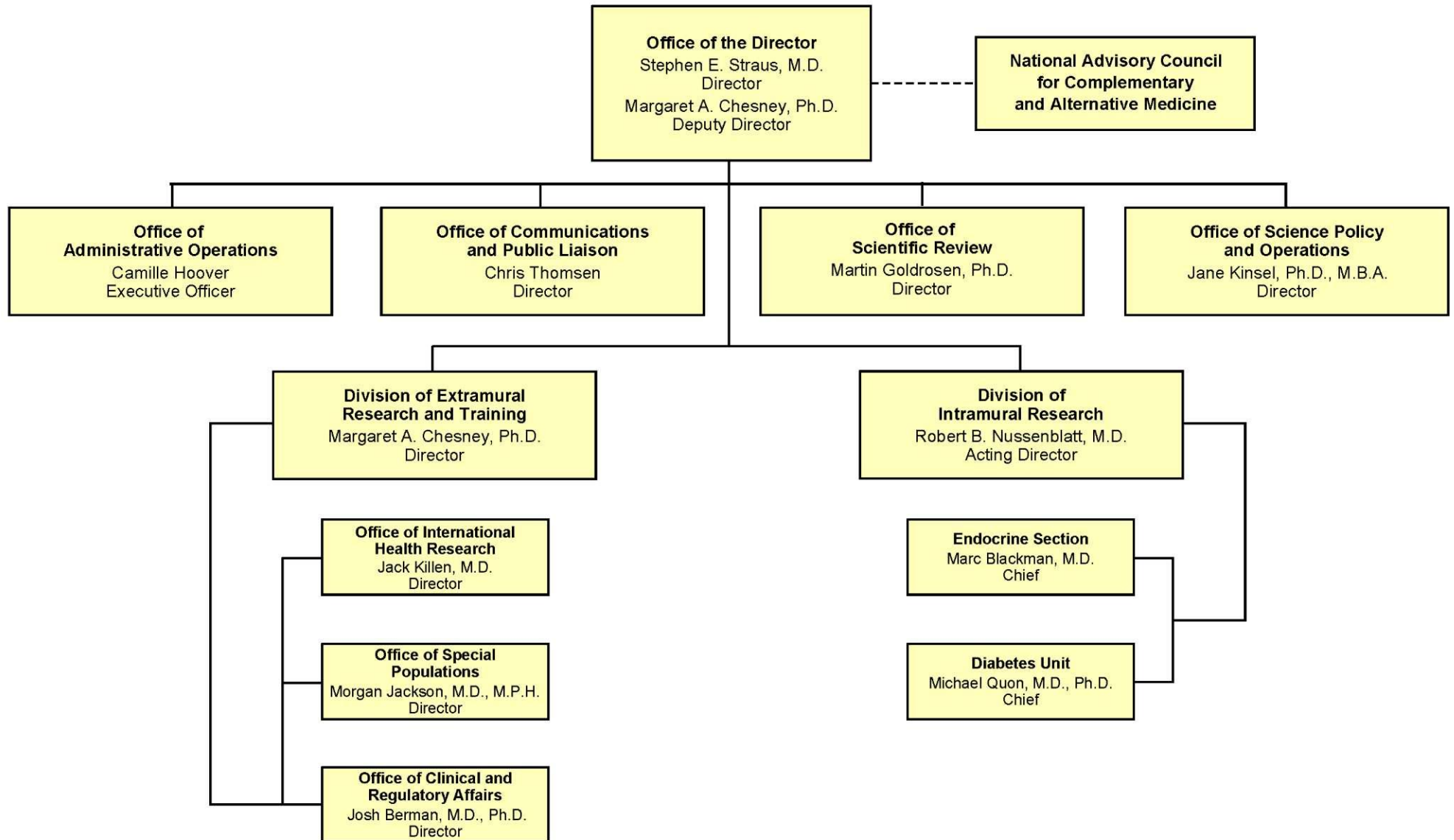


DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

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National Institutes of Health
National Center for Complementary and Alternative Medicine



NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

For carrying out section 301 and title IV of the Public Health Service Act with respect to complementary and alternative medicine, [\$121,465,000] *\$120,554,000*.

[Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2006, as enacted by Public Law (109-149)]

**National Institutes of Health
National Center for Complementary and Alternative Medicine**

Amounts Available for Obligation 1/

Source of Funding	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate
Appropriation	\$123,116,000	\$122,692,000	\$120,554,000
Enacted Rescissions	-1,011,000	-1,227,000	0
Subtotal, Adjusted Appropriation	122,105,000	121,465,000	120,554,000
Real transfer under NIH Director's one-percent transfer authority for Roadmap	-772,000	-1,086,000	
Comparative transfer from OD for NIH Roadmap	772,000	1,086,000	
Subtotal, adjusted budget authority	122,105,000	121,465,000	120,554,000
Unobligated Balance, start of year	0	0	0
Unobligated Balance, end of year	0	0	0
Subtotal, adjusted budget authority	122,105,000	121,465,000	120,554,000
Unobligated balance lapsing	0	0	0
Total obligations	122,105,000	121,465,000	120,554,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2005 - \$150,000 FY 2006 - \$105,000 FY 2007 - \$105,000

Excludes \$0 in FY 2006 and \$0 in FY 2007 for royalties.

Justification

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Authorizing Legislation: Section 301 of the Public Health Service Act, as amended.

Budget Authority:

FY 2005 Actual		FY 2006 Appropriation		FY 2007 Estimate		Increase or Decrease	
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>
75	\$122,105,000	76	\$121,465,000	77	\$120,554,000	1	-\$911,000

This document provides justification for the Fiscal Year 2007 research activities of the National Center For Complementary and Alternative Medicine, including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2007 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR)." Detailed information on the NIH Roadmap for Medical Research may be found in the Overview section.

Introduction

The National Center For Complementary and Alternative Medicine (NCCAM) celebrated its fifth anniversary in 2004 and spent the year developing a new strategic plan: *Expanding Horizons of Health Care 2005-2009*. With a few new innovations, the plan holds firmly to the Center's mission stated in its first strategic plan (2001- 2005) to conduct and support rigorous complementary and alternative medicine (CAM) research, train CAM researchers, and disseminate authoritative findings to public and professional communities. The new strategic plan incorporates lessons learned and articulates priorities that emphasize growth in basic research and mechanistic studies and research on mind-body medicine and biologically based practices. Reflecting the advice of engaged experts and members of the lay public that participated in every step of the process, the plan also highlights the need for growth in health services research and identifies a new area of study: the ethical, legal and social implications of CAM research and practice. Along with these new directions and areas of heightened emphasis, the plan also calls on NCCAM to continue its investments in research on manipulative and body-based practices, energy medicine, and the study of whole medical systems.

Recent key investments, outlined below, are helping inform future directions for the Center. The results of a national survey on CAM use, conducted in collaboration with the Centers for Disease Control and Prevention (CDC) and published in 2004, indicated that over a third of Americans use CAM, most frequently to treat back problems, colds, neck pain, joint pain and stiffness, arthritis, and anxiety and depression. The Center continues to analyze the survey data to learn more about CAM use by the public and plans future collaborations with CDC to follow trends in CAM use. January 2005 also

saw the release of the National Academies' Institute of Medicine (IOM) report on CAM, which affirmed NCCAM's research operating principle, namely that CAM interventions must be evidence-based and tested using the same principles and standards of research that govern conventional medicine. The IOM report also expressed concerns about the consistency and quality of CAM products sold to the public — concerns that NCCAM has also encountered in conducting research on these products, which the Center is addressing with new policies and procedures (described below).

Findings from a number of important NCCAM-funded clinical trials were released within the past year. Two trials addressed CAM approaches for osteoarthritis of the knee. One trial provides the best evidence to date that acupuncture significantly relieves pain and improves mobility when added to standard therapy for osteoarthritis of the knee. Another major trial of the dietary supplements glucosamine and chondroitin sulfate showed that the supplements used together were effective in relieving moderate to severe pain in patients with osteoarthritis of the knee. An ancillary study with the patients in this trial is seeking to understand if glucosamine and chondroitin sulfate also preserve cartilage and prevent further joint deterioration.

Building the CAM Research Enterprise

Six years after being established, NCCAM finds CAM research still in a formative state. In spite of significant progress, much remains to be achieved in building infrastructure, training investigators, and forging a culture of rigorous CAM research. Among the components that NCCAM deems critical toward these ends are the nurturing of a centers program that can support teams of researchers to focus on common CAM themes, and the implementation of training initiatives to enlarge the pool of both conventional and CAM-trained professionals able to carry out rigorous CAM research. Following an external evaluation of its centers program in 2002, NCCAM reorganized its program of multidisciplinary centers to create four distinct types of centers:

Centers of Excellence for Research on CAM (CERCs). The CERCs are directed by investigators with outstanding research records who bring cutting-edge technologies, such as brain imaging, to studies of CAM. These experienced scientists direct teams of CAM and conventional investigators in exploring mechanisms of action of specific CAM modalities. Over the first 3 years of the program, awardees have advanced understanding of acupuncture through the use of brain imaging and laid the foundation for delineating the role of antioxidants in treating asthma. In 2005, the program grew to six CERCs. NCCAM hopes to make additional awards in FY 2007.

Developmental Centers for Research on CAM (DCRCs). DCRCs are designed to forge collaborations between investigators in CAM and conventional institutions to conduct exploratory and developmental research projects. Support enables the CAM partners to strengthen research expertise and infrastructure at their home institutions while affording conventional researchers the clinical and cultural perspectives critical to the conduct of CAM research. In 2005, NCCAM funded 5 DCRCs with collaborations involving 18 CAM and conventional institutions. Recognizing that building the research

capacity at CAM institutions will take time, NCCAM is further refining the DCRC program. Beginning in FY 2007, new awards will support Phase I centers, for investigators and institutions just launching programs of research, and Phase II centers, for institutions with a DCRC award in place and in a position to undertake more sophisticated studies.

Botanical Research Centers (BRCs). A joint venture of NCCAM and the NIH Office of Dietary Supplements (ODS), BRCs promote research on botanicals, particularly on plants whose ingredients in dietary supplements may yield health benefits. In keeping with NCCAM's strategic focus on exploring mechanisms of action of CAM modalities, as well as their safety and efficacy, a re-announcement of the program emphasizes the use of cutting-edge technologies in botanical research. NCCAM and ODS are supporting three new botanical research centers through the program, as well as two continuing centers.

International Centers for Research on CAM (ICRCs). A fourth type of center addresses whole medical systems developed in other parts of the world, promoting collaborations between U.S. investigators and experts in the traditional medical systems of their own countries. These centers are building research expertise and capacity abroad and providing foreign researchers with experience to guide them through the NIH research grant system. In FY 2003, NCCAM awarded planning grants to 11 international research partnerships and has now selected 2 sites for center support in FY 2005; a third center, focusing on cancer research, has been funded by the National Cancer Institute.

Research Training and Career Development. From its start, NCCAM recognized that building a critical mass of skilled investigators in CAM requires a substantial and long-term commitment to research training and career development. While M.D. and Ph.D. degree holders have been well-represented among NCCAM grantees and as awardees in research training and career development programs, the number of CAM-trained professionals receiving such support remains relatively small. This is not entirely surprising, given the larger number of individuals completing M.D. and Ph.D. programs each year compared to those obtaining doctorates in CAM fields. Additionally, individuals with CAM doctorates usually have little research experience, which places them at a disadvantage when competing for research grants.

In recognition of these circumstances, an expert panel that reviewed NCCAM's research training and career development programs recommended targeted training and career initiatives that were announced in FY 2005. One new program, the CAM Practitioner Research Career Development Award (K01), is directed specifically to CAM practitioners interested in research, supporting their work with experienced mentors in conventional research-intensive institutions for up to 5 years — sufficient time, it is hoped, to prepare the practitioner to conduct independent research and compete successfully for grant support. The second new award, the NCCAM Career Transition Award (K22), provides up to 4 years of support to outstanding postdoctoral research fellows. The award provides research funding that can be activated as soon as the

recipient has obtained a faculty appointment or other independent research position, easing the recipient's transition to an independent career in CAM research.

NCCAM will build on these efforts in FY 2007, first by offering special supplements to existing research grants to attract additional CAM practitioners to the research team, as a means of gaining hands-on research experience, and second by holding a workshop in 2007 to allow newly independent career development awardees to present their research findings and interact with other CAM investigators and NIH administrators.

Advances in Neuroscience

NCCAM is participating in two NIH-wide neuroscience initiatives. As part of the NIH Blueprint for Neuroscience Research, several institutions conducting NCCAM training programs have received R25 grants in a Blueprint initiative for course development in neurobiology of disease. The Center is also a member of the NIH Pain Consortium, which provides a forum for the exchange of ideas and promotes research collaborations across NIH. The Center's neuroscience portfolio supports extensive research on pain — the main reason people choose CAM interventions — as well as neurodegenerative diseases, such as Alzheimer's disease. NCCAM's ongoing randomized placebo-controlled clinical trial of *Ginkgo biloba* seeks to prevent age-related dementia. This study, done in collaboration with NIA and NHLBI, is the largest trial of an herbal medicine ever conducted. Additional science advances related to pain and dementia follow.

Individualizing acupuncture for pain. NCCAM-supported investigators found that individuals respond differently to traditional (manual) acupuncture and electroacupuncture, but both modes can reduce pain when compared with a placebo.¹ These findings resulted from experiments in which normal volunteers who had never undergone acupuncture were exposed to short-term painful heat stimuli on their arms and legs and asked to rate the intensity of the pain (low, medium, high). Following training sessions, the volunteers were exposed to these painful stimuli before and after 5 minutes of manual, electro, or sham (placebo) acupuncture. Subjects then rated their post-acupuncture pain. Results showed that manual acupuncture produced significant analgesia for some subjects, electroacupuncture for others, and placebo acupuncture for none. The study is provocative for what it indicates about subjective variation in response to the type of acupuncture applied, as well as suggesting that different nervous system mechanisms are involved in mediating the analgesia associated with manual compared to electroacupuncture.

Placebo analgesia activates pain-suppressing pathways in the brain. Reports in the pain literature have confirmed that the use of placebos, either in patients with painful conditions or healthy individuals subjected to experimentally induced pain, can result in significant pain relief in some people. In keeping with the Center's increasing focus on

¹Kong J, Fufa DT, Gerber AJ, Rosman IS, Vangel MG, Gracely RH, Gollub RL. Psychophysical outcomes from a randomized pilot study of manual, electro, and sham acupuncture treatment on experimentally induced thermal pain. *J Pain*. 2005 Jan;6(1):55-64.

explanatory mechanisms, investigators in an NCCAM-supported study have now shown that placebos can activate the μ -opioid system of the brain, a major network of nerve cells and pathways that can block incoming pain signals. The investigators used PET scans and a radioactive tracer that selectively binds to cells bearing the μ -opioid receptor on their surfaces to obtain brain images of their subjects under three conditions: a baseline scan before any intervention, a scan following the infusion of a saline solution into a jaw muscle, which induces a short period of sustained muscle pain, and the same type of infusion, but with the following instructions. The subjects were told that after getting the pain stimulus they would be given an experimental new pain drug, raising expectations of pain relief. However, according to the IRB-approved study design, the subjects were told that while they might not be able to tell if the drug was working; the monitoring equipment would record any changes in the brain. This was the “pain plus placebo” arm of the experiment. At the outset, subjects rated the severity of the pain caused by the experimental stimulus on a scale of 0 to 100 and did this repeatedly during the course of the experiment. They later also checked which of a standardized list of words best described their feelings in response to the pain. The investigators continuously manipulated the saline infusions during the pain and pain-plus-placebo parts of the experiment so that they matched the subject’s initial rating of pain severity. They could then deduce how large a placebo response was occurring (if any) by virtue of how much stronger they had to make the pain stimulus to match the initial level. Finally, the PET scanning technique rendered a molecular image of the extent to which the brain’s μ -opioid system was activated by a placebo response: the greater the activation, the fewer μ -receptor-bearing nerve cells would be available to pick up the radioactive tracer. The test results clearly showed that participants included high and low placebo responders—measured not only by their subjective responses, but by the degree of activation of the μ -opioid system in the brain as shown by the brain scans. The investigators conclude that what a person expects to occur can and does influence physical and psychological states, an example of mind-body interactions.² This research was funded in response to an RFA on the placebo effect that NCCAM co-sponsored with other NIH Institutes and Centers.

Grape seed extract: food for the brain? Using the tools of proteomics that were developed in the past few years to study proteins, researchers at one of NCCAM’s Botanical Research Centers reported that protein expression in the rat brain was altered after ingestion of grape seed extract (GSE) in ways that might protect brain function. This material is rich in proanthocyanidins (PAs), which are thought to have antioxidant properties. PAs are members of a family of molecules that contribute to the intense colors of fruits and vegetables such as red grapes, cranberries, blueberries, and spinach. The study identified 13 proteins whose amounts increased or decreased in the brains of adult female rats fed for 6 weeks on a diet supplemented with GSE, compared to control animals. The proteins whose levels were increased were all associated with neuroprotective properties and maintenance of the integrity of nerve cells. The proteins whose levels were decreased had previously been seen at elevated levels in Alzheimer’s disease or other neurodegenerative disorders. This was the first study to show that a

²Zubieta J-K, Bueller, JA, Jacksonn, LR, Scott, DJ, Xu, Y, Koeppc, Nichols, TE, Stohler, CS. Placebo effects mediated by endogenous opioid activity on μ -opioid receptors. *Neuroscience* 25(34):7754-7762.

dietary supplement could alter the levels of multiple proteins in body tissues, a key step in understanding the role of supplements in health and disease.

Massage, Chiropractic and Osteopathic Therapies — Next Steps

Manual therapies include techniques that focus primarily on musculoskeletal structures, such as bones and joints, as well as other soft tissues and the circulatory and lymphatic systems. Best-known among such practices are forms of massage and manipulations to the spine and other structures employed by Doctors of Chiropractic or Osteopathy. Chiropractic and massage treatments together were used by 12.5 percent of Americans in the course of a year, according to the 2002 CDC national survey.³ Common to these and other body-based practices is the belief that reducing musculoskeletal stresses elicits the body's innate ability to heal itself.

NCCAM's research portfolio on manual therapies includes assessments of selected therapies in clinical trials. Examples include a trial of the traditional Chinese medicine practice of Tai Chi (which includes meditation as well as gentle movement exercises) to treat the pain of osteoarthritis of the knee and yoga practices for low back pain. Two other trials are assessing the effects of massage on the immune system of preterm infants, with one of the trials also exploring its use by depressed pregnant women to prevent premature birth. One recent trial demonstrated benefits for Tai Chi in older patients:

Tai Chi practice benefits chronic heart failure patients. NCCAM-funded investigators demonstrated that Tai Chi, when practiced twice weekly for 3 months in addition to standard medical care, improved quality of life, exercise capacity, and cardiac function in patients with chronic heart failure, compared to subjects who received only standard medical care.⁴ Importantly, Tai Chi training and practice were not associated with demonstrable adverse effects, and adherence to the regimen was high.

Future Plans. While clinical studies on manual therapies have been promising, the mechanisms of action underlying the effects due to these approaches are little understood. An initiative planned for FY 2007 on the biology of manual therapies will encourage basic science and animal model studies on the mechanisms underlying the biomechanical, immunological, endocrinological and/or neurophysiological consequences of manual therapies.

³Barnes P, Powell-Griner E, McFann K, Nahin R. CDC Advance Data Report #343. Complementary and Alternative Medicine Use Among Adults: United States, 2002. May 27, 2004.

⁴Yeh GY, Wood MJ, Lorell BH, Stevenson LW, Eisenberg DM, Wayne PM, Goldberger AL, Davis RB, Phillips RS. Effects of Tai Chi mind-body movement therapy on functional status and exercise capacity in patients with chronic heart failure: a randomized controlled trial. *Am J Med.* 2004 Oct 15;117(8):541-8.

CAM Approaches to Altering the Immune Response

Many CAM interventions are thought to achieve their health-promoting, disease-preventing benefits by modulating the body's immune system — tuning the system up to thwart infection or suppressing an over-reactive immune system in cases of allergy and autoimmunity. These immune modulating effects may be due to purported antioxidant and/or anti-inflammatory properties of selected dietary supplements or result from adoption of a variety of mind-body or body-based practices, such as mindfulness-based meditation, yoga, or forms of massage, practices aimed at reducing stress and, in traditional medical systems, achieving greater balance of body systems or inner harmony. Because of the ubiquity of these claims and their potential importance, NCCAM has undertaken studies of CAM effects on the immune system, and, through a new research initiative, is committed to supporting more.

Understanding asthma attacks. Asthma affects almost 30 million people in the United States.⁵ These are individuals whose sensitivity to environmental allergens triggers excessive and aberrant immune reactions in the lungs that lead to shortness of breath and wheezing. To better understand these processes, NCCAM-supported researchers exposed healthy volunteers to a mist of lipopolysaccharide (LPS), an irritating bacterial byproduct. The research demonstrated that “immature” dendritic cells — a class of immune cells found in the lung airways and in other tissues, which act as first responders to foreign invaders — changed their behavior when exposed to LPS. Their ability to engulf and destroy the foreign molecules was reduced; instead, they developed into “mature” dendritic cells, further processing the LPS and moving from the lungs to lymph nodes where the LPS could stimulate the T-class of immune cells to mount a response. While the healthy volunteers were not affected clinically by inhaling LPS, such a process could precipitate an asthma attack in asthma-prone patients. These experiments are elucidating little-understood features of the immune system and represent a model system in which CAM modalities can be tested for the ability to prevent or treat asthma attacks.

New hope for allergic asthma and peanut allergy. An extract of three herbs derived from traditional Chinese medicine and given the name ASHMI (antiasthma herbal medicine intervention) has been shown to be effective in patients with moderate-to-severe persistent asthma when compared with conventional treatment with the potent corticosteroid drug used in people with chronic asthma — prednisone. Patients in the experimental group received either an ASHMI capsule or a placebo that resembled a prednisone tablet, while the control group was given a prednisone tablet or a placebo that resembled the ASHMI capsule. After 4 weeks, both groups of subjects were significantly improved. While prednisone treatment was slightly better than the herbal mixture in overall outcome measures, patients in the prednisone group showed significant weight gains compared to the herbal group. Also, prolonged use of corticosteroids has immunosuppressive effects that can lower resistance to infection and adversely affect adrenal gland functioning. In contrast, the herbal treatment appears to have had no such immunosuppressive or adrenal gland effects. The investigators, who had previously

⁵CDC National Health Interview Survey, 2003. Life-time asthma population estimates, 2003. Web accessed on September 16, 2005 (http://www.cdc.gov/asthma/NHIS/2003_table1-1.htm).

studied the herbal extract in a mouse model of allergic asthma, speculate that its effectiveness may lie in the herbs' ability to suppress inflammation-induced airway hyperreactivity and possibly also to relax lung muscle and inhibit the muscle contractions that elicit shortness of breath.

The same group of investigators, in a continuing collaboration between their laboratories in the United States and China, tested another herbal mixture that shows promise for people allergic to peanuts, a potentially life-threatening condition that affects more than 3 million Americans.⁶ In their study, mice allergic to peanuts treated with a Chinese herb mixture known as FAHF-2 were completely protected from allergic reactions when exposed to peanuts up to 5 weeks after treatment.⁷ Further research on FAHF-2 is now needed to determine whether it can prevent the symptoms and signs of peanut allergy in humans.

Other immunological research includes studies to determine the basis for the anti-inflammatory and immunosuppressive actions reported for green tea, in connection with osteoarthritis and irritable bowel syndrome. Similar immunosuppressive activities have been reported for the botanical feverfew, which is under study in an animal model of cystic fibrosis (CF). In another CF study, investigators are assessing whether ginseng is effective as an antibacterial agent against the bacterium that is the most common cause of morbidity and mortality in patients with CF. *Ginkgo biloba*, the herb being tested in NCCAM's dementia prevention trial, may enhance the immune response of candidate vaccines. In this regard, a study is studying whether *Ginkgo biloba* combined with HIV virus-like particles may augment the immune responses induced by the particles alone — a potentially useful outcome as investigators search for safe and effective AIDS vaccines.

Also in connection with AIDS, NCCAM is supporting a randomized clinical trial to determine whether mindfulness-based stress reduction techniques can boost the immune system, slowing disease progression in people with early stage HIV disease and postponing the time when antiretroviral drugs are needed. Outcome measures will note whether the meditating group shows slower declines in CD4 cell counts and in the blood level of HIV RNA, as compared to control HIV-positive subjects.

Future Plans. NCCAM will pursue mechanistic studies to explore the immunomodulatory effects of CAM interventions. An initiative planned for FY 2007 will encourage studies of the immune effects of CAM interventions focusing on the underlying mechanisms involved and emphasizing the use of advanced technologies that are available for immune function studies.

⁶Sicherer SH, Munoz-Furlong A, Sampson HA. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: a 5-year follow-up study. *J Allergy Clin Immunol* 2003;112:1203-7.

⁷Srivastava KD, Kattan JD, Zou ZM, Li JH, Zhang L, Wallenstein S, Goldfarb J, Sampson HA, Li XM. The Chinese herbal medicine formula FAHF-2 completely blocks anaphylactic reactions in a murine model of peanut allergy. *J Allergy Clin Immunol.* 2005 Jan;115(1):171-8.

Biologically Based Practices

The pervasive appeal and use by Americans of products characterized as natural and healthful — herbs, botanicals, and other products derived from “nature,” including high dosages of vitamins, minerals, amino acids, fatty acids, and even whole species of “friendly” bacteria — pre- and probiotics — explain why NCCAM initially invested heavily in research on biologically based CAM practices, and continue to give this area high priority. Because NCCAM’s early research demonstrated some inconsistency and contamination of commercial products used in research, the Center, acting with the advice of consultants and its Advisory Council, established new polices and procedures to guide further research on botanicals.

New Policy on Biological Products. In April 2005, with the advice and approval of experts in dietary supplement use and research, NCCAM issued a policy requiring newly funded researchers to provide evidence of the quality of their study materials, submit selected samples for independent testing, and justify the proposed dose. To assess product information provided by applicants, NCCAM has created a working group of its Advisory Council that includes members with expertise in natural products used for medical purposes, their chemistry, and characterization and standardization approaches.

New Resource Centers. In FY 2005, NCCAM established a Phase I Resource Center to conduct early stage clinical tests of botanical products to determine the optimal dose ranges, adverse reactions and drug interactions, if any, and the best mode of administration of a test agent. Results will guide decisions about the design and advisability of proceeding to larger Phase II/III clinical trials. NCCAM also established a Virtual Analytic Resource Center that provides the capacity to characterize the physical and chemical properties of dietary supplements intended for NCCAM-supported studies.

Cranberry for Urinary Tract Infections (UTIs). Under the Small Business Innovation Research (SBIR) program, NCCAM contracted to develop a research-quality product made from cranberries for use in research, including studies of UTIs. Drinking cranberry juice or consuming cranberry in other forms has long been touted as a way to prevent or treat UTIs — stubborn and painful conditions more common in women than men, but also frequently a problem for hospitalized patients subjected to urinary catheterization. NCCAM is supporting research using the SBIR product to determine the active ingredients and optimal dosages of cranberry and whether the berry affects the action of other drugs an individual is taking. Other research is exploring whether cranberry can reduce the rate of UTIs, the effects it may have on yeast as well as bacterial infections, and if cranberry has anti-inflammatory effects on the cardiovascular system.

Milk Thistle for Liver Disease. There has been considerable interest in therapies for liver diseases, including infectious hepatitis as well as alcohol- and non-alcohol-related steatohepatitis (NASH). Patients with viral hepatitis frequently use milk thistle, and, like cranberry, NCCAM is developing a standardized form for research studies. In 2005, NCCAM and NIDDK issued a Request for Applications for Phase I/II clinical trials of *silymarin*, an extract from milk thistle plant seeds, to determine efficacy and optimal dose

for use against chronic hepatitis C and NASH, either in conjunction with, or as an alternative to, standard therapies.

Vitamin E and Cancer. Cancers of the lung and prostate are the leading causes of cancer deaths in men and the use of CAM interventions for cancer is prominent in NCCAM's research portfolio. Several studies are exploring whether certain forms of vitamin E have anti-cancer properties.⁸ One form of the vitamin, gamma-tocopherol, is commonly found in foods, while another form, alpha-tocopherol, is found primarily in dietary supplements. Investigators have now shown that gamma tocopherol, but not the alpha form, slows the growth of prostate and lung cancer cells in cell culture and induces cancer cell death. Use of both gamma and delta forms had even greater effects on cancer cells than either one alone. Further research is needed to see if these observations hold up in human studies and to determine the appropriate dosage.

NIH Roadmap

Several NIH Roadmap initiatives that promote interdisciplinary research are particularly key to NCCAM's mission. Interdisciplinary research is the development of a new science from the integration of two or more existing disciplines. Many important medical advances occur as diverse scientific disciplines work cooperatively on a common mission; this intersection is vital for optimal collaborations among conventional and CAM researchers. One roadmap initiative, "Meetings and Networks for Methodological Development in Interdisciplinary Research," was designed to stimulate meetings and networks to further develop innovative and interdisciplinary methodology in the behavioral and social sciences. These unique networks work to integrate conceptual and analytic tools from a wide range of CAM and conventional medical disciplines to promote new ways of approaching and solving complex and difficult medical problems. Such teams could include geneticists, biostatisticians, medical anthropologists, clinical investigators, and epidemiologists, as well as others, to develop unique teams and approaches. Another NIH Roadmap initiative, "Exploratory Centers (P20) for Interdisciplinary Research," is consistent with NCCAM's goal of supporting a research agenda that incorporates innovative collaborations between CAM and conventional researchers, and could lead to the development and organization of teams of neuroscientists, pulmonologists, and immunologists to collaborate on understanding the physiological mechanisms linking central nervous system activity to the periphery and environment.

A third NIH Roadmap initiative, "NIH Roadmap Administrative Supplements to Support Interdisciplinary Research in the Behavioral/Social and Biological Sciences," was designed to stimulate interdisciplinary research among social and behavioral scientists and biological scientists. This initiative provides additional funding support for existing grants that forge new collaborations between these areas of medical science. For example, obesity is a complex medical issue that is difficult to treat using conventional

⁸Jiang Q, Wong J, Fyrst H, Saba JD, Ames BN. γ -Tocopherol or combinations of vitamin E forms induce cell death in human prostate cancer cells by interrupting sphingolipid synthesis. Proc Natl Acad Sci U S A. 2004 Dec 21;101(51):17825-30.

interventions. The development of new interdisciplinary teams of scientists that focus on the underlying brain states and mechanisms associated with the use of CAM therapies for weight loss could both improve understanding of this complex problem and optimize CAM approaches to obesity to provide maximum benefit. The study of CAM therapies for patients with HIV/AIDS is another complex health issue that could benefit from an interdisciplinary approach. Teams of social and behavioral scientists, using innovative CAM therapies to assist HIV patients in coping with disease and enhance immune function, could work with biological scientists to study the impact of these therapies on physiological response systems to the infection. Such approaches allow an understanding of mechanisms by which such therapies might offer relief.

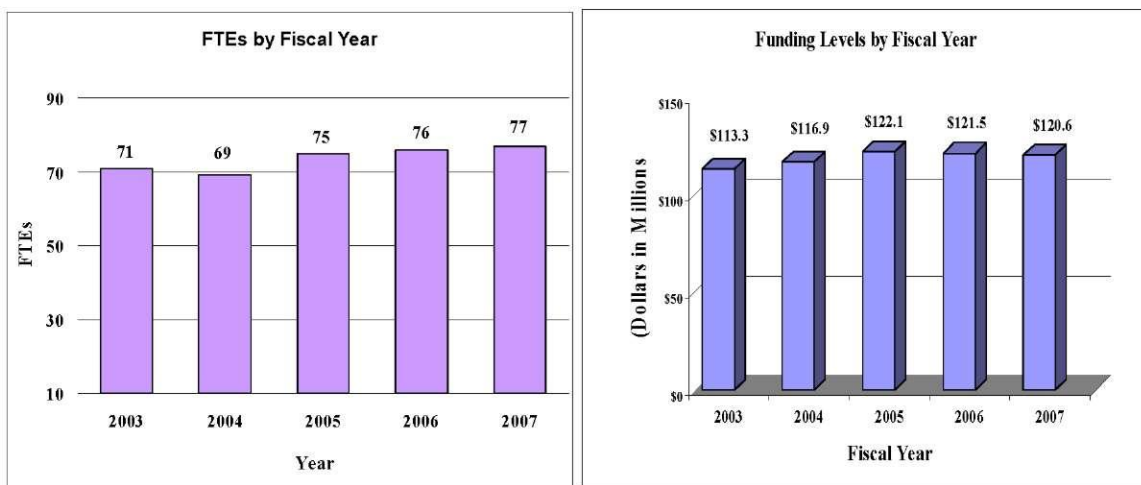
Conclusion

The lessons learned in conducting CAM research and the science advances achieved guide the Center in planning for future research. This experience has been critical to the Center’s gaining the respect of both the CAM and conventional scientific communities — enabling NCCAM to fund over 1,200 research, training, and career projects at over 260 U.S. institutions — while fulfilling the Center’s vision: “NCCAM will advance research to yield insights and tools derived from complementary and alternative medicine to benefit the health and well-being of the public.”

Budget Policy

The Fiscal Year 2007 budget request for the NCCAM is \$120,554,000, a decrease of \$911,000 and 0.8 percent below the FY 2006 Appropriation. Included in the FY 2007 request is NCCAM’s support for the trans-NIH Roadmap initiatives, estimated at 1.2% of the FY 2007 budget request. A full description of this trans-NIH program may be found in the NIH Overview.

A five year history of FTEs and Funding Levels for NCCAM are shown in the graphs below. Note that as the result of several administrative restructurings in recent years, FTE data is non-comparable.



NIH's highest priority is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while pursuing new research opportunities. We estimate that the average cost of competing RPGs will be \$269,000 in FY 2007. While no inflationary increases are provided for direct recurring costs in noncompeting RPGs, where the NCCAM has committed to a programmatic increase for an award, such increases will be provided.

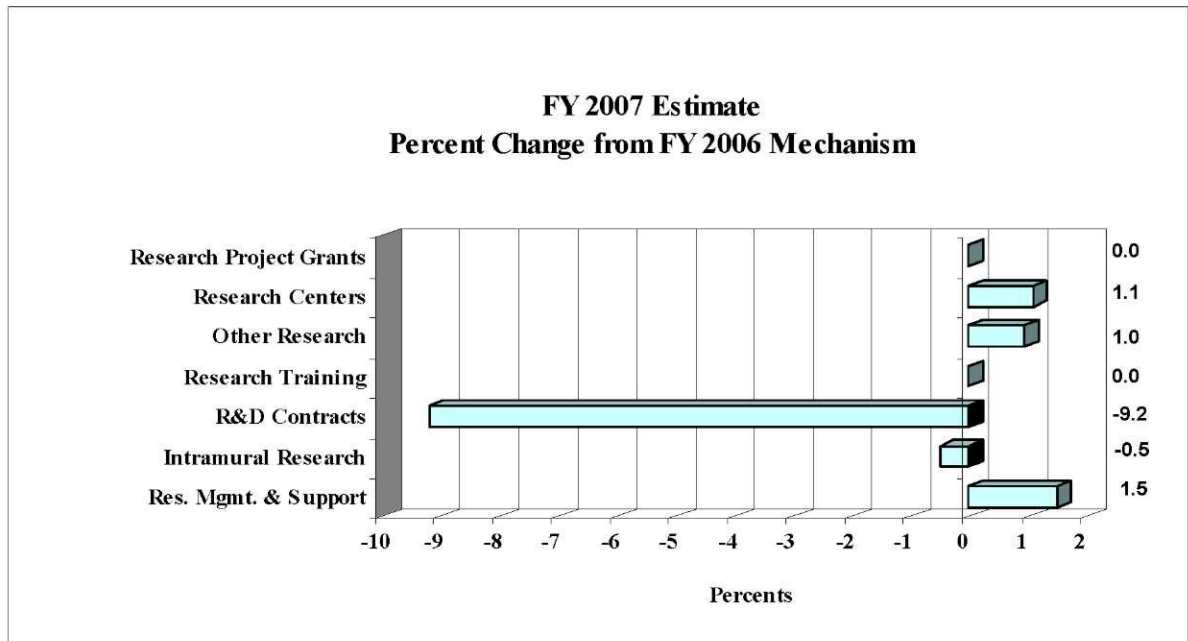
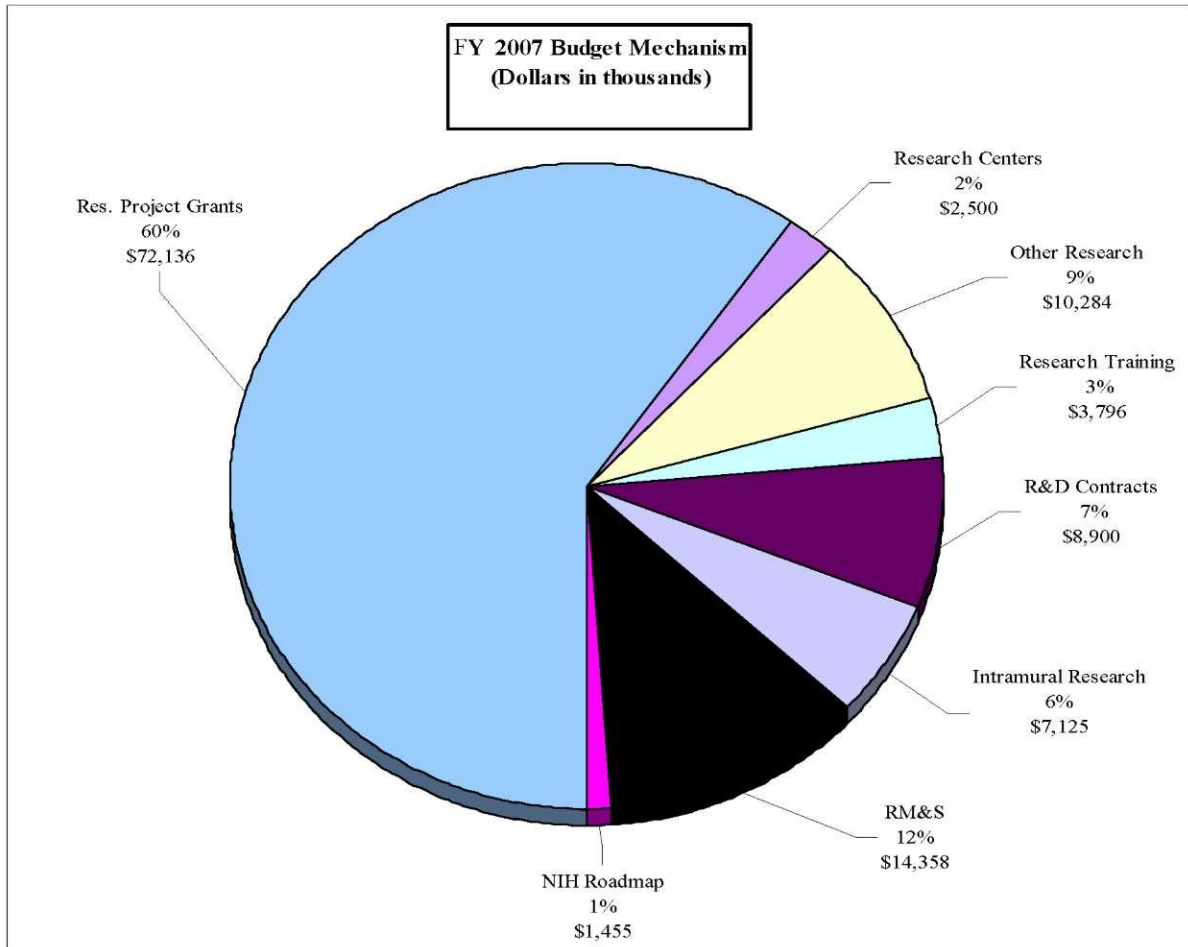
NIH must nurture a vibrant, creative research workforce, including sufficient numbers of new investigators with new ideas and new skills. In the FY 2007 budget request for NCCAM, \$90 thousand will be used to support 1 award for the new K/R "Bridges to Independence" program.

NCCAM will also support the Genes, Environment, and Health Initiative (GEHI) to: 1) accelerate discovery of the major genetic factors associated with diseases that have a substantial public health impact; and 2) accelerate the development of innovative technologies and tools to measure dietary intake, physical activity, and environmental exposures, and to determine an individual's biological response to those influences. The FY 2007 request includes \$205 thousand to support this project.

In the FY 2007 request, stipend levels for trainees supported through the Ruth L. Kirschstein National Research Service Awards will remain at the FY 2006 levels.

The FY 2007 request includes funding for 7 research centers, 67 other research grants, including 45 career awards, and 6 R&D contracts. Intramural Research decreases by 0.5 percent. Research Management and Support increases by 1.5 percent.

The mechanism distribution by dollars and percent change are displayed below:



**NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine**

Budget Mechanism - Total

MECHANISM	FY 2005 Actual		FY 2006 Appropriation		FY 2007 Estimate		2006/2007 % Change	Avg. Cost % Change
	No.	Amount	No.	Amount	No.	Amount		
Research Grants:								
<u>Research Projects:</u>								
Noncompeting	125	\$41,472,000	165	\$56,983,000	131	\$48,088,000	-15.6	
Administrative supplements	(12)	831,000	(10)	742,000	(10)	700,000	-5.7	
Competing:								
Renewal	4	3,937,000	5	4,900,000	5	4,900,000	0.0	
New	95	22,701,000	41	7,468,000	71	15,769,000	111.2	
Supplements	1	55,000	1	55,000	1	55,000	0.0	
Subtotal, competing	100	26,693,000	47	12,423,000	77	20,724,000	66.8	1.8
Subtotal, RPGs	225	68,996,000	212	70,148,000	208	69,512,000	-0.9	
SBIR/STTR	11	2,765,000	8	2,668,000	8	2,624,000	-1.6	
Subtotal, RPGs	236	71,761,000	220	72,816,000	216	72,136,000	-0.9	
<u>Research Centers:</u>								
Specialized/comprehensive	6	2,137,000	7	2,473,000	7	2,500,000	1.1	
Clinical research	0	0	0	0	0	0	0.0	
Biotechnology	0	0	0	0	0	0	0.0	
Comparative medicine	0	0	0	0	0	0	0.0	
Research Centers in Minority Institutions	0	0	0	0	0	0	0.0	
Subtotal, Centers	6	2,137,000	7	2,473,000	7	2,500,000	1.1	
<u>Other Research:</u>								
Research careers	46	6,297,000	44	5,835,000	45	5,954,000	2.0	
Cancer education	0	0	0	0	0	0	0.0	
Cooperative clinical research	0	1,000,000	0	0	0	0	0.0	
Biomedical research support	0	0	0	0	0	0	0.0	
Minority biomedical research support	0	0	0	0	0	0	0.0	
Other	27	4,794,000	22	4,352,000	22	4,330,000	-0.5	
Subtotal, Other Research	73	12,091,000	66	10,187,000	67	10,284,000	1.0	
Total Research Grants	315	85,989,000	293	85,476,000	290	84,920,000		
<u>Research Training:</u>								
Individual awards	17	658,000	17	663,000	17	663,000	0.0	
Institutional awards	57	3,168,000	57	3,133,000	57	3,133,000	0.0	
Total, Training	74	3,826,000	74	3,796,000	74	3,796,000	0.0	
Research & development contracts (SBIR/STTR)	13 (0)	10,238,000 (7)	6 (0)	9,800,000 (7)	6 (0)	8,900,000 (7)	-9.2	
Intramural research	18	7,198,000	18	7,161,000	18	7,125,000	-0.5	
Research management and support	57	14,082,000	58	14,146,000	59	14,358,000	1.5	
Cancer prevention & control	0	0	0	0	0	0	0.0	
Construction		0		0		0	0.0	
Buildings and Facilities		0		0		0	0.0	
NIH Roadmap for Medical Research	0	772,000	0	1,086,000	0	1,455,000	34.0	
Total, NCCAM	75	122,105,000	76	121,465,000	77	120,554,000	-0.8	
(Clinical Trials)		(31,545,000)		(31,340,000)		(31,340,000)		

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Budget Authority by Activity
(dollars in thousands)

ACTIVITY	FY 2005		FY 2006		FY 2007		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<u>Extramural Research:</u>		\$100,053		\$99,072		\$97,616		(\$1,456)
Subtotal, Extramural research		100,053		99,072		97,616		(1,456)
Intramural research	18	7,198	18	7,161	18	7,125	0	(36)
Res. management & support	57	14,082	58	14,146	59	14,358	1	212
Cancer Control & Prevention	0	0	0	0	0	0	0	0
NIII Roadmap for Medical Research	0	772	0	1,086	0	1,455	0	369
Total	75	122,105	76	121,465	77	120,554	1	(911)

Includes FTEs which are reimbursed from the NIII Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Summary of Changes

FY 2006 Estimate		\$121,465,000	
FY 2007 Estimated Budget Authority		120,554,000	
Net change		(911,000)	
CHANGES	FY 2006 Appropriation		Change from Base
	FTEs	Budget Authority	FTEs Budget Authority
A. Built-in:			
1. Intramural research:			
a. Within grade increase		\$2,101,000	\$26,000
b. Annualization of January 2006 pay increase		2,101,000	16,000
c. January 2007 pay increase		2,101,000	35,000
d. Payment for centrally furnished services		1,042,000	16,000
e. Increased cost of laboratory supplies, materials, and other expenses		4,018,000	38,000
Subtotal			131,000
2. Research Management and Support:			
a. Within grade increase		7,292,000	118,000
b. Annualization of January 2006 pay increase		7,292,000	57,000
c. January 2007 pay increase		7,292,000	123,000
d. Payment for centrally furnished services		1,756,000	26,000
e. Increased cost of laboratory supplies, materials, and other expenses		5,098,000	65,000
Subtotal			389,000
Subtotal, Built-in			520,000

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Summary of Changes--continued

CHANGES	FY 2006			
	Appropriation		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	165	\$57,725,000	(34)	(\$8,937,000)
b. Competing	47	12,423,000	30	8,301,000
c. SBIR/STTR	8	2,668,000	0	(44,000)
Total	220	72,816,000	(4)	(680,000)
2. Research centers	7	2,473,000	0	27,000
3. Other research	66	10,187,000	1	97,000
4. Research training	74	3,796,000	0	0
5. Research and development contracts	6	9,800,000	6	(900,000)
Subtotal, extramural				(1,456,000)
6. Intramural research	<u>FTEs</u> 18	7,161,000	<u>FTEs</u> 0	(167,000)
7. Research management and support	58	14,146,000	1	(177,000)
8. Cancer control and prevention	0	0	0	0
9. Construction	0	0	0	0
10. Buildings and Facilities	0	0	0	0
11. NIH Roadmap for Medical Research	0	1,086,000	0	369,000
Subtotal, program		121,465,000		(1,431,000)
Total changes	76		1	(911,000)

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Budget Authority by Object

	FY 2006 Appropriation	FY 2007 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	76	77	1
Full-time equivalent of overtime & holiday hours	0	0	0
Average FS salary	\$0	\$0	\$0
Average GM/GS grade	11.9	11.9	0.0
Average GM/GS salary	\$84,878	\$87,509	\$2,631
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$131,727	\$135,811	\$4,084
Average salary of ungraded positions	88,106	90,837	2,731
	FY 2006 Appropriation	FY 2007 Estimate	Increase or Decrease
OBJECT CLASSES			
Personnel Compensation:			
11.1 Full-Time Permanent	\$4,727,000	\$4,916,000	\$189,000
11.3 Other than Full-Time Permanent	2,134,000	2,219,000	85,000
11.5 Other Personnel Compensation	144,000	150,000	6,000
11.7 Military Personnel	173,000	180,000	7,000
11.8 Special Personnel Services Payments	226,000	235,000	9,000
Total, Personnel Compensation	7,404,000	7,700,000	296,000
12.0 Personnel Benefits	1,822,000	1,895,000	73,000
12.2 Military Personnel Benefits	167,000	173,000	6,000
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	9,393,000	9,768,000	375,000
21.0 Travel & Transportation of Persons	215,000	215,000	0
22.0 Transportation of Things	20,000	20,000	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	2,000	2,000	0
23.3 Communications, Utilities & Miscellaneous Charges	130,000	130,000	0
24.0 Printing & Reproduction	140,000	140,000	0
25.1 Consulting Services	5,000	5,000	0
25.2 Other Services	1,300,000	1,300,000	0
25.3 Purchase of Goods & Services from Government Accounts	12,965,000	12,788,000	(177,000)
25.4 Operation & Maintenance of Facilities	835,000	835,000	0
25.5 Research & Development Contracts	6,132,000	4,310,000	(1,822,000)
25.6 Medical Care	45,000	45,000	0
25.7 Operation & Maintenance of Equipment	75,000	75,000	0
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	21,357,000	19,358,000	(1,999,000)
26.0 Supplies & Materials	585,000	585,000	0
31.0 Equipment	165,000	165,000	0
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	88,372,000	88,716,000	344,000
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	110,986,000	109,331,000	(1,655,000)
NIH Roadmap for Medical Research	1,086,000	1,455,000	369,000
Total Budget Authority by Object	121,465,000	120,554,000	(911,000)

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Salaries and Expenses

OBJECT CLASSES	FY 2006 Appropriation	FY 2007 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-Time Permanent (11.1)	\$4,727,000	\$4,916,000	\$189,000	4.0
Other Than Full-Time Permanent (11.3)	2,134,000	2,219,000	85,000	
Other Personnel Compensation (11.5)	144,000	150,000	6,000	4.2
Military Personnel (11.7)	173,000	180,000	7,000	4.0
Special Personnel Services Payments (11.8)	226,000	235,000	9,000	4.0
Total Personnel Compensation (11.9)	7,404,000	7,700,000	296,000	4.0
Civilian Personnel Benefits (12.1)	1,822,000	1,895,000	73,000	4.0
Military Personnel Benefits (12.2)	167,000	173,000		
Benefits to Former Personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	9,393,000	9,768,000	375,000	4.0
Travel (21.0)	215,000	215,000	0	0.0
Transportation of Things (22.0)	20,000	20,000	0	0.0
Rental Payments to Others (23.2)	2,000	2,000	0	0.0
Communications, Utilities and Miscellaneous Charges (23.3)	130,000	130,000	0	0.0
Printing and Reproduction (24.0)	140,000	140,000	0	0.0
Other Contractual Services:				
Advisory and Assistance Services (25.1)	5,000	5,000	0	0.0
Other Services (25.2)	1,300,000	1,300,000	0	0.0
Purchases from Govt. Accounts (25.3)	7,347,000	7,148,000	(199,000)	-2.7
Operation & Maintenance of Facilities (25.4)	835,000	835,000	0	0.0
Operation & Maintenance of Equipment (25.7)	75,000	75,000	0	0.0
Subsistence & Support of Persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	9,562,000	9,363,000	(199,000)	-2.1
Supplies and Materials (26.0)	585,000	585,000	0	0.0
Subtotal, Non-Pay Costs	10,654,000	10,455,000	(199,000)	-1.9
Total, Administrative Costs	20,047,000	20,223,000	176,000	0.9

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

SIGNIFICANT ITEMS IN HOUSE, SENATE, AND CONFERENCE APPROPRIATIONS COMMITTEE REPORTS

FY 2006 House Appropriations Committee Report Language (109-143)

Item

Ameliorating Liver Disease - The Committee is pleased with NCCAM's efforts to conduct clinical trials in collaboration with NIDDK regarding the use of milk thistle as a possible treatment in slowing the progression of nonalcoholic steatohepatitis and to reduce the side effects of hepatitis C interferon treatments. The Committee looks forward to the development and dissemination of the research results associated with the use of milk thistle as a treatment to ameliorate liver disease (p. 97).

Action taken or to be taken

Recognizing the public health importance of chronic liver diseases, the National Center for Complementary and Alternative Medicine (NCCAM) supports a strong research portfolio in this area, including studies of milk thistle (*Silymarin marianum*), a botanical used widely by complementary and alternative medicine (CAM) practitioners.¹ Although milk thistle has long been used by traditional medicine practitioners, there is no consensus on the optimal preparation, dose, or target population for treatment. Thus, to optimize the chances that a large (Phase III) clinical trial of a *silymarin* preparation (defined as milk thistle above) would succeed, it is critical to first conduct Phase I and II studies to determine the pharmacokinetics, bioavailability, dosing effects, safety, and efficacy of these products.

To this end, in June 2005 NCCAM, in collaboration with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), issued a Request for Applications (RFA) for Phase I/II trials of milk thistle preparations in untreated chronic hepatitis C, previously treated chronic hepatitis C, and non-alcoholic steatohepatitis. The results of studies funded under this initiative will inform NCCAM's liver disease research agenda, including whether Phase III trials of milk thistle should be done and under what conditions. Preparatory to this major new initiative, NCCAM also funded in FY 2005 a number of investigator-initiated projects regarding the actions of milk thistle including a study of potential pharmacological interactions between *silymarin* and prescription drugs used by patients with chronic liver diseases.

¹ Agency for Healthcare Research and Quality, Department of Health and Human Services. "Milk Thistle: Effects on Liver Disease and Cirrhosis and Clinical Adverse Effects." *Evidence Report/Technology Assessment*. Number 21. Accessed at www.ahrq.gov/clinic/epcsums/milksum.htm. [2000]

Item

Parkinson's Disease - The Committee encourages NCCAM to continue exploration of aerobic exercise and Chinese exercises such as Tai Chi Chuan in the treatment of Parkinson's. Recent studies show exercise may increase neuroprotective chemicals in the brain and decrease falls in the elderly. The Committee also encourages continued research into magnetic stimulation for depression and the phytochemistry Valerian for sleep dysfunction, as both symptoms are significant non-motor co-morbidities in Parkinson's. Finally, NCCAM is encouraged to work the Office of Dietary Supplements in investigating supplements, which may be neuroprotective, such as berries, alpha lipoic acid, N-acetyl-L-cysteine, acetyl-L-carnitine, vitamin E, ginkgo biloba, vitamin D, vitamin B12, phosphatidylcholine, and glyconutrients (p. 97)

Action taken or to be taken

NCCAM continues its support for basic and clinical research to determine the safety and efficacy of various CAM approaches for the treatment of Parkinson's disease. As part of this effort, in FY 2005 NCCAM funded a study in animals that develop a Parkinsonian-like disease to determine whether dietary supplementation with blueberry constituents has the potential to increase survival of transplanted neural tissues. The knowledge gained from this study can provide new insights into whether and how nutritional therapy could improve patient outcomes. In addition, NCCAM supported a study to evaluate whether the Ayurvedic (the traditional Indian medical system) product, *Mucuna pruriens*, can lessen the disabling side effects of medications used to treat Parkinson's disease, including drug-induced dyskinesias (movement disorders).

In FY 2005, NCCAM continued its support for the Emory University Center for Complementary and Alternative Medicine in Neurodegenerative Diseases, which focuses on the potential of CAM therapies to treat Parkinson's disease. The Center's investigations have included examinations of valerian root extract for sleep disturbances in patients with Parkinson's disease; Tai Chi (which includes meditation as well as gentle movement exercises) to improve patients' function and quality of life; and repetitive transcranial magnetic stimulation to treat depression, a common complication of Parkinson's disease as it progresses. In addition, this NCCAM-funded center has conducted several promising pilot studies that address Parkinson's disease, including examinations of meditation to address attention deficits; studies of exercise in animals predisposed to Parkinson-like movement disorders; megadose nutrient and vitamin treatments; neuromuscular massage; and spirituality to improve patients' functioning and quality of life. Using the knowledge gained from these and other studies, NCCAM will pursue promising CAM research directions for Parkinson's.

NCCAM continues its fruitful partnerships on neurodegenerative disorders with the other NIH Institutes and Centers, including the NIH Blueprint for Neuroscience Research, to investigate how and whether CAM therapies may slow the progression of or treat neurodegenerative diseases such as Parkinson's disease. For example, in FY 2005 NCCAM, in collaboration with the NIH Office of Dietary Supplements, supported an

evidence-based review by the Agency for Healthcare Quality and Research (AHRQ) of the *in vitro*, *in vivo*, animal, and clinical data on the safety and efficacy of antioxidants in berries to prevent age-related neurodegenerative disorders, such as Parkinson's and Alzheimer's diseases. Results of this analysis are expected in early 2006, and should provide insights into whether B vitamins and the constituents of berries have the potential to slow disease progression or reverse neuronal death associated with neurodegenerative disorders. In addition, NCCAM will participate with other NIH ICs in sponsoring the World Congress on Parkinson's, to be held in Washington, D.C., in February 2006. Specific sessions have been planned to discuss the potential of CAM therapies in Parkinson's disease.

FY 2006 Senate Appropriations Committee Report Language (S. Rpt. 109-103)

Item

Antioxidants - The Committee is aware that the role of antioxidants in maintaining health in a variety of organ systems has been attracting attention in recent years. Recent evidence suggests that the delicate inner ear structures can be protected against the ravages of acoustic trauma produced by noise such as that encountered on the battlefield, and may have a role to play in preventing or slowing the progression of age-related hearing loss in the elderly by routine administration of commonly available antioxidant food supplements. Other applications may be found for these compounds in the treatment or prevention of auditory or vestibular disorders. The Committee encourages the institute to collaborate with NIDCD to fund research in this very promising area (p. 154).

Action taken or to be taken

Hearing loss is commonly associated with increasing age. While preliminary evidence suggests that oxidative stress may play a role in adult-onset hearing loss, additional explorations are warranted. Currently, widely used dietary supplements, including antioxidants such as vitamins, are beginning to be tested for their potential hearing protective qualities.

For example, in FY 2005 NCCAM supported a study in animal models to examine the long-term effects of resveratrol, an antioxidant compound found in the skin of red grapes, on age-related hearing loss. The information gained from this preliminary study and others could inform future research on hearing loss.

NCCAM will continue to encourage investigator-initiated applications on the role of antioxidants to slow the progression of hearing loss. Also, the Center will be pleased to collaborate with the National Institute on Deafness and Other Communications Disorders regarding possible directions for research.

Item

Ameliorating Liver Disease - The Committee is pleased with NCCAM's efforts to conduct clinical trials in collaboration with NIDDK regarding the use of milk thistle as a possible treatment in slowing the progression of nonalcoholic steatohepatitis and to reduce the side effects of hepatitis C interferon treatments. The Committee looks forward to the development and dissemination of the research results associated with the use of milk thistle as a treatment to ameliorate liver disease (p. 154).

Action taken or to be taken

Please refer to page NCCAM-24 of this document for NCCAM's response to this significant item regarding ameliorating liver disease.

Item

Bone Health - The Committee encourages NCCAM to conduct research on complementary and alternative medical approaches to bone health, bone pain and nutrition, including supplements and nutraceuticals, for osteoporosis and later life fractures (p. 154).

Action taken or to be taken

As an alternative to the hormone therapy, numerous CAM modalities, including dietary supplements, are used to address age-related bone loss. However, there is only limited evidence that these approaches are safe and effective as a long-term strategy to sustain or improve bone health. For example, in August 2005 the Agency for Healthcare Research and Quality released the results of an evidenced-based review on the effects of soy on health outcomes. NCCAM, in partnership with the NIH Office of Dietary Supplements (ODS), requested and funded this review.

As part of its analysis of the available evidence on soy, AHRQ reported that there are few long-term randomized clinical trials regarding bone health and that a wide variety of soy interventions have been examined in many small studies.² For these reasons, it is difficult at present to draw overall conclusions about the effects of soy consumption on bone health.³

In this regard, to enhance the understanding of the role of CAM approaches to bone health, NCCAM funded in FY 2005 a double-blind, placebo-controlled trial in healthy postmenopausal women that is examining the effect of isoflavone-rich soy protein supplementation on bone mineral density, bone metabolism, and bone turnover. Results

² Agency for Healthcare Research and Quality, Department of Health and Human Services. "Effects of Soy on Health Outcomes." *Evidence Report/Technology Assessment*. Number 126. Accessed at <http://www.ahrq.gov/clinic/epcsums/soysum.pdf>. [2005]

³ Ibid.

from this long-term study should provide more definitive data on the promise of this dietary supplement to improve bone health. In addition, in FY 2005 NCCAM-supported researchers at Columbia University's Center for CAM Research in Aging examined whether dietary sources of estrogenic compounds can prevent postmenopausal bone loss. NCCAM also supported studies of the short- and long-term effects of several low-carbohydrate and high-carbohydrate diets on bone health in healthy women.

In spring 2005, NCCAM partnered with the NIH ODS to issue a new round of awards under the Botanical Research Centers program, which facilitates collaborative research on the safety, efficacy, and mechanisms of actions of plants and their constituents. As part of this effort, NCCAM and ODS funded a botanical center for age-related disease that will investigate the potential of polyphenols, a group of chemical components in several plants, including soy and kudzu root, to prevent and treat bone loss.

Item

Behavioral Research on Stress - NCCAM is encouraged to continue collaborations with other NIH offices, Institutes and Centers to identify mechanisms through which various stressors produce adverse health effects, and the extent to which stress reduction interventions improve health (p. 154).

Action taken or to be taken

As articulated in NCCAM's strategic plan, *Expanding Horizons of Health Care: Strategic Plan 2005-2009*, basic and clinical research on mind-body medicine, including the role of stress and disease, is a high priority. In this regard, in FY 2005 NCCAM supported studies on stress and disease progression, such as yoga to manage high blood pressure. Other studies explored the potential of mind-body interventions to address health conditions that may be exacerbated by stress, including a form of meditation used in traditional Chinese medicine to prevent weight gain after successful weight loss. In addition, in FY 2005 NCCAM funded several clinical trials on chronic illness. One project at Harvard University's Osher Institute for Research and Education in Complementary and Integrative Medical Therapies is studying how the placebo response to attentive care may help patients better manage conditions including irritable bowel syndrome.

NCCAM is also funding a number of collaborations among research centers to examine the roles of behavior, stress, and disease. For example, in FY 2005 investigators at the NCCAM-supported research center at the University of California, San Francisco, are assessing whether mindfulness-based stress reduction, a type of meditation, can slow disease progression in HIV-positive patients, and delay the need to initiate treatment with highly active anti-retroviral drugs, which have numerous side effects, despite their clear life-extending benefits. In addition, in a collaboration among conventional and CAM institutions, investigators at an NCCAM-funded Developmental Center for Research on CAM are examining how patient expectations and other factors related to patient-provider interactions can improve health outcomes. Also, as part of a trans-NIH initiative

to foster research infrastructure to investigate mind-body interactions and health, NCCAM is funding a study of mind-body interactions in stress-related disorders, including such common chronic conditions as gastrointestinal disorders, anxiety, and depression, at the University of California, Los Angeles.

NCCAM also is supporting studies to capitalize on state-of-the-art diagnostic technologies, including functional Magnetic Resonance Imaging, to better define how stress-reducing CAM therapies, such as meditation, can produce changes in the brain. The knowledge gained from such studies will inform the Center's future directions. In July 2005, as part of this effort, NCCAM convened a meeting of leading scientific experts in the fields of neuroscience, cardiology, immunology, endocrinology, pulmonology, and physiology to discuss ways to advance research on mind-body interactions to determine how stress plays a role in illness.

Item

Integrative Medicine Model - The Committee supports the concept of integrative medicine, which reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing. The Committee encourages NCCAM and other relevant ICs to accelerate the infusion of this model throughout their research, research training and communication activities (p. 154).

Action taken or to be taken

As highlighted in NCCAM's strategic plan, facilitating the integration of proven CAM therapies into conventional medicine remains an important goal. Since its inception, NCCAM has supported a wide range of activities, including extra- and intramural research, research training, and outreach, including integrative medicine conferences and lectures, to advance integration. For example, investigators in NCCAM's intramural research program are working to identify and investigate the most promising CAM approaches to the treatment of stress-related disorders that affect aging Americans.

In July 2005, NCCAM launched an online continuing education series on CAM for health care professionals. These online seminars offer health care providers an opportunity to earn continuing medical education credits by learning more about CAM therapies and the scientific evidence about them. Under the new program, experts on topics such as herbs and dietary supplements, acupuncture, chiropractic and spinal manipulation present video lectures (nccam.nih.gov/videlectures).

NCCAM continues to fund curriculum development grant awards to expand innovative educational approaches incorporating CAM information into medical, dental, nursing, and allied health professions schools curricula and residency training programs. For example, in FY 2005 NCCAM-supported researchers developed an educational program on CAM for medical students at Georgetown University's School of Medicine. In FY

2005, NCCAM also provided support to the American Medical Student Association Foundation to provide comprehensive CAM curricula and programs to allopathic and osteopathic medical institutions to enhance medical students' knowledge of CAM. Also, in FY 2005, under the initiative, *Integration of Complementary and Alternative Medicine: A Health Services Research Perspective*, NCCAM supported a study at the California Pacific Medical Center, Pacific Campus, to examine potential barriers to incorporating mind-body practices into conventional clinical practice. In addition, NCCAM-funded researchers worked to develop a model of integrative care within an academic health center to treat back pain.

In addition, NCCAM is recruiting for a director of the Integrative Medicine Consult Service, to be established in FY 2006, at the NIH Clinical Center in Bethesda, MD, will provide delivery of high-quality integrative medicine consultation and clinical care to in- and outpatients at the NIH Clinical Center. The service will include a cadre of practitioners in integrative medicine, including licensed acupuncturists and clinical fellows. In addition, the service plans to establish a teaching program in integrative medicine at the Clinical Center.

Item

Parkinson's Disease - The Committee encourages NCCAM to continue exploration of aerobic exercise and Chinese exercises such as Tai Chi Chuan in the treatment of Parkinson's. Recent studies show exercise may increase neuroprotective chemicals in the brain and decrease falls in the elderly. The Committee also encourages continued research into magnetic stimulation for depression and the phytochemistry Valerian for sleep dysfunction, as both symptoms are significant non-motor co-morbidities in Parkinson's. Finally, NCCAM is encouraged to work the Office of Dietary Supplements in investigating supplements, which may be neuroprotective, such as berries, alpha lipoic acid, N-acetyl-L-cysteine, acetyl-L-carnitine, vitamin E, ginkgo biloba, vitamin D, vitamin B12, phosphatidylcholine, and glyconutrients (p.155).

Action taken or to be taken

Please refer to page NCCAM-25 of this document for NCCAM's response to this significant item regarding Parkinson's disease.

Item

Practice-Based Research Network - One of the major advances achieved through the work of NCCAM has been the development of CAM or integrative medicine research centers at many of the Nation's top medical centers. In order to build upon this important new research infrastructure base, the Committee expects NCCAM to implement one of the major recommendations of the recent Institute of Medicine CAM report, the development and utilization of an Integrative Medicine Practice-Based Research Network [PBRN]. The Committee concurs with the IOM that the PBRN model is very well suited for the study of CAM therapies and would greatly enhance the ability to conduct high

quality cost-effective clinical trials of CAM therapies and treatment modalities. Such a network would also allow for the rapid dissemination of data, which would directly affect the provision of health care to consumers. Key to the establishment of such a network would be funding for a data tracking system linking the network practice members and a centralized data-coordinating center. The Committee considers the PBRN to be one of its top priorities for NCCAM this year (p. 155).

Action taken or to be taken

In January 2005, the Institute of Medicine (IOM) released a report on CAM use in the United States.⁴ NCCAM and 16 other Federal cosponsors requested this study to assist in the development of research methods and priority setting to evaluate the safety and effectiveness of CAM therapies. Among the report's many conclusions was that CAM treatments should be subjected to the same research principles and standards that are applied to conventional medicine. However, to explore CAM's potential fully, innovative methods to test certain CAM modalities would need to be devised.

As part of these new methods, the IOM report recommended the use of practiced-based research networks (PBRNs) -- affiliations of health care practitioners linked to academic or professional organizations to investigate questions regarding health care practices. NCCAM agrees that PBRNs have the potential to play a role in determining how CAM is practiced in health care settings and in answering important questions about the safety and efficacy of CAM modalities and has begun to use such networks in its research. For example, in FY 2005 NCCAM supported a study at the University of Colorado Health Sciences Center, in conjunction with the Population-Based Palliative Care Research Network, a PBRN with a network of hospice centers, to examine the effects of massage on physical and emotional symptoms at the end of life. Also in FY 2005, NCCAM funded a PBRN that is investigating ways to integrate allopathic and CAM care among primary care clinicians who serve patients from New Mexico's Hispanic and Native American communities.

This year, in further efforts to explore the potential of PBRNs to enhance CAM research, NCCAM has begun to meet with representatives from AHRQ to learn more about how CAM research networks might collaborate with AHRQ's existing Primary Care Practice-Based Research Networks. In addition, in FY 2006 NCCAM will participate in a meeting of several NIH Institutes and Centers and other Federal agencies to learn more about diverse models of PBRNs and how they may facilitate CAM research. NCCAM also will continue to support research collaborations among numerous CAM and conventional practitioners, such as the Trial to Assess Chelation Therapy for coronary artery disease (TACT), the largest clinical trial to date to investigate the potential of chelation therapy to prevent and treat coronary artery disease.

⁴ National Academy of Sciences, Institute of Medicine, "Complementary and Alternative Medicine in the United States." Committee on the Use of Complementary and Alternative Medicine by the American Public, 2005. Accessed at: <http://www.nap.edu/books/0309092701/html/R1.html>.

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2006 Amount Authorized	FY 2006 Appropriation	2007 Amount Authorized	FY 2007 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	\$117,669,000	Indefinite	\$116,758,000
Complementary and Alternative Medicine	Section 41B	42§285b	Indefinite		Indefinite	
National Research Service Awards	Section 487(d)	42§288	<u>a/</u>	3,796,000		3,796,000
Total, Budget Authority				121,465,000		120,554,000

a/ Amounts authorized by Section 301 and Title IV of the Public Health Act.

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation ^{1/}
2000	50,168,000 ^{2/}	68,000,000	56,214,000	68,753,000
Rescission				(363,000)
2001	71,362,000 ^{2/}	78,880,000	100,089,000	89,211,000
Rescission				(54,000)
2002	100,063,000	99,288,000	110,000,000	104,644,000
Rescission				(52,000)
2003	112,547,000	112,547,000	114,149,000	114,149,000
Rescission				(742,000)
2004	116,202,000	116,202,000	117,902,000	117,752,000
Rescission				(774,000)
2005	121,116,000	121,116,000	121,900,000	123,116,000
Rescission				(1,011,000)
2006	122,692,000	122,692,000	126,978,000	122,692,000
Rescission				(1,227,000)
2007	120,554,000			

^{1/} Reflects enacted supplementals, rescissions, and reappropriations.

^{2/} Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research

NATIONAL INSTITUTES OF HEALTH
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Detail of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate
Office of the Director	7	7	7
Office of Administrative Operations	15	15	15
Office of Communication and Public Liaison	8	8	8
Office of Science Policy and Operations	7	7	7
Division of Extramural Research and Training	10	11	12
Office of Scientific Review	4	4	4
Office of International Health Research and Office of Special Populations	3	3	3
Office of Clinical and Regulatory Affairs	3	3	3
Division of Intramural Research	18	18	18
Total	75	76	77
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research FTEs supported by funds from Cooperative Research and Development Agreements			
	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2003	11.2		
2004	11.6		
2005	11.8		
2006	11.9		
2007	11.9		

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Detail of Positions

GRADE	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate
Total - ES Positions	\$0	\$0	\$0
Total - ES Salary	\$0	\$0	\$0
GM/GS-15	9	9	9
GM/GS-14	13	13	13
GM/GS-13	11	12	13
GS-12	13	13	13
GS-11	4	4	4
GS-10	0	0	0
GS-9	4	4	4
GS-8	3	3	3
GS-7	2	2	2
GS-6	0	0	0
GS-5	0	0	0
GS-4	2	2	2
GS-3	0	0	0
GS-2	1	1	1
GS-1	0	0	0
Subtotal	62	63	64
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General			
Director Grade	2	2	2
Senior Grade	0	0	0
Full Grade			
Senior Assistant Grade			
Assistant Grade			
Subtotal	2	2	2
Ungraded	25	25	25
Total permanent positions	64	65	66
Total positions, end of year	89	90	91
Total full-time equivalent (FTE) employment, end of year	75	76	77
Average ES level	ES-4	ES-4	ES-4
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	11.8	11.9	11.9
Average GM/GS salary	\$82,055	\$84,878	\$87,509

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

**NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine**

New Positions Requested

	FY 2007		
	Grade	Number	Annual Salary
Program Officer	GS-13	1	\$85,431
Total Requested		1	