

Researching CAM Approaches to the Problems of Obesity

**Comment Now on NCCAM's
Draft Strategic Plan**
See pg. 3 for details

Obesity is an epidemic in the United States today. According to the Centers for Disease Control and Prevention, about two-thirds of American adults (nearly 130 million people) are either overweight or obese.¹ These conditions put people at increased risk for serious medical problems, including type 2 diabetes, heart disease, stroke, certain cancers, and osteoarthritis. They can also impact people's quality of life, cause disability, and reduce life expectancy.

More Facts About the Obesity Epidemic

- ▶ Poor diet and lack of exercise combined—the prime causes of obesity—could overtake tobacco use as the leading preventable cause of death in the United States in the next few years.
- ▶ In 2000, the economic costs of obesity were about \$117 billion in both direct costs—such as doctor visits, medicine, and hospital or nursing home care—and indirect costs, such as lost wages from illness and disability, and loss of future earnings from early death.
- ▶ Obesity has become a serious problem among children and adolescents. Approximately 16 percent of young people aged 6 to 19 years are now overweight. Many health problems that used to be associated only with overweight adults are now being seen in young people.
- ▶ Obesity and overweight are complex conditions with a variety of causes—including behavior (such as consuming too many calories and not getting enough exercise), environment (for example, living in a place that does not offer opportunities for an active lifestyle and healthy food choices), and genetics.

In 2004, the Federal Government put new programs and initiatives into place to address this public health issue—including scientific research on the causes of obesity and on what can be done to help treat and manage it more effectively. The National Center for Complementary and Alternative Medicine (NCCAM) is an active participant in this research effort.

The U.S. Department of Health and Human Services has identified obesity as a priority area for action. The National Institutes of Health (NIH) is playing a major role—through scientific research to better understand the forces contributing to obesity, the diseases that can develop from it, and strategies for prevention and treatment. NIH Director Elias A. Zerhouni, M.D., created the NIH Obesity Research Task Force (of which NCCAM is a member), which is charged with speeding the progress of this research. In August 2004, the Task Force released its first strategic plan (see “Government Resources” on pg. 3).

At NCCAM, research on obesity is a priority area. NCCAM Director Stephen E. Straus, M.D., noted, “Obesity results from complex interactions among biology, behavior, and the environment. Therefore, multidisciplinary approaches, not unlike those that characterize much of



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CAM research, are needed to fully understand, prevent, and treat it.”

NCCAM scientists contributed to the overarching NIH obesity strategic plan to ensure that it includes ways in which complementary and alternative medicine (CAM) approaches could be addressed. However, before the plan was completed, NCCAM had already begun to invest in obesity-related investigations, both in its intramural laboratories (on the NIH campus) and in extramural studies.

Reducing risks for obesity, as well as the health problems associated with it, involves making changes in diet and physical activity. An array of nutritional practices claim to prevent, treat, or manage these problems—ranging from well-researched, biochemically understood treatments on which national public health recommendations are based (such as the U.S. Department of Agriculture’s Food Pyramid), to scientifically unproven treatments advertised in the popular press. NCCAM is supporting studies to answer questions about the safety and effectiveness of some popular diets, such as:

- ▶ Three diets—the Atkins, Zone, and Ornish diets—for their impact not only on weight loss but on other aspects of health. This work was done at the Stanford University School of Medicine, and the data are being analyzed.
- ▶ The Atkins diet, compared with two other diets: the Department of Agriculture’s Food Pyramid, in a study at the University of Pennsylvania School of Medicine; and the National Heart, Lung, and Blood Institute’s

Complementary and Alternative Medicine at the NIH

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

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Our mission: NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine researchers, and disseminating authoritative information to the public and professionals.

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DASH (Dietary Approaches To Stop Hypertension), in a study at the Kaiser Foundation Research Institute. Both studies are examining outcomes such as weight loss, risk factors for cardiovascular disease, nutrient intake, sense of hunger and fullness, and quality of life.

In addition, NCCAM investigators are exploring the potential of some other complementary and alternative treatments, such as practices from traditional Chinese medicine, to yield new and better ways to control the obesity epidemic. Included are investigations of:

- ▶ The biological actions of insulin (a hormone in the body that promotes transport of sugar from food into cells and conversion of sugar into energy) and the molecular aspects of insulin resistance (a condition in which the body does not respond properly to its own insulin; it is present in obesity and can be a predecessor of type 2 diabetes). The Diabetes Unit of NCCAM’s Division of Intramural Research is studying these in relation to obesity, diabetes, and other health problems.
- ▶ Qi gong and acupuncture, for their effectiveness in keeping off lost weight.² Maintaining weight loss over the long term is a challenge, as many people regain lost weight within 1 year. A team from the Center for Health Research in Portland, Oregon, is conducting the study.
- ▶ A meditation-based treatment for binge-eating disorder in obese women. In this disorder, probably the most common of the eating disorders, people eat large amounts of food and feel that they cannot control how much they are eating. The researchers are based at Indiana State University, the University of Pennsylvania, and Duke University’s Center for Integrative Medicine.
- ▶ A counseling and diet program at Wayne State University, designed to help breast cancer survivors make lifestyle changes needed to lose weight.



Dr. Straus added, “The obesity epidemic demands our best efforts. We at NCCAM are committed to helping the public determine whether CAM approaches can keep their promises of overcoming this threat to the public’s health.”

New NCCAM Obesity Research Initiatives

Prevention and Treatment of Childhood Obesity in Primary Care Settings (RFA-HD-04-020). Sponsors: NCCAM and eight other components of NIH. These grants will support projects to test programs that aim to improve dietary and physical activity behaviors in children.

Ancillary Studies to Obesity-Related Clinical Trials (RFA-DK-03-022). Sponsors: NCCAM, National Institute of Diabetes and Digestive and Kidney Diseases, and National Institute on Aging. These grants will support CAM studies investigating obesity-related research questions.

Neurobehavioral Basis of Obesity (not yet released at press time). NCCAM will cosponsor this new NIH initiative, which will study how the brain, behavior, and environment interact to determine eating patterns, preferences, and food habits, and ultimately influence the development of overweight and obesity.

To find out more, go to nccam.nih.gov/research/announcements/index.

Government Resources on Obesity

Weight-control Information Network (WIN) National Institute of Diabetes and Digestive and Kidney Diseases

WIN provides information and distributes many publications on weight control, obesity, physical activity, and nutrition. A new brochure, "Diet Myths," addresses, among other topics, fad and special diets. Go to www.niddk.nih.gov/health/nutrit/nutrit.htm or call 1-877-946-4627 (toll-free in the U.S.).

Obesity Education Initiative/Aim for a Healthy Weight National Heart, Lung, and Blood Institute

This program offers publications and other resources to help people stay active and make healthy food choices. Go to www.nhlbi.nih.gov/about/oei or call 301-592-8573.

HealthierUS Initiative

The President's HealthierUS initiative is designed to help Americans, especially children, take steps to live longer, better, and healthier lives. Its Web site is www.healthierus.gov.

Obesity Research, National Institutes of Health

This NIH Web site is at www.obesityresearch.nih.gov and includes the *Strategic Plan for NIH Obesity Research*.

Your Input Invited on Draft Strategic Plan

NCCAM invites your comments on the Center's draft strategic plan for the years 2005 to 2009, available on NCCAM's Web site at nccam.nih.gov/about/plans/2005 now through November 15, 2004. The draft is the result of a strategic planning effort launched in January 2004 to establish NCCAM's goals and vision for its second 5 years. Numerous people have contributed insights so far to help shape the plan (NCCAM thanks you), through channels such as two Stakeholder Forums and our Web site. We look forward to further comment.

NCCAM Clearinghouse

For more information about NCCAM or any aspect of complementary and alternative medicine, contact the Clearinghouse (see box, pg. 2). ■

Sources

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Foster GD, Wyatt HR, Hill JO, et al. A multicenter, randomized, controlled trial of a low-carbohydrate diet for obesity. *New England Journal of Medicine*. 2003;348(21):2082-2090.

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Notes

1. The most common tool used in medical settings to determine whether a person is overweight or obese is the body mass index (BMI), a calculation that uses height and weight. A BMI of 25 to 29.9 is considered overweight, and a BMI of 30 or more is considered obese. However, the BMI may overestimate body fat in people who have a lot of weight from lean muscle (such as athletes) and underestimate the body fat of people who have lost a lot of muscle. Therefore, other factors may be considered, such as a person's waist measurement or his risk factors for obesity-related diseases.

2. Qi gong (pronounced "chee-GUNG") combines movement, meditation, and regulation of breathing to enhance the flow of qi (an ancient term given to what is believed to be vital energy) in the body, improve blood circulation, and enhance immune function. Acupressure ("ACK-you-preh-shur") is acupuncture using pressure applied by the hands instead of needles.

Diet Products and Plans: Weigh the Claims

Are you one of the estimated 50 million Americans who will go on a diet this year? Before you spend money on products or programs that promise fast or easy weight loss, the Federal Trade Commission recommends that you consider these tips about typical claims, such as:



- ▶ **“Lose 30 Pounds in Just 30 Days.”** As a rule, the faster you lose weight, the more likely you are to gain it back. Also, fast weight loss could harm your health. Unless your doctor advises it, don't look for programs that promise quick weight loss.
- ▶ **“Lose All the Weight You Can For Just \$39.99.”** Some weight-loss programs have hidden costs such as prepackaged meals. Before you sign up, ask for all the costs, and get them in writing.
- ▶ **“Lose Weight While You Sleep.”** Claims for diet products and programs that promise weight loss without effort are phony.
- ▶ **“Lose Weight And Keep It Off for Good.”** Be suspicious about products promising long-term or permanent weight loss. To lose weight and keep it off, you must change how you eat and how much you exercise.
- ▶ **“John Doe Lost 84 Pounds in Six Weeks.”** Don't be misled by someone else's weight loss claims. Even if the claims are true, someone else's success may have little relation to your own chances of success.
- ▶ **“Scientific Breakthrough... Medical Miracle...”** There are no miracle weight-loss products or plans. To lose weight, you have to reduce your intake of calories and increase your physical activity. Be skeptical about exaggerated claims.

Source: www.ftc.gov/bcp/online/pubs/alerts/paunch

Visit nccam.nih.gov/research/announcements/active for more information on NCCAM funding opportunities and notices.

- ▶ **RFA-AT-05-004: The Use of Complementary and Alternative Medicine (CAM) in the Management of HIV/AIDS.** These grants, targeted to institutions with extensive research experience with HIV/AIDS, will support well-designed studies on CAM to manage the disease, its complications, and medication side effects, and to improve quality of life.
- ▶ **PA-04-071: Pathogenesis and Treatment of Lymphedema and Lymphatic Diseases.** Sponsors: NCCAM and six other components of NIH. These grants will support research on the biology and genetics of the lymphatic system, and on the treatment of primary and secondary lymphedema. The goal is to determine the safety and effectiveness of complementary and alternative therapies for lymphedema.



NCCAM's Office of Clinical and Regulatory Affairs has developed **“Applying for NCCAM Clinical Trials Grants: Points to Consider,”** a policy document outlining important issues that applicants for phase II and III studies must consider. It is located at nccam.nih.gov/research/instructions/poc. ■

Research Centers Grants Available

NCCAM announces the final year of funding for research centers for CAM. Letters of intent are due **January 15, 2005**. Receipt date is **February 15, 2005**. Grants will be for two types of centers:

- ▶ **Centers of Excellence for Research on CAM,** which support established researchers in investigating the potential benefits and underlying mechanisms of CAM practices
- ▶ **Developmental Centers for Research on CAM,** which provide a means for CAM institutions to partner with established research institutions to conduct exploratory and developmental research projects

To find out more, including a list of frequently asked questions about these grants, go to nccam.nih.gov/research/announcements/active.htm#pa and scroll down to PAR-03-046 and PAS-03-038. ■

Web Chat on CAM and Cancer

On September 20, 2004, Stephen E. Straus, M.D., NCCAM Director, hosted his second Web chat on “Complementary and Alternative Medicine and Cancer,” sponsored by NCCAM, the American Society of Clinical Oncology, and CancerCare. He was joined by Patrick Mansky, M.D., an oncologist and researcher at NCCAM. An excerpt appears below. To read the full chat, go to www.plwc.org, select “Community Center,” then “PLWC Live Chat Series”; or contact the NCCAM Clearinghouse (see box, pg. 2).

Q: I would like to try some CAM therapies, but I am afraid my doctor will think I'm “crazy.” How can I bring this up?

Dr. Straus: This is a very important question. It's common that there is a tension between patients and physicians. There are times that physicians are afraid their patients will ask them questions about CAM, because they don't know all the answers; and there are many patients who are afraid that their physician will think poorly of them. But this is a dialogue that must take place. As a physician, I may not agree with everything my patient believes in, but it is important that I understand and respect their beliefs. Patients should ask any questions they have about CAM, and physicians should do their best to try to help find good answers and work out a strategy that both should be comfortable with.

Q: My mother recently finished treatment for colorectal cancer and likes to self-medicate with various dietary and herbal supplements. How can I find out which of these are potentially dangerous?

Dr. Straus: The possibility of interactions is the first thing to consider. Herbs contain potent chemicals that can interact with cancer drugs, either to make the drug less effective or more toxic. Beyond that, it depends on the supplement. Some information sources are nccam.nih.gov, dietary-supplements.info.nih.gov, CAM on PubMed, and the Natural Medicines Comprehensive Database.

Q: Is there any evidence that acupuncture can boost a person's immunity?

Dr. Straus: No. There is a lot of belief that things can boost people's immunity. With some CAM systems, there is a little bit of evidence that the immune system is affected, but there is no evidence that the changes are beneficial.

Q: What cancer side effects respond the best to CAM treatments?

Dr. Mansky: The best research-based evidence exists for the treatment of pain and nausea. Acupuncture appears to have efficacy in the treatment of cancer-related pain, as well as chemotherapy-induced nausea and vomiting.

Q: Is there any evidence that taking vitamins can prevent a recurrence of my cancer?

Dr. Straus: Recovery from cancer and health in general requires good nutrition, including adequate vitamin intake, but there is no evidence that vitamins can prevent a recurrence.

Q: My brother is only considering CAM to treat his lung cancer. What should I say to him to help him understand that traditional treatments are important, too?

Dr. Straus: I think you've said the important message. You care about your brother and his well-being and respect his decisions, but want to see him get the best care he can.

There are proven treatments for cancer, and one should be hesitant to throw away things that are proven to be good in the hopes of something else that is unproven.

Q: What CAM approaches should be avoided before surgery?

Dr. Straus: There is a danger of doing too much of any one approach. (This is a general concern.) It's common to believe that more is better, but too much of an herbal medicine, exercise regimen, or extreme diet, for example, can be harmful. Certain herbal medications (such as St. John's wort and ginkgo) can decrease the ability of blood to clot; good blood clotting is important for surgical recovery.

Q: I saw an article saying that doctors won't use the word “cure” when talking about cancer. Many CAM sites, however, promise a cure. Why the difference?

Dr. Straus: Things that sound too good to be true, in general, are. It's very appealing when patients are struggling desperately with cancer, their own cancer or in a loved one, and the promise of a cure sounds great—but it's not fair or reasonable. There are cancers that can be cured through conventional, proven therapies, and there are some cancers that are rarely cured. CAM approaches should not honestly promise to cure cancer.

Q: How effective is the mistletoe treatment in first or second occurrence of cancer and/or metastasis?

Dr. Mansky: NCCAM is currently conducting a study of a whole-plant mistletoe preparation given together with gemcitabine (Gemzar), a conventional chemotherapy drug.

While there is a substantial body of laboratory studies suggesting a role for mistletoe extracts, in the stimulation of components of the immune system, there are currently no conclusive clinical studies published that would provide clear evidence of the effectiveness of mistletoe in the treatment of cancer. Mistletoe is generally well tolerated. The most frequent side effects include local rashes, sometimes low-grade fevers, and rarely generalized rashes or allergic reactions. ■

NCCAM Adds Six New Research Centers

In October 2004, NCCAM announced the addition of six new centers to its research centers program. The centers are of two types:

- ▶ Centers of Excellence for Research on CAM
- ▶ Developmental Centers for Research on CAM

The **Centers of Excellence** support established researchers in applying advanced technologies to explore the potential benefits and underlying mechanisms of CAM practices; the grantees and their topic areas are:

- ▶ **Center on Mindfulness-Based Stress Reduction, Stress Arousal and Immune Response in Early HIV.** Principal Investigator: Susan Folkman, Ph.D. Institution: Osher Center for Integrative Medicine, University of California, San Francisco. This center will investigate the use in people with early-stage HIV of mindfulness-based stress reduction, a meditation-based approach, to slow disease progression and delay the need for antiretroviral treatment.

- ▶ **Alternative Therapies for Alcohol and Drug Abuse.** Principal Investigator: Yue-Wei Lee, Ph.D. Institution: McLean Hospital/Harvard Medical School. Cofunded with the National Institute on Alcohol Abuse and Alcoholism, this center will evaluate whether certain traditional Chinese herbals and an electrical acupuncture technique can be used to prevent addiction relapse and craving for alcohol and drugs of abuse. It will also



Chinese herbal medicine is being studied at McLean Hospital/Harvard Medical School

seek to determine the physiological mechanisms by which these Chinese therapies affect addictive behavior.

- ▶ **Translational Research Center for CAM Therapy of Asthma.** Principal Investigator: David Peden, M.D. Institution: University of North Carolina, Chapel Hill. This center will identify antioxidant CAM therapies for asthma and determine if these therapies can minimize airway inflammation in response to common triggers of asthma, such as ozone or inhaled allergens.

The **Developmental Centers** provide a means for CAM institutions to partner with established research institutions to conduct exploratory and developmental CAM research projects, as follows:

- ▶ **Trametes Versicolor (Mushroom)-Induced Immunopotentialiation.** Principal Investigator: Joel Slaton, M.D. Institutions: University of Minnesota and Bastyr University. This center will conduct research on

the use of specific mushroom extracts to enhance the immune system's response to tumors and to reduce radiation therapy side effects.

- ▶ **Complementary/Alternative Medicine: Expectancy and Outcome.** Principal Investigator: Barry Oken, M.D. Institutions: Oregon Health and Science University, National College of Naturopathic Medicine, Oregon College of Oriental Medicine, and Western States Chiropractic College. This center will focus on defining and understanding "placebo effects," particularly patient expectation and other factors related to patient-provider interactions that produce desired biological effects. The investigators will seek ways to maximize these effects' benefits, improve clinical trial design, and gain insight into mechanisms underlying mind-body medicine.
- ▶ **Mechanisms of Osteopathic Manipulative Medicine.** Principal Investigator: Michael Smith, Ph.D. Institutions: University of North Texas Health Science Center, Texas College of Osteopathic Medicine, and Arizona College of Osteopathic Medicine. This team will conduct laboratory, animal, and clinical research to study the effects of osteopathic manipulation on the musculoskeletal system, lymphatic fluid flow, and the reduction of pain from back and neck strain.

To see the full press release on these awards, go to nccam.nih.gov/news/2004/index. ■

Update on Chelation Therapy Study

September 2004 marked the first anniversary of participant recruitment for the Chelation Therapy Study, cosponsored by NCCAM and the National Heart, Lung, and Blood Institute. Chelation (pronounced key-LAY-shun) is an investigational therapy that uses a manmade amino acid, EDTA, which is added to the blood through a vein. Some people consider using chelation therapy because of a belief that it may treat heart disease. However, this has not been scientifically proven. This large national research study is seeking to find out whether this therapy is safe and effective.

There are now more than 100 medical centers, clinics, and physicians' offices around the United States participating in the Chelation Therapy Study, and more than 375 patients have enrolled. Total enrollment is expected to be about 2,400. Participants are men and women who are 50 years of age or older and have had at least one heart attack. More information is available by calling 1-888-644-6226 (toll-free in the U.S.) or visiting nccam.nih.gov/chelation. ■

OTHER INFORMATION

NCCAM is developing and posting **new fact sheets and other information products** on an ongoing basis. Titles recently posted include:

- ▶ “The Use of Complementary and Alternative Medicine in the United States,” which is based on findings from an NCCAM-supported survey released in May 2004 by the National Center for Health Statistics
- ▶ A research report, “Questions and Answers About Using Magnets To Treat Pain”
- ▶ A consumer advisory, “Colloidal Silver Products”
- ▶ New Spanish translations of “Herbal Supplements: Consider Safety, Too”; “Selecting a Complementary and Alternative Medicine Practitioner”; “What’s in the Bottle? An Introduction to Dietary Supplements”; and “Complementary and Alternative Medicine in Cancer Treatment: Questions and Answers” (coproduced with the National Cancer Institute)
- ▶ Scientific backgrounders on the CAM domains and whole medical systems, “Energy Medicine: An Overview”; “Biologically Based Practices: An Overview”; “Manipulative and Body-Based Practices: An Overview”; “Mind-Body Medicine: An Overview”; and “Whole Medical Systems: An Overview” (series scheduled for posting this fall)



All NCCAM publications mentioned in this newsletter are also available from the NCCAM Clearinghouse (see box, pg. 2).



George Tucker, M.B.A.



NCCAM thanks our readers who took time to respond to a **recent survey** on this newsletter. Starting with this

issue, we are offering you an expanded publication. We appreciate the many suggestions readers provided.



NCCAM Web Site Awarded

NCCAM was selected by *Prevention* magazine as one of three “Best of the Web: Alternative Medicine” sites (as published in the September 2004 issue).



Carnitine Conference Information

In March 2004, four components of NIH (including NCCAM) sponsored a conference on carnitine, technically a “conditionally essential” nutrient that is also sold as an over-the-counter supplement. Summary information from the conference is now available at ods.od.nih.gov/news/carnitine_conference_summary.aspx. ■

Calendar of Events



This calendar lists events on complementary and alternative medicine (CAM) that are sponsored or organized by NCCAM or other components of NIH, and includes information available at press time.

DECEMBER 2004

NIH State-of-the-Science Conference on Improving End-of-Life Care: December 6–8, 2004. Natcher Conference Center, NIH, Bethesda, Maryland. Primary sponsors: National Institute of Nursing Research and NIH Office of Medical Applications of Research. See nccam.nih.gov/news/upcomingmeetings.

JANUARY 2005

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

January 28, 2005. NIH Neuroscience Building, 6001 Executive Boulevard, Rockville, Maryland. Go to nccam.nih.gov/about/advisory/naccam.

Official Business

Penalty for Private Use \$300

New NACCAM Members

U.S. Health and Human Services Secretary Tommy G. Thompson has appointed five new members to NCCAM's principal advisory body, the National Advisory Council for Complementary and Alternative Medicine (NACCAM).

- ▶ **Carlo Calabrese, N.D., M.P.H.**, is research professor at the National College of Naturopathic Medicine, senior investigator at its Helfgott Research Institute, clinical assistant professor at Oregon Health Sciences University, and clinical investigator at Kaiser Center for Health Research in Portland, Oregon.
- ▶ **Jeanette M. Ezzo, Ph.D., M.P.H., Ms.T.**, is research director of James P. Swyers Enterprises, Takoma Park, Maryland, a company that specializes in designing and developing evidence-based CAM materials, and a certified massage therapist.
- ▶ **L. David Hillis, M.D.**, is professor and vice chair of the Department of Internal Medicine, University of Texas Southwestern Medical School in Dallas.
- ▶ **Bala V. Manyam, M.D.**, is professor at Texas A&M University Health Science Center College of Medicine,

director of the Plummer Movement Disorders Center, Temple, Texas, and an expert in Ayurvedic medicine.

- ▶ **Joel G. Pickar, D.C., Ph.D.**, is associate professor at the Palmer Center for Chiropractic Research at Palmer College of Chiropractic, Davenport, Iowa.

To find out more about these new appointees, go to nccam.nih.gov/news/2004/060404. ■

New Version of IBIDS Database

The NIH Office of Dietary Supplements and the U.S. Department of Agriculture have launched a new, improved version of the International Bibliographic Information on Dietary Supplements (IBIDS) database. IBIDS, which celebrates its fifth anniversary this year, contains over 730,000 citations to the scientific literature on dietary supplements, including vitamins, minerals, and botanicals (such as herbs). IBIDS is publicly available free of charge at dietary-supplements.info.nih.gov/health_information/ibids.aspx. ■