D.



Stephen E. Straus, M.D., founding Director of the National Center for Complementary and Alternative Medicine (NCCAM), died of brain cancer on May 14, 2007. He was 60.

“As NCCAM’s first Director, Dr. Straus articulated an uncompromising and compelling agenda for scientific research and research training that engendered broad interest and collaboration,” said Elias A. Zerhouni,

M.D., Director of NIH. “His success stemmed from the fact that he understood that the commitment to help patients had to be constantly evolving in order to meet their needs. The NIH has lost a great leader, an outstanding scientist, and a dear friend.”

Ruth L. Kirschstein, M.D., Acting Director of NCCAM, said, “As NCCAM’s founding Director from 1999 to 2006, Dr. Straus built a comprehensive research enterprise,

championing the efforts to establish the efficacy and safety of CAM practices while upholding the rigorous standards of science for which the NIH is known. Under his leadership, CAM research at NIH grew threefold, facilitating his vision of an evidence-based integrative approach to health care for the benefit of the public.”

In addition to his NCCAM position, Dr. Straus was an internationally recognized research scientist who served as Senior Investigator in the Laboratory of Clinical Investigation at the National Institute of Allergy and Infectious Diseases.

Dr. Straus’s survivors include his wife, Barbara Straus; daughters, Kate Straus and Julie Straus; son, Benjamin Straus; mother, Dora Straus; sister, Miriam Wallach; and brother, Marc J. Straus, M.D.

To read more about Dr. Straus, go to [nccam.nih.gov/news/](http://nccam.nih.gov/news/).

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## NCCAM’s Centers of Excellence: Focusing on the Big—and (Very) Small—Picture

The National Institutes of Health (NIH) is the Nation’s medical research agency—making medical discoveries to improve people’s health, save lives, and reduce the burdens of illness and disability. As NIH’s lead agency for research on complementary and alternative medicine (CAM), NCCAM shares in this pursuit of scientific discovery by supporting research

studies on CAM at medical and scientific institutions throughout the United States.

### Centers Pursue Topics in Depth

An important piece of NCCAM’s extramural research program consists of

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## NCCAM's Centers of Excellence

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21 centers of research at leading medical and scientific institutions. The Research Centers Program is intended to build long-term programs that use expertise from a variety of disciplines, integrate research efforts from the laboratory bench to human studies, and develop and refine research methods and resources.

The Centers of Excellence for Research on CAM (CERCs) represented 9.1 percent of NCCAM's total budget for research in fiscal year 2006. In this issue, *CAM at the NIH* presents a closer look at the eight CERCs.

### What Is a CERC?

Each NCCAM CERC:

- Has a grant that is 5 years long.
- Is pursuing three to four major projects that are related to each other and have a common theme—one or more CAM therapies (and/or themes important in CAM, such as wellness or the placebo effect) and one or more diseases or conditions that are a major health burden in the United States.
- Has a principal investigator highly skilled and experienced in research.
- Focuses on understanding “mechanisms of action”—in other words, how a CAM therapy works at the level of molecules, cells, and systems (for example, in animals). Some CERCs also conduct phase I or phase II clinical trials. In studies of substances like herbs, there may also be laboratory studies on characterization (to improve understanding of the substance's chemical composition), standardization (to improve the consistency of products in studies), and related topics.
- Is “synergistic”—that is, “the whole” (the results of the entire CERC program) is expected to be greater than “the sum of the parts” (the results of individual studies).

- Cuts across disciplines and is collaborative.
- Uses advanced research tools and techniques.

Says Acting NCCAM Director Ruth L. Kirschstein, M.D., “The CERC program is a key part of NCCAM's efforts to build and sustain research capacity across the Nation. Each CERC has put together a program in which several studies add to and play off of one another, and the collaborative approach helps create even more opportunities for discovery.”

The following are snapshots of work being done at each of these centers.

### Antioxidants for Lou Gehrig's Disease, Heart Disease, and Aging



Balz Frei, Ph.D.

Principal investigator: Balz Frei, Ph.D., director and endowed chair, Linus Pauling Institute, and professor of biochemistry and biophysics, Oregon State University, Corvallis.

Dr. Frei was personally touched by Lou Gehrig's disease, also called ALS (amyotrophic lateral sclerosis), when a good friend died of it at a young age. Lou Gehrig's disease attacks the nerve cells responsible for control of voluntary muscles. The patient's muscles gradually weaken and waste away, although his senses (and, in most cases, his mental abilities) are not impaired. Dr. Frei and his colleagues study antioxidants as possible future therapies for Lou Gehrig's and heart disease, and to possibly counteract the effects of human aging.

An antioxidant is a substance that protects cells from the damage caused by free radicals (unstable molecules made by a

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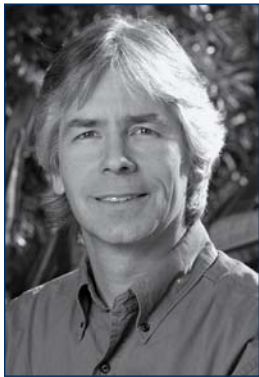
CAM at the NIH

P.O. Box 7923

Gaithersburg, MD

20898-7923, or

[info@nccam.nih.gov](mailto:info@nccam.nih.gov)



Christopher Gardner, Ph.D.

**Christopher Gardner, Ph.D.**, is assistant professor of medicine (research) in the Department of Medicine, Stanford University. Dr. Gardner received his Ph.D. in nutrition science from the University

of California at Berkeley and did his postdoctoral work at Stanford University. In early 2007, he published studies on four popular diets for weight loss and on garlic's effects on LDL cholesterol (see summaries on pg. 4).

***How did you become interested in your particular area of research?***

After receiving my Ph.D. in nutrition, I took a postdoctoral fellowship at the Stanford Prevention Research Center, which focuses on research to prevent chronic diseases through healthy lifestyle approaches. There, I received an opportunity from William L. Haskell, Ph.D., to direct a clinical trial investigating the effects of soy protein with or without soy isoflavones on serum cholesterol levels in postmenopausal women. With Dr. Haskell's mentoring and NCCAM funds, I conducted and published this small trial. Since then, my primary interest has been in trying to address controversial nutrition topics and health claims by designing appropriate clinical trials.

***You've commented in a couple of interviews that some of the reporting on the four-diets study was, perhaps, not as balanced as you would have liked. Could you give us your view of the most important messages?***

The gist of some of the more sensationalistic headlines and stories was that "the Atkins diet trounced all the other diets" or "eating all the bacon, eggs, and whipped cream you want is the best way to lose weight." This is not accurate.

What we found, in fact, was that the group assigned to the Atkins diet did modestly better overall at the end of 12 months than the groups assigned to the Zone diet, the Ornish diet, or the LEARN diet. All four groups lost weight, on average, and all four experienced improvements in related metabolic risk factors (e.g., cholesterol, blood pressure, insulin). There were statistically significant differences among the diet groups at the end of 12 months, and in each case the differences favored the Atkins group over one or more of the other groups. However, the differences tended to be modest.

We were also studying how well real people followed these diets as prescribed, on their own, over an extended period of time. The answer was, not very well.

But the most important message, we believe, is that the findings reinforce the need to cut back on or eliminate refined carbohydrates from our diets when trying to lose weight and keep it off. The most common sources of refined carbohydrates are sweetened caloric drinks, white bread, cookies, candy, and products with high-fructose corn syrup added. Many people think of Atkins as "all the steak and butter you can eat," but its primary focus is cutting out refined carbohydrates and choosing nutrient-dense vegetables as your primary source of carbohydrates.

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## The Cochrane Collaboration: A Reliable Source of Evidence on CAM

Are you interested in a reliable source of evidence on the use of CAM? The Cochrane Database of Systematic Reviews is one resource. Its content is prepared by the Cochrane Collaboration, an international nonprofit organization of health care professionals. Using a systematic process, Cochrane authors analyze the results of clinical trials and other published and unpublished sources to explore the evidence for and against the effectiveness and appropriateness of treatments.

Two examples of recent CAM topics are Chinese herbs for the common cold and glutamine supplementation for severe gastrointestinal disease in infants. Each review has an abstract of the key findings, often in plain language for the public. Abstracts are available free of charge at [www.cochrane.org](http://www.cochrane.org). Full reports are available by paid subscription from The Cochrane Library. They may also be available in medical school and hospital libraries. Through a grant to the Center for Integrative Medicine at the University of Maryland, NCCAM helps fund maintenance and expansion of the Cochrane database of studies of CAM. ❖



NIH has begun requiring that grant applications be submitted via the Web portal Grants.gov ([www.grants.gov](http://www.grants.gov)) using Form 424 (Research and Related, or R&R, application). To find out more, go to [era.nih.gov/electronicreceipt](http://era.nih.gov/electronicreceipt).

For more information on these and other funding opportunities, go to [nccam.nih.gov/cgi-bin/grants/funding.pl](http://nccam.nih.gov/cgi-bin/grants/funding.pl).

### PAR-07-248: Developmental Centers for Research on Complementary and Alternative Medicine: Phase I

*Sponsor:* NCCAM. These awards (a reissue of PAR-06-108) will support Developmental Centers for Research on CAM (DCRCs): Phase I, with each DCRC pursuing three or four developmental/exploratory research projects on CAM. The initiative is intended to promote the development of CAM research expertise and infrastructure, support developmental projects, and encourage partnerships between CAM and conventional institutions and investigators. NCCAM urges that people interested in submitting an application for a DCRC also familiarize themselves with NCCAM's:

- Research funding priorities ([nccam.nih.gov/research/priorities/index.htm#5](http://nccam.nih.gov/research/priorities/index.htm#5))

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### Perspective: Christopher Gardner

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#### ***What are the most important things a person should consider about a dietary approach to losing weight or keeping it off?***

For both purposes, the most important thing to do is choose a diet you can follow for the rest of your life, not just for a month or two. If you find a way to lose weight right now, right away, but you cannot maintain the same type of diet long-term, then when you stop the diet and return to old eating patterns, the weight is likely to return. Extreme very low-fat, very low-carbohydrate, or very high-protein diets are all difficult for most people to maintain long-term. Also, such approaches may not be best for long-term health—for example, if you develop deficiencies in vitamins and minerals; if taking in more protein than you need over

a long period leads to impaired kidney function and a deficiency in calcium; or if an approach that is low in fiber and high in saturated fat raises several risks related to heart disease and cancer.

#### ***What are some areas that you find compelling for future research?***

We still do not fully understand how to best create the feeling of fullness from a meal that gives us the cue to stop eating (satiety). Nor do we understand enough about the best strategies for maintaining that feeling of fullness for the longest time and delaying the sense of hunger from returning (satiety). The key to all this likely involves some combination of portion sizes; energy density; manipulations of carbohydrate, fat, and protein; and hormones like leptin and ghrelin that the body produces. We also need to develop better tools for assessing outcomes in these studies. ❖



## Focus

# Four Plans for Weight Loss; Garlic for LDL Cholesterol

### Comparing Four Weight-Loss Plans

The Atkins diet, a very-low-carbohydrate diet, may contribute to greater weight loss than higher carbohydrate plans, without negative effects such as increased cholesterol, Dr. Christopher Gardner and his colleagues have found (see pg. 3). The NCCAM-funded study was conducted in 311 premenopausal women, all of whom were overweight or obese. Each woman was randomly assigned to one of four diets. All diets had been selected for their different levels of carbohydrate consumption:

- The Atkins diet is very low in carbohydrate consumption: less than



20 grams of carbohydrates per day and increasing to 50 grams per day.

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- The Zone diet is designed so that a person's daily calorie consumption is made up of 40 percent carbohydrates, 30 percent protein, and 30 percent fat.
- The LEARN (Lifestyle, Exercise, Attitudes, Relationships, and Nutrition) diet instructs participants to get 55 to 60 percent of their calories from carbohydrates and not more than 10 percent from saturated fat. It is based on the U.S. Department of Agriculture food pyramid.
- The Ornish diet's primary guideline states that participants should not get more than 10 percent of their calories from fat.

All participants received books accompanying their assigned diet plan and attended hour-long classes with a registered dietician once a week for the first 8 weeks. Data on the participants was collected at the beginning of the study and at 2, 6, and 12 months. The researchers recorded body mass index (BMI); body fat percentage; waist-hip ratio; and metabolic measures such as insulin, cholesterol, glucose, triglyceride, and blood pressure levels.

The Atkins group reported the most weight loss at 12 months, with an average loss of just over 10 pounds (4.7 kilograms). They also had more favorable overall metabolic effects. Average weight loss across all four groups ranged from 3.5 to 10.4 pounds. The authors note that "even modest reductions in excess weight have clinically significant effects on risk factors such as triglycerides and blood pressure."

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Gardner CD, Kiazand A, Alhassan S, et al. Comparison of the Atkins, Zone, Ornish, and LEARN diets for change in weight and related risk factors among overweight premenopausal women. The A to Z Weight Loss Study: a randomized trial. *Journal of the American Medical Association*. 2007;297(9):969-977.

## Garlic and "Bad" Cholesterol

LDL (low-density lipoprotein) cholesterol is widely known as "bad cholesterol" and is believed to be a leading contributor to heart disease. This study's results cast doubt on garlic's effectiveness in lowering LDL cholesterol levels in adults with moderately high cholesterol.



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Dr. Gardner and his team conducted a randomized, placebo-controlled trial studying whether three different formulations of garlic could lower LDL cholesterol. The study participants were randomly divided into four groups to receive either raw garlic, a powdered garlic supplement, an aged extract supplement, or a placebo.

The 169 participants who completed the study had their cholesterol levels checked monthly during the 6-month trial. None of the formulations of garlic had a statistically significant effect on the LDL cholesterol levels. The authors caution that their results should not be generalized for all populations or all health effects. An accompanying editorial in the journal points out that LDL cholesterol levels are only one factor contributing to heart disease and that this trial did not investigate garlic's effects on other risk factors, such as high blood pressure.

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Gardner CD, Lawson LD, Block E, et al. Effect of raw garlic vs. commercial garlic supplements on plasma lipid concentrations in adults with moderate hypercholesterolemia: a randomized clinical trial. *Archives of Internal Medicine*. 2007;167(4):346-353. ❖

## News for Researchers

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- Policies relevant to the proposed research ([nccam.nih.gov/research/policies/index.htm](http://nccam.nih.gov/research/policies/index.htm))
- A sample leadership plan posted on the Web, if the application would be for a multi-PD/PI collaboration ([nccam.nih.gov/research/multi\\_pi.htm](http://nccam.nih.gov/research/multi_pi.htm)).

### PA-07-218: Diet Composition and Energy Balance

Sponsors: NCCAM and eight other NIH components.

Overweight and obesity have increased dramatically in the United States. An important gap in knowledge about weight conditions is the role of the composition of the diet in energy balance (the balance between energy taken in, generally by food and drink, and energy expended). The announcement (a reissue of PA-06-173) invites applications that explore this topic. Collaborations between basic and clinical researchers are particularly encouraged.

### PAR-07-335: International Research Collaboration—Basic Biomedical (FIRCA-BB)

Sponsors: NCCAM and nine other NIH components. The goal in this initiative (a reissue of PA-06-436) is to foster discovery and reduce global health disparities by supporting international research cooperation across the health sciences. NCCAM is specifically interested in projects that

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focus on the science underlying traditional medicine (TM) practices and that involve collaborations between investigators in the United States and investigators in eligible countries who are knowledgeable about indigenous TM practices.

**PA-07-280: Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research (SBIR) Grant Applications** and **PA-07-281: Omnibus Solicitation of the NIH for Small Business Technology Transfer (STTR) Grant Applications**

*Sponsors:* NIH, the Centers for Disease Control and Prevention, and the U.S. Food and Drug Administration (PA-07-280); and NIH (PA-07-281). The goals of the SBIR program include stimulating technological innovation, strengthening the role of small business in meeting Federal research or research and development needs, and increasing commercial application of federally supported research results. The STTR program is designed to stimulate partnerships of innovative ideas and technologies between small business concerns and research institutions. NCCAM is specifically encouraging applications for innovative technological research and for basic, preclinical, and early phase clinical studies that could ultimately lead to commercial CAM products fulfilling NCCAM's mission. ❖

## New Integrative Medicine Consult Service Established

NCCAM has established an Integrative Medicine Consult Service at the National Institutes of Health (NIH) Clinical Center. The new service, announced in May 2007, will provide integrative medicine support to health care providers and patients participating in research studies at the Clinical Center, the world's largest hospital dedicated solely to research.

Integrative medicine combines treatments from conventional medicine and CAM for which there is some high-quality evidence of safety and effectiveness.

CAM is not a new concept to the Clinical Center. Currently, the Pain and Palliative Care Service and the Rehabilitation Medicine Department offer acupuncture, Reiki, hypnosis, guided imagery, and massage therapy, as well as tai chi and qi gong training. The Pharmacy Department and members of NCCAM's intramural research program provide expertise on herbals and herb-drug interactions. The new service will

coordinate these existing resources and develop further to meet the clinical and educational needs of Clinical Center staff and patients.

The service's four major functions will include clinical consultation on CAM therapies, a CAM education program, and a research program embedded in NIH's clinical and translational research structure.

The director of the new service will be Patrick J. Mansky, M.D., a clinical oncologist and researcher at NCCAM (an interview with Dr. Mansky appears on pg. 7).

"We are pleased with the creation of the Integrative Medicine Consult Service and the role we hope it will play in providing Clinical Center patients with the best possible integrated care," said Ruth L. Kirschstein, M.D., Acting Director of NCCAM. "Dr. Mansky's blend of clinical and research experience at the crossroads of CAM and conventional medicine makes him an excellent choice to lead this new service." ❖



The NIH Clinical Center, Bethesda, Maryland

# Meet the IMCS Director

**Patrick J. Mansky, M.D.**, is Director of the new Integrative Medicine Consult Service (IMCS) at the NIH Clinical Center. Dr. Mansky received his medical degree from Witten/Herdecke University Medical School, Witten, Germany, where his interest in CAM began (one of its teaching hospitals combined aspects of anthroposophical, psychosomatic, and naturopathic medicine). Dr. Mansky completed a postdoctoral research fellowship in immunogenetics at Memorial Sloan-Kettering Cancer Center, New York, and received combined residency training in pediatrics and internal medicine at Case Western Reserve University, Cleveland.



Patrick J. Mansky, M.D.

Dr. Mansky joined NIH in 1997 as a clinical and research fellow in pediatric hematology/oncology and medical oncology at the National Cancer Institute. He came to NCCAM in 2001 as a staff clinician and clinical investigator in the intramural oncology program. His research focuses on CAM approaches in the care and treatment of cancer patients and cancer survivors.

### ***What will be at the top of your list when you start as Director of the IMCS?***

I will be familiarizing myself with the expectations and needs of the Clinical Center and the other NIH institutes and centers (ICs) with respect to CAM and integrative medicine. I will also be learning more about current CAM offerings at the Clinical Center. Establishing a

credentialing procedure for some NIH health care practitioners who have CAM training and expertise and wish to practice CAM is another priority.

### ***What is your vision for the IMCS?***

The IMCS will be developing programs and services to meet the clinical, educational, and research needs of NIH staff, patients, and their families. At first, it will use CAM approaches that are

already available at NIH. It may eventually add other approaches based on need, the evidence base, and, in keeping with NIH's mission, research questions. I see the consultations provided both as a clinical service function and as research on outcomes and the integrative approach. This should help advance medical knowledge and improve patient care. Collaboration (e.g., in practice, among practitioners, and among the ICs) will be important.

### ***Training and education are two key areas.***

#### ***What are some examples of things you plan to do?***

The IMCS will develop educational programs on CAM and integrative medicine for NIH staff, patients, and their families. This will be done in collaboration with the Clinical Center departments and with the NIH ICs. The IMCS will also reach out to national and international experts in the field and to patient advocacy groups. Examples of activities could include lectures, seminars, workshops, and conferences. ♦

## New Iowa Center To Study Botanicals

St. John's wort, echinacea, and a plant called self-heal (prunella) are more than colorful additions to the summer herb garden. Each has a history of use in herbal medicine and is an ingredient in dietary supplements.

A new research center in Iowa, cofunded by NCCAM and the NIH Office of Dietary Supplements, will zoom in closer on these botanicals to



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Self-heal (prunella)

better understand the compounds in them, their chemical profiles, and their potential to fight viruses and inflammation. In recent years, scientists have identified inflammation as a factor in a number of chronic diseases, such as heart disease.

The new center, announced on May 3, 2007, is headed by Diane Birt, Ph.D., distinguished professor of food science and human nutrition at Iowa State University (ISU). It will bring together teams from a variety of disciplines at ISU, the University of Iowa, and Yale University. The Iowa center joins five others funded by NIH and focused on botanicals. For descriptions of all research centers funded or cofunded by NCCAM, go to <http://nccam.nih.gov/training/centers/descriptions.htm>.

## Research Roundup

The content of the **Research Roundup** column is now found on the “Research Results” page on NCCAM’s Web site, at [nccam.nih.gov/research/results/](http://nccam.nih.gov/research/results/) (under “Spotlight on New Research Results”). Among the findings from recent studies:

- Tai chi, a traditional Chinese form of exercise, may help older adults avoid getting shingles by increasing immunity to varicella-zoster virus (which causes chickenpox and shingles) and boosting their immune response to varicella vaccine, according to findings from a randomized, controlled clinical trial.
- Black cohosh, whether used alone or with other botanical supplements, did not relieve hot flashes and night sweats in a group of women who were approaching menopause or were postmenopausal. The participants in this large, randomized, double-blind, and placebo-controlled study who used menopausal hormone therapy did receive significant relief from these symptoms.

Both studies were cosponsored by NCCAM and the National Institute on Aging.

## NCCAM’s Centers of Excellence

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process of oxidation during normal metabolism). This process of damage, called oxidative stress, may play a part in certain diseases (including Lou Gehrig’s disease and heart disease) and in aging.

The team is studying several antioxidants—including alpha-lipoic acid (also called lipoic acid), vitamin C, and vitamin E. The hope, Dr. Frei says, is that “we can better target treatment and eventually move the work into human studies”—first on heart disease and later on ALS and aging. He adds, “The CERC has been a great vehicle for our institute to bring people together, enhance interactions and collaborations, involve students, and move us to ‘the next level.’”

### An Herbal Formula for Asthma



Xiu-Min Li, M.D.

*Principal investigator:* Xiu-Min Li, M.D., associate professor of pediatric allergy/immunology, Mount Sinai School of Medicine, New York, New York.

Dr. Li and her colleagues are studying a three-herb Chinese formula called ASHMI as a therapy for asthma. ASHMI, which was developed at Mount Sinai, is based on a formula that Dr. Li was familiar with from her practice of medicine in China. Dr. Li notes that there is not yet any effective therapy for persistent, severe asthma, nor any way to prevent it. Also, while conventional therapies can be helpful for many asthma patients, she says, corticosteroids (the cornerstone of treatment) often cause serious side effects and, if the medication is stopped, worsen the disease.

This CERC’s three studies are looking at the mechanism of action of ASHMI in an animal model, finding out more about its active components, and investigating it in phase I and phase II clinical trials. So far, the team has found that ASHMI has broad therapeutic actions on multiple asthma-related mechanisms in an animal model, and that the effects are long lasting. They have almost completed their phase I study and are moving toward a proposed phase II clinical trial. “The beauty of a CERC,” says Dr. Li, “is that we have three independent but highly interactive projects and experts from many fields. Studying and developing a first-generation botanical drug is a very big project.”

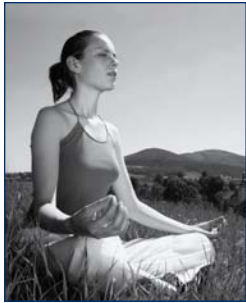
### MBSR Meditation in Early Stage HIV

*Principal investigator:* Susan Folkman, Ph.D., director, Osher Center for Integrative Medicine, professor of medicine and Osher Foundation distinguished professor of integrative medicine, University of California, San Francisco, School of Medicine.

Physicians faced with a patient who has been diagnosed with early stage HIV (the virus that causes AIDS) are in an uncertain position. Anti-HIV drugs are typically used only once the disease has advanced; it is not clear what, if anything, should be recommended to maintain immune function in earlier stages. Dr. Folkman and her colleagues hope to help change that situation by studying whether a type of meditation can benefit people in early stage HIV and improve their ability to cope with the stress of the disease. The researchers’ work is based on prior studies showing that stress and depression are linked to the progression of HIV disease.

The research group’s “Staying Well” study is a large, randomized, controlled trial on whether mindfulness-based stress reduction (MBSR) meditation can slow the progression of HIV, delay the need to start anti-HIV drugs (which have difficult side





effects), and help participants with depression and quality of life. The control group attends an educational session covering many

topics on living with HIV. Two related projects are examining the effects of MBSR on biological structures and processes, especially on the autonomic nervous system, secretion of the stress hormone cortisol, and immune system function.

“The CERC grant has greatly expanded our capacity to do research (including through infrastructure support), train researchers, and attract additional grant support,” says Dr. Folkman. “We’ve had to wrestle with the question of ‘what’s a good comparison group?’ for a mind-body therapy in which blinding is not possible, and I think we have one. When we do a clinical study at the Osher Center now, we also develop hypotheses about how the effects may be happening and test them. I think this should be the standard—not just in CAM, but in all clinical research, when possible.”

### CAM Therapies for Alcohol and Drug Abuse

*Principal investigator:* David Yue-Wei Lee, Ph.D., director, Bio-organic and Natural Products Laboratory, McLean Hospital, Belmont, Massachusetts, and associate professor of psychiatry, Harvard Medical School. (This CERC is cofunded by the National Institute on Alcohol Abuse and Alcoholism.)

“It’s a huge problem, it’s the tip of the iceberg, and there’s no cure.” So Dr. David Lee sums up what has compelled him to turn a doctoral degree in natural products chemistry, an interest in Chinese herbal medicine, and the resources of Harvard’s McLean Hospital toward a very challenging health problem: drug and alcohol abuse.

Addiction problems will cost the United States an estimated \$426 billion in 2007, says Dr. Lee. There is no uniformly effective treatment for drug and alcohol abuse, and the small number of prescription drug treatments available have side effects and a low success rate. Could two herbal remedies developed in China to treat opium smoking and alcohol intoxication be helpful? Dr. Lee and his colleagues are seeking to answer this question.



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**Kudzu (*Pueraria lobata*) is a primary ingredient of the Chinese herbal formula XJL (NPI-028)**

One of the herbal formulas, YGT (NPI-025), was developed because of a crisis that began in the mid-19th century in China, during which it is estimated that many millions of Chinese people became addicted to opium. Dr. Lee’s

team is also testing a traditional formula called XJL (NPI-028) to treat alcohol intoxication, and a device that delivers electrical stimulation to acupuncture points on the hand and wrist. The device has been successfully used in China as a combination treatment with herbal remedies.

The therapies are being studied on several levels: in a laboratory study on brain receptors, in animal models of alcohol and drug addiction, in a preclinical evaluation of the electrical device, and in future clinical studies. Dr. Lee says, “This packaged approach of a CERC grant works well for us, step by step, and has facilitated close working relationships within our group and with collaborators,” including at Temple University, the University of North Carolina, and a national botanicals institute in China.

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## Spotlight on Clinical Trials

*The clinical trials below are among the many NCCAM-sponsored trials that were recruiting, or planning to start recruitment soon, at press time. To see others, go to [nccam.nih.gov/clinicaltrials/alltrials.htm](http://nccam.nih.gov/clinicaltrials/alltrials.htm). Readers who do not have access to the Internet can inquire with the NCCAM Clearinghouse (see pg. 2).*

### Polarity Therapy or Massage Therapy in Cancer Patients

Cancer-related fatigue is a frequent side effect of cancer. This randomized clinical trial is comparing two hands-on therapies—polarity therapy



Bob Stockfield

**Massage therapy**

and massage therapy—to see if they reduce fatigue and improve quality of life and sleep in patients with breast cancer who are undergoing radiation therapy.

*Principal investigator:* Karen Mustian, Ph.D., University of Rochester

*More information:* Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and enter “NCT00288795” in the search box.

*(continued on pg. 10)*

## Spotlight on Clinical Trials

(continued from pg. 9)

### **Omega-3 Fatty Acids for Adolescents With Major Depression**

Major depression (a severe depressive disorder) in adolescents is a public health concern because of the risk of functional impairment and suicide. Conventional treatment with antidepressant medications has serious side effects in adolescents; other effective treatments are needed. Omega-3 fatty acids are substances found in the oils of some fish and vegetables and also manufactured in the form of dietary supplements (often as fish oil). This randomized, placebo-controlled study is investigating whether supplementation with omega-3s is an effective CAM treatment for major depression in young people 12 to 18 years old.

*Principal investigator:* Vilma Gabbay, M.D., New York University School of Medicine

*More information:* Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and enter "NCT00312897" in the search box.

(continued on pg. 11)

## NCCAM's Centers of Excellence

(continued from pg. 9)



**Dr. Ziskin works with participant Ashok Bhanushali in a study of millimeter wave therapy for hypoalgesia**

### **Millimeter Wave Therapy**

*Principal investigator:* Marvin C. Ziskin, M.D., professor of radiology and director of the Center for Biomedical Physics, Temple University School of Medicine, Philadelphia.

Millimeter wave (MW) therapy is part of the CAM domain of energy medicine. It is based on a technology originally developed in the Soviet Union, during the Cold War, for military purposes. For health purposes, a MW device delivers a low-intensity electromagnetic beam to the skin at targeted points (for example, at an acupuncture point or a painful joint). The beam is absorbed by the skin at a shallow level.

MW therapy has been used in Eastern Europe for over 30 years to treat a wide variety of conditions, including skin diseases, wound healing, certain cancers, and gastrointestinal and cardiovascular diseases. "Reports of benefit have been mostly in the Russian literature," says Alexander Radziewsky, M.D., Ph.D., research assistant professor at Temple. "Hypoalgesia [lessened pain response],

immunomodulation [activation or suppression of the immune system], and stimulation of repair are among its most important reported biological effects." He adds that a lack of quantitative study and/or blinding in past research and of precise explanations about the therapy are two reasons it is largely unknown in Western medicine.

This CERC is seeking to evaluate the biological effects of MW exposure, find the mechanisms of action, and develop strict indications for treatment. MW therapy is being studied in animal models for chronic neuropathic pain and pruritus (intense itching). "Chronic neuropathic pain, as one might have from an injury to the nerves or as a complication of diabetes, is very difficult to manage medically," says Dr. Radziewsky. "Sometimes even morphine or morphine-containing drugs don't help. MW therapy might offer another option. We hope our results will provide an appropriate theoretical basis for future clinical use. So far, the results have been very promising."

### **CAM Approaches for Arthritis**

*Coprincipal investigators:* Brian Berman, M.D., professor and director, and Lixing Lao, Ph.D., L.Ac., associate professor and director of traditional Chinese medicine research, Center for Integrative Medicine, University of Maryland School of Medicine, Baltimore.

Dr. Berman is leading a team studying approaches from traditional Chinese medicine for treating arthritis. They are partnering in this endeavor with colleagues at McLean Hospital and the University of Illinois at Chicago. This CERC is preparing to conduct a clinical trial on HLXL, a traditional Chinese formula made up of 11 herbs, to treat osteoarthritis of the knee. They are also exploring HLXL's mechanism of action.

Dr. Berman says, "Arthritis is a big problem in our society, especially in the elderly.

There is no cure, and conventional treatments to manage it can have issues for many people. We're trying to find out whether this formula could potentially offer another option." He adds, "The grant is also giving us the opportunity to meet the challenges involved in a clinical trial of an herbal formula—such as addressing quality control and quality assurance, developing a convincing placebo, and preparing an Investigational New Drug application for the Food and Drug Administration." In addition, this CERC is conducting two mechanism-of-action studies: on acupuncture to treat inflammatory pain and on HLXL to treat rheumatoid arthritis.

### Acupuncture and Brain Activity

*Principal investigator:* Bruce Rosen, M.D., Ph.D., director, Athinoula A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital, and professor of radiology, Harvard Medical School, Boston.



Bruce Rosen, M.D., Ph.D.

Dr. Rosen and his colleagues are working to increase knowledge of the possible pathways and circuitries in the brain involved in the effects of acupuncture. They are using functional magnetic resonance imaging (fMRI), a noninvasive neuroimaging technique used to observe the brain's functioning by detecting changes in oxygen content in the blood flowing to different brain regions. Their projects include:

- Characterizing the brain's response to acupuncture stimulation
- Studying acupuncture-induced sensation
- Exploring acupuncture's effects on the brain's response to amphetamine
- Defining parts of the brain involved in expectancy and the placebo effect in acupuncture.

"By looking directly into the brains of our subjects as they receive acupuncture, we can begin to tease out the complex mechanisms that underlie this ancient therapy," says Dr. Rosen. "With better understanding, we can then better design treatments that take advantage of acupuncture's unique properties." Currently, they are beginning to apply their findings in conditions such as arthritis and carpal tunnel syndrome (CTS). Results of preliminary studies, Dr. Rosen says, suggest that acupuncture can not only improve symptoms in CTS, but also affect objective measures of nerve function at the wrist and CTS-affected circuitry in the brain.

### Antioxidants for Asthma

*Principal investigator:* David B. Peden, M.D., M.S., professor of pediatrics, medicine, and toxicology, and director of the Center for Environmental Medicine, Asthma, and Lung Biology, University of North Carolina School of Medicine, Chapel Hill.

This CERC is conducting bench-to-bedside research on antioxidant CAM therapies for asthma. In the laboratory, Dr. Peden and his colleagues are seeking to understand the mechanisms of action and the effects of antioxidants that are vitamins and compounds derived from soy and red wine. In clinical studies, they will attempt to discover whether these treatments can decrease inflammation of the airway in response to common asthma triggers, such as ozone or inhaled allergens. One of the current clinical studies is on gamma tocopherol, a naturally occurring form of vitamin E that is found in many foods and is also manufactured as a supplement.

*You can read more on these CERCs' grants by searching the CRISP database ([www.crisp.cit.nih.gov](http://www.crisp.cit.nih.gov)) and on published results to date by searching the PubMed database ([www.ncbi.nlm.nih.gov/entrez](http://www.ncbi.nlm.nih.gov/entrez)).* ❖

### Spotlight on Clinical Trials (continued from pg. 10)

#### Tai Chi in Patients With Congestive Heart Failure

Tai chi (also known by some other names such as taijiquan) is a mind-body practice that originated in China as a martial art. It involves slow and gentle physical movement, deep breathing, and meditation, and it can be practiced for health purposes. This randomized study is examining tai chi for its potential as a complementary treatment for congestive heart failure (CHF; a condition in which the heart cannot pump enough blood to the rest of the body). The researchers are studying tai chi's effects on physical symptoms, psychological symptoms, and quality of life in CHF patients who are age 50 or older. Tai chi is being compared with walking exercise and health education.

*Principal investigator:* Laura Redwine, Ph.D., Veterans Medical Research Foundation, San Diego, California

*More information:* Go to the CRISP database at [www.crisp.cit.nih.gov](http://www.crisp.cit.nih.gov) and enter "5R21AT001910-02" in the "grant number" box. ❖

**CAM at the NIH:**

**Focus on Complementary and Alternative Medicine**

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## More Information

## Calendar of Events



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

- Herbs at a Glance fact sheets: *Fenugreek, Grape Seed Extract, Lavender, Peppermint Oil, Turmeric, and*

*Yohimbe* ([nccam.nih.gov/health/herbsataglance.htm](http://nccam.nih.gov/health/herbsataglance.htm))

- *An Introduction to Naturopathy* ([nccam.nih.gov/health/naturopathy/](http://nccam.nih.gov/health/naturopathy/))
- Spanish versions of *Ask Your Patients About Their Use of CAM* and

*Tell Your Doctor About Your Use of CAM* ([nccam.nih.gov/timetotalk/](http://nccam.nih.gov/timetotalk/))

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NCCAM's **Congressional Justification 2008** is available on the Web at [nccam.nih.gov/about/congressional/index.htm](http://nccam.nih.gov/about/congressional/index.htm). This document, prepared each year for the consideration of the U.S. Congress, outlines NCCAM's plans and priorities for fiscal year 2008 (which begins October 1, 2007). It also includes details of the proposed budget, a legislative history, and other items.

\* \* \*

**Alerts and Advisories** items are now found on NCCAM's "News and Events" Web page, at [nccam.nih.gov/news/](http://nccam.nih.gov/news/). Readers who do not have access to the Internet can inquire with the NCCAM Clearinghouse (see pg. 2). ❖



This calendar lists events on CAM in which NCCAM or other components of NIH are sponsors or participants. It includes information available at press time.

### September 2007

#### Meeting of the National Advisory Council for Complementary and Alternative Medicine:

September 5. *Location:* Neuroscience Center Building, 6001 Executive Blvd., Rockville, Maryland.

For more information on this meeting, see [nccam.nih.gov/about/advisory/naccam/](http://nccam.nih.gov/about/advisory/naccam/). ❖