

ANNUAL REPORT ON
**Complementary
and Alternative Medicine**

FISCAL YEAR 2008



Director's Message

The research the National Cancer Institute (NCI) supports, both in our own laboratories and at institutions worldwide, is focused on the ultimate goal of helping cancer patients. That mission – achieved through rigorous science – extends, as well, to NCI's complementary and alternative medicine program, also known as CAM.

It is with great pleasure and pride that we once again provide NCI's research partners, physicians, the advocacy community, policymakers and cancer patients with this fourth annual review of NCI's extensive accomplishments in advancing evidence-based CAM interventions and therapies.

While the study of CAM is challenging, we are fortunate to have many partners in this endeavor, as demonstrated in the brief research profiles you'll find featured in this report.

A significant new CAM partnership commenced in July 2008 when U.S. Department of Health and Human Services and the Chinese Health Ministry signed a landmark memorandum of understanding to foster collaboration between researchers who study integrative and traditional Chinese medicine in both countries.

One of the first and most promising of these projects is a partnership between the Kunming Institute of Botany of China Academy of Sciences and NCI. The Kunming Institute supplies rare and promising specimens, while NCI's Natural Products Branch of the Developmental Therapeutics Program screens them in their system of 60 human cancer cell lines.

NCI's Office of Cancer Complementary and Alternative Medicine does an excellent job of coordinating the endeavors that resulted from our agreement with the Chinese researchers and in developing the Institute's CAM research portfolio and partnerships with extramural researchers as well as within NCI's intramural programs. This effort expands our ability to extend the search for effective therapies into areas outside the mainstream of conventional biomedical research.

I hope you find this report helpful and informative. I also hope that it will generate an enhanced dialogue – especially between patients and health care professionals – about the appropriate uses of CAM interventions in conjunction with conventional medicine. Cancer patients deserve credible, unbiased information about any intervention or treatment regimen that they are considering. It is our duty to conduct the science that makes wise and informed decisions possible.



John E. Niederhuber, M.D.

Director

National Cancer Institute

The following acronyms are used throughout this report:

| | |
|--------|--|
| NCI | National Cancer Institute |
| CAM | complementary and alternative medicine |
| OCCAM | Office of Cancer Complementary and Alternative Medicine |
| DCB | Division of Cancer Biology |
| DCTD | Division of Cancer Treatment and Diagnosis |
| CCR | Center for Cancer Research |
| DCEG | Division of Cancer Epidemiology and Genetics |
| FY | fiscal year |
| RDSP | Research Development and Support Program |
| PAP | Practice Assessment Program |
| BCS | Best Case Series |
| COP | Communications and Outreach Program |
| NCCAM | National Center for Complementary and Alternative Medicine |
| NIH | National Institutes of Health |
| CARRA | Consumer Advocates in Research and Related Activities |
| MOU | Memorandum of Understanding |
| TCM | Traditional Chinese Medicine |
| CRTA | Cancer Research Training Award |
| PDQ | Physicians Data Query |
| CIS | Cancer Information Service |
| FASEB | Federation of American Societies for Experimental Biology |
| CBT | cognitive behavioral therapy |
| ACCC | Arizona Comprehensive Cancer Center |
| UA | University of Arizona |
| FOA | Funding Opportunity Announcement |
| RFA | Request for Applications |
| PA | physical activity |
| HDAC | histone deacetylases |
| PPT | Polyp Prevention Trial |
| ESCC | esophageal squamous cell carcinoma |
| PAH | polycyclic aromatic hydrocarbons |
| PanINs | pancreatic intraepithelial neoplasias |
| EGCG | epigallocatechin-3-gallate |
| CSC | cancer stem cells |
| DIM | diindolylmethane |
| PDGF | platelet derived growth factor |
| QOL | quality of life |
| TCC | Tau Chi Chuan |
| PMID | PubMed Identifier |

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Figure 1. Major Categories of CAM Therapies

Alternative Medical Systems

Definition: Alternative medical systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the United States.

Examples: Acupuncture, Ayurveda, Homeopathy, Naturopathy, Traditional Chinese Medicine, Tibetan Medicine

Energy Therapies

Definition: Energy therapies involve the use of energy fields. There are two types:

- **Biofield therapies** are intended to affect energy fields that purportedly surround and penetrate the human body. The existence of such fields has not yet been scientifically proven.

Examples: Qi gong, Reiki, Therapeutic touch

- **Electromagnetic-based therapies** involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct current fields.

Examples: Pulsed electromagnetic fields, Magnet therapy

Exercise Therapies

Definition: Exercise therapies include health-enhancing systems of exercise and movement.

Examples: T'ai chi, Yoga asanas

Manipulative and Body-Based Methods

Definition: Manipulative and body-based methods in CAM are based on manipulation and/or movement of one or more parts of the body.

Examples: Chiropractic, Therapeutic massage, Osteopathy, Reflexology

Mind-Body Interventions

Definition: Mind-body medicine uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptom.

Examples: Meditation, Hypnosis, Art therapy, Biofeedback, Imagery, Relaxation therapy, Support groups, Music therapy, Cognitive-behavioral therapy, Aromatherapy

Nutritional Therapeutics

Definition: Nutritional therapeutics are an assortment of nutrients and non-nutrients, bioactive food components used as chemo-preventive agents, and specific foods or diets used as cancer prevention or treatment strategies.

Examples: Macrobiotic diet, Vegetarianism, Gerson therapy, Kelley/Gonzalez regimen, Vitamins, Soy phytoestrogens, Antioxidants, Selenium, Coenzyme Q10

Pharmacological and Biologic Treatments

Definition: Pharmacological and biologic treatments include the off-label use of prescription drugs, hormones, complex natural products, vaccines, and other biological interventions not yet accepted in mainstream medicine.

Examples: Antineoplastons, 714X, Low dose naltrexone, Immunoenhancement therapy, Laetrile, Hydrazine sulfate, Melatonin

Complex Natural Products

Definition: Complex natural products are an assortment of plant samples (botanicals), extracts of crude natural substances, and un-fractionated extracts from marine organisms used for healing and treatment of disease.

Examples: Herbs and herbal extracts, Mistletoe, Mixtures of tea polyphenols, Shark cartilage

Spiritual Therapies

Definition: Spiritual therapies are therapies that focus on deep, often religious beliefs and feelings, including a person's sense of peace, purpose, connection to others, and beliefs about the meaning of life.

Examples: Intercessory prayer, Spiritual healing

Introduction

Each year, Congress requests a report of the National Cancer Institute's (NCI) annual expenditures in complementary and alternative medicine* (CAM) research. To give more meaning to the numbers provided to Congress, a more detailed account of the Institute's investment in CAM has been produced for the last three years. The reports, (including last year's *NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2007*), are intended as a way for NCI to communicate its progress in this area of medical research, not only to Congress, but also to other interested stakeholders including cancer researchers, CAM practitioners, health care providers, advocacy organizations, cancer patients, and the general public.

This year, the NCI's Office of Cancer Complementary and Alternative Medicine (OC-CAM) is proud to present the latest such report, *NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2008*. Similar to the previous reports, this publication provides an overview of NCI-supported work in this field along with details on selected CAM projects relating to research, communication, and training and conferences.

This report highlights projects, grants, and cooperative agreements supported by each of the Institute's extramural grant funding divisions – Division of Cancer Biology (DCB), Division of Cancer Control and Population Sciences, Division of Cancer Prevention, and the Division of Cancer Treatment and Diagnosis (DCTD), along with projects from NCI's intramural laboratories – Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG). These projects represent a variety of CAM categories, cancer types, research types, and grant mechanisms. For the first time, this year's report includes an analysis of the different types of training grant awards in NCI's CAM research portfolio and summaries of some of these grants. In fiscal year (FY) 2008, NCI's research expenditures for CAM are an estimated \$121,264,507 for the funding of 444 CAM research projects.

As this report on cancer CAM indicates, we at the NCI are committed to an integrated approach to marshalling all of the many resources and approaches necessary to make cancer a condition that is – at worst – a manageable, chronic illness similar to heart disease and diabetes. We believe that evidence-based CAM techniques, systems, and products can have an important role in helping us reach that worthwhile goal.

* CAM is often defined as any medical system, practice, or product that is not thought of as "western medicine" or standard medical care. Complementary medicine means it is used along with standard medicine, also called conventional medicine. Alternative medicine is used in place of standard treatments. CAM treatments may include dietary supplements, megadose vitamins, herbal preparations, acupuncture, massage therapy, magnet therapy, spiritual healing, and meditation. (See Figure 1, on page 4 for the major categories of CAM therapies.)

Office of Cancer Complementary and Alternative Medicine





NCI's OCCAM is a coordinating office responsible for: identifying gaps in the science and creating corresponding funding opportunities for cancer CAM research; partnering with NCI program staff and other governmental and non-governmental organizations to increase the testing of CAM approaches for cancer prevention, diagnosis, treatment, symptom management, and rehabilitation; developing communication products for various audiences concerning the investigation and use of these approaches; and helping to build bridges between CAM practitioners and the cancer research community.

OCCAM is part of DCTD. The division's mission is to improve the lives of the American public by discovering and conducting better ways to diagnose, assess, treat, and cure cancer through stimulating, coordinating, and funding a national program of cancer research. OCCAM's programs and activities complement DCTD's mission and are enhanced by the other major programs and branches within DCTD.

OCCAM Programs

Research Development and Support Program

As previously noted, NCI sponsored more than 444 cancer CAM research projects in FY 2008, each of which is managed within the various Divisions and Centers of the Institute. OCCAM's Research Development and Support Program (RDSP) staff manages a portion of this portfolio and works with other program staff throughout NCI, assists investigators in identifying funding opportunities, and provides guidance in the pre- and post-review periods of grant application. The RDSP staff also coordinates programs and initiatives designed to stimulate research in cancer CAM as well as activities to develop the foundation of the science in cancer CAM research. RDSP also works with other NCI program staff to fund new grants and supplements to existing grants.

For example, OCCAM awarded a grant supplement during FY 2008 to Yale University researcher Dr. Yung-Chi Cheng for his study on "Nucleoside Analogs as Anti-cancer Compounds" (R01CA063477). The supplement supported research on the interaction of the herbal supplement PHY906 with the chemotherapy drug irinotecan.

In addition, OCCAM awarded the following research grants to:

- Dr. Rakesh Srivastava at the University of Texas Health Center at Tyler for his project "Chemoprevention of Pancreatic Cancer by EGCG." (R01CA125262)
- Dr. Fazlul Sarkar at Wayne State University in Detroit, Michigan for his project "A Novel and Targeted Approach to Inhibit Invasion and Angiogenesis." (R01CA131151)
- Dr. Shengmin Sang at North Carolina Central University, Kannapolis for his project "Ginger Extract Bioavailability Study and Lung Cancer Preventive Effect." (R21CA138277)

Journal Article on Survey of CAM Researchers

OCCAM staff published the article "Survey of cancer researchers regarding complementary and alternative medicine" in the *Journal of the Society for Integrative Oncology* (Winter 2008; 16(1) 2-12). About 85% of the respondents had participated in cancer CAM research. For all CAM categories, the percentage of respondents who would like to conduct research was greater than the percentage of those who have already done so. About two-thirds of the respondents rated research in pharmacologic and biologic treatments and nutritional therapeutics for cancer treatment and symptom/side-effect management as high-priority areas.



Practice Assessment Program

OCCAM's Practice Assessment Program (PAP) reviews retrospective and prospective data on cancer patients treated with alternative therapies. PAP manages the NCI Best Case Series (BCS) Program, which provides an opportunity for CAM practitioners to submit medical data regarding cancer CAM treatments used in their settings. Practitioners are asked to submit patient records for evaluation by experts in clinical assessment and cancer treatment research. Results of the NCI BCS Program are used to inform decisions regarding NCI-initiated research and to share well-documented best cases with interested members of the scientific community in order to stimulate research.

Communications and Outreach Program

OCCAM's Communications and Outreach Program (COP) develops and disseminates information about NCI program initiatives and funding opportunities, workshops and other events, and educational materials through OCCAM's Web site (<http://www.cancer.gov/cam>) and publications.

This program also assesses the opinions, interests, and informational needs of cancer researchers, CAM practitioners, and cancer patients regarding CAM research through surveys, public comment sessions, and focus groups. Results from these explorations are used to guide outreach efforts to these communities.

COP also developed the following publications in FY 2008:

- *NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2007*
- *NCI CAM News* – Spring 2008
- *NCI CAM News* – Fall 2008

National Institutes of Health Yoga Week

In FY 2008, OCCAM's COP partnered with the National Heart, Lung, and Blood Institute; the Office of Research Services; the National Center for Complementary and Alternative Medicine (NCCAM); and the National Institutes of Health (NIH) Recreation and Welfare Association to host NIH's first annual Yoga Week. The five-day series of events took place May 19-23, 2008 and highlighted the science and practice of yoga. The events were planned to serve NIH employees and the public, allowing participants to learn about the benefits of yoga and experience them first-hand through stretching and poses.

Yoga week included presentations by leading yoga instructors, lectures by current NIH grantees conducting research on yoga, including Dr. Lorenzo Cohen, director of the Integrative Medicine Program at the University of Texas M.D. Anderson Cancer Center, and a discussion of NCI's yoga research portfolio by OCCAM Director Dr. Jeffrey D. White. Yoga classes were taught by local instructors throughout the week.

Some participants brought donations of non-perishable foods for Manna Food Center in Rockville, Maryland and the Safra Family Lodge at NIH. Lectures and practice sessions at facilities outside of NIH's main campus in Bethesda, Maryland (Rockledge I and II and 6001 Executive Blvd., in Rockville) allowed off-campus NIH staff to experience yoga.

In addition, COP expanded OCCAM's outreach efforts through exhibiting or sending publications to numerous professional meetings during FY 2008:

- Society for Integrative Oncology International Conference – November 2007
- Evidence-based CAM for Cancer Patients – January 2008
- Oncology Nursing Society – May 2008
- American Association of Naturopathic Physicians/ American Holistic Medical Association Annual Meeting – August 2008
- Fourth International Conference on Holistic Health and Medicine – September 2008

Working with Advocates

In FY 2008, cancer patient advocates were involved in the review of NCI's CAM Annual Report. COP solicited feedback from four Consumer Advocates in Research and Related Activities (CARRA) members who agreed to review a draft of the FY 2007 report. These members provided comments on whether the document was easy to read, contained relevant information to the cancer patient community, or omitted topics of patient interest. Feedback from CARRA members improved the quality of the NCI's Annual Report on Complementary and Alternative Medicine: Fiscal Year 2007.

Cancer CAM Researchers Directory

In FY 2008, COP launched OCCAM's searchable directory of cancer CAM researchers. This resource assists researchers in this growing field to identify others with similar or related research interests. In order to be included in the online directory, researchers must register and demonstrate that they have published original research on a cancer and CAM topic by providing a literature citation. Once registered, users have full access to information provided by other registered users. The Cancer CAM Researcher Directory is located online at http://www.cancer.gov/cam/research_directory.html

OCCAM Highlights

United States and China Accord on Traditional Chinese Medicine

On July 16, 2008, the U.S. Department of Health and Human Services and the Chinese Health Ministry signed a Memorandum of Understanding (MOU) agreement to foster collaboration between researchers studying integrative and Traditional Chinese Medicine (TCM) in both countries. The MOU follows an earlier agreement, signed in 2006, between NCCAM and the Chinese Ministry of Science and Technology. The new agreement encompasses a much larger number of interested institutions in the United States, including NCI, and those in China.

The 2008 MOU on TCM was signed at the beginning of a two-day research roundtable held at NIH that highlighted research in areas of TCM and displayed examples of opportunities for future collaborations between U.S. and Chinese researchers. The presenters discussed diagnostic approaches that might help identify subgroups of cancer patients with different reactions to conventional treatments, as well as quality control of herbal medicines and how to standardize herbal approaches in a way that would make research results more reproducible.

CAM Researchers and Practitioners Conference

In October 2007, OCCAM hosted the conference, *Cancer Researchers and CAM Practitioners: Fostering Collaborations; Advancing the Science*, to bring together people who work in a myriad of varying fields of cancer research, ranging from apoptotic cancer cells to acupuncture. The goal of the conference was to facilitate one of the most important factors in science—teamwork.

OCCAM has long recognized that building and sustaining strong interdisciplinary partnerships is a critical factor in the success of some cancer CAM research endeavors. To promote this, OCCAM Director Dr. Jeffrey D. White and his staff organized the two-day conference at the NIH Natcher Conference Center for over 100 participants from around the world. Conference sessions included “Developing CAM for Cancer: U.S. Regulations,” “Understanding and Designing Clinical Case Reports,” and “Research Basics and Training Opportunities for CAM Practitioners.”

Videocasts from the conference are archived at http://www.cancer.gov/cam/news_occamconferences.html.

OCCAM's Participation at Major Professional Conferences

OCCAM staff members are active in both domestic and international professional conferences through presentations and engaging in dialog with cancer CAM researchers, practitioners, and patient advocacy groups.

During FY 2008, this encompassed several important meetings:

- Drs. Jeffrey D. White and Libin Jia attended the International Traditional Chinese Medicine Conference for Cooperation in Science and Technology in Beijing, China, November 28-29, 2007.
- Dr. Jeffrey D. White attended the 3rd International Congress on Complementary Medicine Research in Sydney, Australia, March 29-31, 2008.
- Dr. Libin Jia participated in an “NCI Meet the Experts” session during the American Association of Cancer Research meeting in San Diego, CA, April 12-16, 2008.
- Drs. Jeffrey D. White and Dan Xi attended the Society of Integrative Oncology’s Shanghai International Symposium: Integrative Oncology Theory, Research, and Practice in China, April 25-26, 2008.
- Ms. Lauren Rice attended the National Conference on Health Communication, Marketing, and Media in Atlanta, GA, August 12-14, 2008.
- Dr. Oluwadamilola Olaku presented at the Research Working Group on Case Reports in Heidelberg, Germany, September 5, 2008.
- Dr. Farah Zia presented at the Insulin Potentiation Therapy Conference in San Diego, CA, September 26-28, 2008.

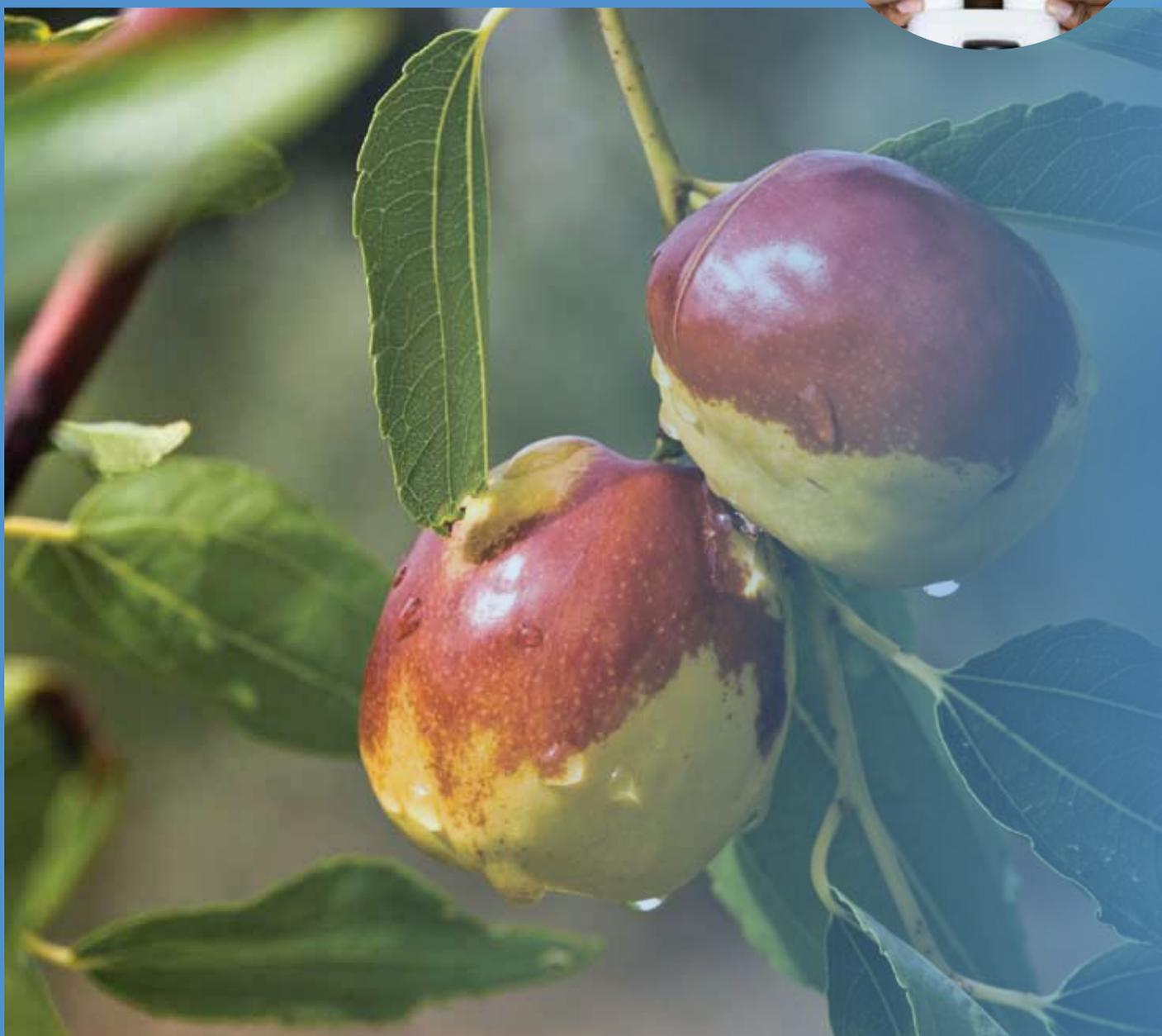
NCI participation at other conferences and events can be found in the Training and Conferences section on pg. 18).

OCCAM Staff List: FY 2008

| | |
|---|--|
| Jeffrey D. White, M.D. | Director, OCCAM |
| Christina Armstrong | Administrative Program Specialist |
| Akia Samuda | Administrative Assistant |
| April Woodfork | Administrative Assistant |
| Dan Xi, Ph.D. | Program Officer |
| Oluwadamilola Olaku, M.D., M.P.H. | Scientific Program Analyst |
| Libin Jia, M.D. | Health Scientist Administrator |
| Obianuju Igbokwe, M.S. | Cancer Research Training Award (CRTA) Fellow |
| Shadia Kawa, M.S. | CRTA Fellow |
| Farah Zeba Zia, M.D. | Director, Practice Assessment Program |
| Colleen Lee, CDR (U.S. PHS), M.S., CRNP, AOCN® | Coordinator, Practice Assessment Program |
| Shea Buckman, M.A. | Coordinator, Communications and Outreach Program |
| Lauren Rice, M.S. | Communications Analyst |
| Jennifer Frazier, M.P.H. | Health Communications Intern |
| Vera Rosenthal, M.P.H. | Health Communications Intern |

NCI CAM Communications Programs

NCI directs communications programs that are committed to providing current and credible information resources about CAM to its stakeholders.



Providing Information Online

OCCAM's Web site (<http://www.cancer.gov/cam>) serves as NCI's information hub on CAM issues. It provides a wealth of information resources and timely updates about the Institute's CAM research portfolio, grant opportunities, and other news.

Included on the OCCAM site are links to other information sources such as the Physician Data Query (PDQ®), NCI's comprehensive cancer database. PDQ produces a registry of clinical trials and summaries covering topics such as cancer treatment, prevention, screening, and CAM.

Most Frequently Accessed PDQ CAM Summaries

NCI tracks the number of page views for both patient and health professional versions of each PDQ CAM summary on Cancer.gov. The number of page views is determined by the number of views/visits to the first page of each PDQ summary.

In FY 2008, the patient version summary with the highest number of page views was Coenzyme Q10, with 30,163 page views. The second highest number of page views was for the patient version of Essiac/Flor-Essence, with 25,581 page views. Third in the rankings was the Mistletoe patient summary, with 18,442 page views.

Note: NCI's Web sites do not offer personalized medical advice to individuals about their condition or treatment, and the resources on the sites should not be used as a substitute for professional medical care.



Figure 2. PDQ CAM Summaries

Patient summary page views

| | 714X | Acupuncture | Antineoplastons | Aromatherapy | Cancell/Entelev | Cartilage | Coenzyme Q10 | Essiac/Flor-Essence | Gerson Therapy |
|---------------|-------------|--------------|-----------------|--------------|-----------------|-------------|--------------|---------------------|----------------|
| Totals | 4242 | 11596 | 2663 | 8306 | 3725 | 9347 | 30163 | 25581 | 10885 |

Health professional summary page views

| | 714X | Acupuncture | Antineoplastons | Aromatherapy | Cancell/Entelev | Cartilage | Coenzyme Q10 | Essiac/Flor-Essence | Gerson Therapy |
|---------------|-------------|-------------|-----------------|--------------|-----------------|-------------|--------------|---------------------|----------------|
| Totals | 1772 | 3871 | 2055 | 4581 | 1334 | 2067 | 5743 | 3932 | 2451 |

During FY 2008, the highest number of page views received for a health professional version of a PDQ CAM summary was 6,997 for Mistletoe. Coenzyme Q10 had the second most page views for a health professional version with 5,743 page views. The Aromatherapy professional summary, with 4,581 page views, had the third most page views.

Figure 2 shows the total number of page views during FY 2008 for all of the PDQ CAM summaries.

PDQ CAM Clinical Trials

NCI sponsors clinical studies on CAM approaches for cancer. On the OCCAM Web site, there is a table which organizes CAM clinical trials by cancer types and types of symptoms. Clicking on an entry in the table triggers a search of NCI's PDQ Cancer Clinical Trials Registry, which includes abstracts of approximately 4,500 protocols that are open and approved to accept patients as well as trials that are closed. The Registry is available on the NCI Web site at <http://www.cancer.gov/clinicaltrials/search/>. In FY 2008, there were 111 cancer CAM clinical trials. (See appendix on page 67 for the complete list.)

For the current list of CAM clinical trials by cancer type and to access the CAM clinical trials table, go to http://www.cancer.gov/cam/clinicaltrials_list.html.

The NCI fact sheet "Complementary and Alternative Medicine in Cancer Treatment: Questions and Answers" was viewed 23,981 times in FY 2008. To view this publication, please visit <http://www.cancer.gov/cancertopics/factsheet/therapy/cam>.

| Gonzalez Regimen | Hydrazine Sulfate | Laetrile/Amygdalin | Milk Thistle | Mistletoe Extracts | Newcastle Disease Virus | PC-SPES | Selected Vegetables/Sun's Soup | Spirituality in Cancer Care |
|------------------|-------------------|--------------------|--------------|--------------------|-------------------------|---------|--------------------------------|-----------------------------|
| 3158 | 6007 | 18101 | 11972 | 18442 | 5255 | 5670 | 479 | 6174 |

| Gonzalez Regimen | Hydrazine Sulfate | Laetrile/Amygdalin | Milk Thistle | Mistletoe Extracts | Newcastle Disease Virus | PC-SPES | Selected Vegetables/Sun's Soup | Spirituality in Cancer Care |
|------------------|-------------------|--------------------|--------------|--------------------|-------------------------|---------|--------------------------------|-----------------------------|
| 2071 | 1084 | 2988 | 3459 | 6997 | 2014 | 3193 | 152 | 7581 |

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