

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

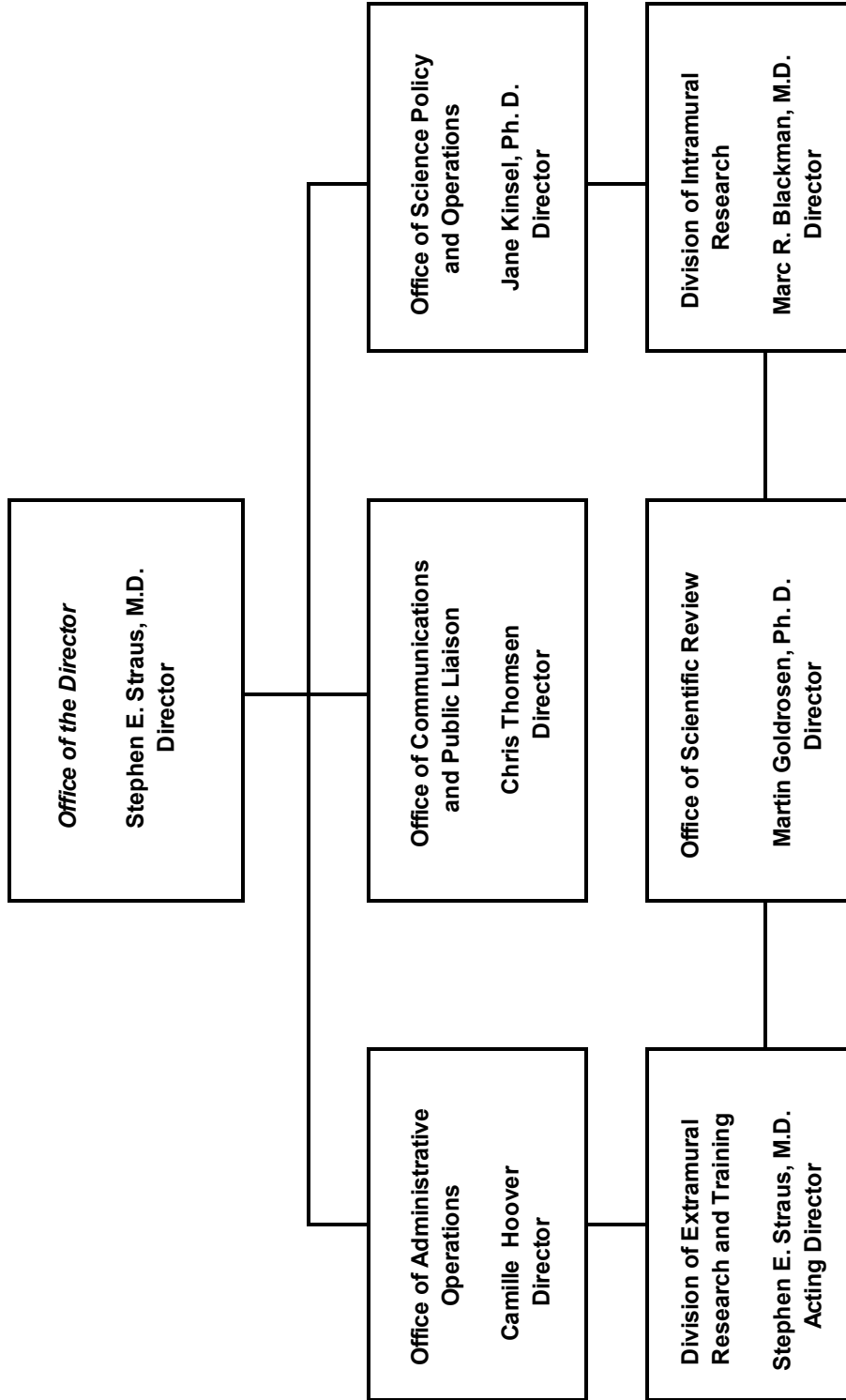
National Center for Complementary and Alternative Medicine

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NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

Organization Structure



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, \$116,202,000.

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

Amounts Available for Obligation 1/

Source of Funding	FY 2003 Amended		
	FY 2002 Actual	President's Budget	FY 2004 Estimate
Appropriation	\$104,644,000	\$112,547,000	\$116,202,000
Enacted Rescissions	(193,000)	(0)	—
Subtotal, Adjusted Appropriation	104,451,000	112,547,000	116,202,000
Real transfer to:			
Other HHS Agencies through Secretary's one-percent transfer authority	(113,000)	(0)	(0)
Comparative transfer from:			
Fogarty International Center for International Services Branch	0	0	0
Comparative transfer to:			
Office of the Director for program changes	(97,000)	(105,000)	(0)
National Institute of Biomedical Imaging and Bioengineering	(0)	(0)	(0)
Subtotal, adjusted budget authority	104,241,000	112,442,000	116,202,000
Unobligated Balance, start of year	0	0	0
Unobligated Balance, end of year	0	0	0
Subtotal, adjusted budget authority	104,241,000	112,442,000	116,202,000
Unobligated balance lapsing	(4,000)	—	—
Total obligations	104,237,000	112,442,000	116,202,000

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

FY 2002 - \$410,000 FY 2003 - \$600,000 FY 2004 - \$700,000

Excludes \$0 in FY 2002 and \$0 in FY 2003 for royalties.

Justification
National Center for Complementary and Alternative Medicine

Authorizing Legislation: Section 301 of the Public Health Service Act, as amended.
 Reauthorizing legislation will be submitted.

Budget Authority:

FY 2002 Actual		FY 2003 Amended President's Budget		FY 2004 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>
65	\$104,241,000	75	\$112,442,000	74	\$116,202,000	(1)	\$3,760,000

This document provides justification for the Fiscal Year 2004 activities of the National Center for Complementary and Alternative Medicine (NCCAM), including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2004 HIV/AIDS activities can be found in the NIH section entitled “Office of AIDS Research (OAR).”

Introduction

The mission of the National Center for Complementary and Alternative Medicine (NCCAM) is to support rigorous research on complementary and alternative medicine (CAM), to train researchers in CAM, and to disseminate information to the public and professionals on the safety and efficacy of CAM therapies. To fulfill our mission, we support a broad-based portfolio of research, research training, and outreach activities to disseminate information and to facilitate integration of proven CAM therapies into conventional medical practice.

We seek to advance our mission through FY 2004 by continuing support for investigator-initiated studies, and targeting research in areas that are now most pivotal to advancing the scientific analysis of CAM. The accompanying information highlights, in the following four sections, our accomplishments, recent scientific findings, and future plans:

- What's in the Bottle*** – The Standardization and Characterization of Dietary Supplements
- How CAM Therapies Work*** – Determining the Mechanisms of Action of CAM Interventions
- Preparing for the Future*** – Building Critical Research Infrastructure and Intellectual Capital
- Bringing It All Together*** – Evaluating CAM Therapies in Rigorous Clinical Trials

What's in the Bottle?

The Standardization and Characterization of Dietary Supplements

Many consumers use dietary supplements with the expectation that they are effective in the self-treatment and prevention of disease and the promotion of wellness. As we scientifically examine the substance of these expectations, we ask if dietary supplements are truly capable of benefitting our health as claimed, and thus, whether they are appropriate alternatives to conventional drugs. Many supplements look like drugs, are packaged similarly to drugs, are sold in pharmacies next to over-the-counter drug products, and may be marketed with claims of health benefits. However, under the law they are classified as foods, and therefore not held to the same rigorous standards as drugs. For example, after examining 25 commercial ginseng products, one NCCAM grantee recently reported that, although each product was appropriately labeled for the type of ginseng, the concentrations of ginseng differed by as much as ten-fold from that stated on the label. In spite of what is on the label, what is in the bottle of a dietary supplement is not always predictable. Since the lack of standardized dietary supplements continues to impede our research efforts, we are investing in new ways to overcome this obstacle.

Product Contamination Halts Clinical Studies. PC SPES is a patented mixture of eight Chinese herbs, used primarily by men with prostate cancer. In recent years, NCCAM funded four PC SPES research studies, including one clinical trial, to learn about its safety, efficacy, and mechanisms of action. On February 8, 2002, the California Department of Health Services and the Food and Drug Administration reported that PC SPES was contaminated with undeclared prescription drug ingredients. The manufacturer recalled the product and subsequently ceased operations. NCCAM placed all four studies on hold. Based on meetings we convened with the scientists performing PC SPES studies, prostate cancer specialists, experts in herbal medicine, members of our Advisory Council, and representatives of government agencies and industry, we permitted the three laboratory studies of PC SPES to resume. The clinical trial, however, was terminated because it was deemed unethical to treat patients with a contaminated product. The laboratory studies seek to determine the cellular and molecular mechanisms of action of the herbs as opposed to those of the drug ingredients that contaminated the product. Because of the promising data from the early studies of PC SPES and the public health importance of addressing advanced and hormone-refractory prostate cancer, we are interested in resuming clinical studies and funding new laboratory studies of unadulterated PC SPES. However, we can only do so when a fully characterized and standardized, contaminant-free product, using the original product formulation, becomes available. We announced publicly our intent to work with potential new manufacturers of research-grade PC SPES so that studies of its safety and efficacy can proceed.

Small Business Development of Standardized Products. To obtain well-characterized and standardized clinical-trial-grade materials, NCCAM has made awards under the Small Business Innovative Research (SBIR) program. Among the botanicals being prepared for us are feverfew (*Tanacetum parthenium*) used for migraine, echinacea (*Echinacea purpurea*) for upper respiratory infections, and milk thistle (*Silybum marianum*) for liver disease. These products were specifically identified as high priorities for use in future basic and clinical research studies.

Characterizing Alternatives to Conventional Hormone Therapy. On July 9, 2002, the National Heart, Lung, and Blood Institute (NHLBI) announced that one arm of their study of postmenopausal hormone therapy (HT) would end. A part of the Women's Health Initiative (WHI), the study found increased risks for breast cancer, cardiovascular disease, stroke, and blood clots among study participants who were taking estrogen plus progestin compared to women taking placebo. While there were noteworthy benefits of estrogen plus progestin in reducing hip fractures and colon cancer, on balance the harm was deemed to be greater than the benefit. In the aftermath of the WHI data, many women are considering alternatives to conventional HT to relieve menopausal symptoms and to lower their risks of conditions such as osteoporosis and heart disease. According to results of SWAN (Study of Women Across the Nation, a 10-year prospective cohort study of women's health cofunded by NCCAM) almost half of all perimenopausal women use some form of CAM. At this time, there is not enough scientific evidence to determine whether these therapies are beneficial. In addition, we do not have sufficient information to show whether these therapies are as safe as, or safer than, conventional drugs being used for menopausal symptoms, osteoporosis, or heart disease. Botanical products containing or acting like estrogens may provide both the benefits and risks of estrogen in relieving menopausal symptoms. Recently, a team of NCCAM investigators demonstrated that out of the eight botanical preparations most commonly purchased by women for the treatment of menopausal symptoms, three – hops (*Humulus lupulus*), red clover (*Trifolium pratense*), and chasteberry (*Vitex agnus-castus*) – showed significant estrogenic activity. This team of investigators is continuing its characterization of these plants and plans to develop standardized research products for one or more.

Future Plans. Since standards applied to drugs regarding manufacturing, product characterization, safety, efficacy, and health claims do not apply to dietary supplements, the identification of appropriate materials for clinical and basic CAM research is complex, frustrating the rigorous evaluation of their medical use. Moreover, recurring reports of undesirable effects of some dietary supplements, contamination of products with prescription drugs, and interactions between dietary supplements and conventional drugs raise genuine public health concerns. In light of these limitations, NCCAM plans to establish a *Dietary Supplement Standardization and Characterization Center* (DSSCC) in FY 2004. The DSSCC will serve as a resource for the analysis of dietary supplements, especially botanical products. These analyses are important to basic and preclinical research and necessary before conclusive clinical trials of the products can be initiated. Standardization and characterization studies will include: assays for composition and contamination; studies on bioavailability, pharmacokinetics, pharmacodynamics, and stability; and *in vitro* and *in vivo* testing for interactions with drugs. A prioritized list of dietary supplements slated for analysis by the DSSCC will be determined and regularly updated by NCCAM, reflecting the current evidence base for dietary supplements and gaps and opportunities in the field. We plan to build sufficient capacity into the highly flexible center to promote and accommodate opportunities for collaboration and partnership with other NIH Institutes and Centers and Federal agencies, as well as to enable rapid responses to changes in public health priorities.

How CAM Therapies Work

Determining the Mechanisms of Action of CAM Interventions

Full acceptance and willingness to integrate new CAM practices into routine medical care require that these practices prove safe and effective, that they fill some public health need, and that their mechanisms of action can be explained. In concert with our portfolio of studies to define the safety and effectiveness of CAM therapies, we invest in studies of their mechanisms of action.

Closing in on a Scientific Explanation of Acupuncture's Effects. For more than two thousand years, acupuncture has been used for the treatment of pain and other conditions, even though conventional medical science has not been able to explain how it works. Chinese tradition explained acupuncture as working through “meridians,” a concept largely abandoned by conventional medicine in favor of an interpretation that it acts through the biochemical processes of the nervous system. Modern research has continued to reinforce this interpretation; however, until recently there has not been a rigorously controlled clinical trial successfully connecting the acupuncture needling event to a therapeutic effect. Now, a team of NCCAM grantees has shown that insertion of the needle, whether along traditional meridians or in non-acupuncture points, causes measurable changes to connective tissue and the mechanoreceptors deep within the skin. The investigators believe these changes are communicated along a complex signaling network ultimately reaching the nervous system. This research provides a tantalizing hypothesis for future investigations of the mechanical and neurochemical effects of acupuncture.

Alternatives to Conventional Hormone Therapy: Mechanisms of Action. Long-term use of estrogen in combination with progestin results in more risks than benefits. More than ever, women are seeking information on safe and effective alternatives to conventional hormone therapy. Several NCCAM studies are employing *in vitro* models to examine how some popular dietary supplements act on biochemical pathways responsive to estrogen. In addition, one investigator is examining the estrogenic activity and specific mechanisms of estrogen receptor regulation of a Chinese herbal extract. In another study, black cohosh (*Cimifuga racemosa*) and red clover (*Trifolium pratense*) are undergoing analysis to identify and isolate active compounds and define their structures. The range and mechanism(s) of action of two plant-based estrogens, genistein and diadzein, and extracts of soy (*Glycine max*) on immune function are being investigated. Such studies will clarify what biochemical effects supplements might have on women, and provide clues as to which, if any, would be worthy of clinical trials.

Biological Action of SAME. S-Adenosyl-L-Methionine, also known as SAME, is a widely sold dietary supplement that is known to play an important role in a number of metabolic functions. In FY 2002, in partnership with the Agency for Healthcare Research and Quality (AHRQ), we completed a detailed review of scientific studies that identified leading opportunities for SAME research. We have already begun to support research in some of those leading areas. One researcher is using cultured cells to better characterize the biochemistry of liver injury and what role SAME may play in preventing liver damage. Another investigator is using a mouse model of hepatitis and liver cancer to study the role of SAME in regulating liver cell growth and death.

The Treatment of Diabetes and Its Complications. NCCAM supports a variety of research on CAM therapies for diabetes and its resulting complications. An SBIR grantee is developing technology to improve the detection and quantification of chromium levels in diabetics. Another SBIR grantee is evaluating a standardized botanical extract, PMI-5011, which appears to lower blood glucose in insulin-deficient and insulin-resistant animals. We are supporting a study of mechanisms by which *Ginkgo biloba* may accelerate pancreatic function and reduce glucose metabolism, identifying the anti-hyperglycemic constituents of ginseng berry (*Panax ginseng*), and studying the synergistic effects between these constituents. NCCAM sponsors a study of the effectiveness and underlying mechanism of the angiogenic agent picroliv (*Picrorhiza kurrooa*) for better management of diabetic wounds. Finally, we established a Diabetes Unit within NCCAM's Division of Intramural Research. The research goals of the Diabetes Unit are to develop simple methods for assessing insulin sensitivity and insulin secretion *in vivo*, to evaluate the effects of nutritional supplements on insulin sensitivity, and to understand the molecular mechanisms of insulin action.

Hyperbaric Oxygen Therapy: How Might It Work? Hyperbaric oxygen therapy (HBOT) – breathing oxygen that has been pressurized 1.5 to 3 times above the pressure normally found in the earth's atmosphere at sea level – was originally designed for caisson workers and undersea divers suffering from decompression sickness. HBOT appears to be effective for some other medically important purposes; however, how it works in some applications is not well-understood. For example, it is used to minimize tissue damage in cancer patients undergoing radiation therapy, with the belief that it enhances blood flow and stimulates the growth of new blood vessels surrounding the radiation target site. Scientists knew little about how HBOT stimulated blood flow and new blood vessel growth until a group of NCCAM grantees reported that it stimulates the expression of the enzyme, nitric oxide synthase, causing increases in tissue levels of nitric oxide. This small molecule causes blood vessels to dilate, consequently enhancing blood flow. These studies should lead to a better understanding of the effects of HBOT and elucidate the circumstances under which it may provide therapeutic benefit for cancer and other conditions as well.

CAM Therapies for Neurological Disorders. Again in FY 2002, NCCAM invested in new CAM studies of conditions that have an impact on the brain and central nervous system. Employing functional magnetic resonance imaging, one investigator is examining the effects of acupuncture therapy on the cerebral cortex and brainstem, in order to localize the anatomic correlates of healing by this ancient practice. In another study, researchers are attempting to determine whether various forms of acupuncture can protect the brain from injury following stroke-induced reduction of blood flow. An animal model for joint pain is being studied to determine if manipulation, as in chiropractic and osteopathic practice, registers any effect on pharmacological receptors of analgesics. In an animal model of stroke, an investigator is attempting to understand the role of the antioxidants *Ginkgo biloba* and alpha lipoic acid on inflammation following blood flow-related injury. An extract of the plant known as Indian Pennywort or Gota Cola (*Centella asiatica*) is under study to determine if it can improve memory and inhibit an early stage in the development of Alzheimer's disease in a mouse model system.

CAM Cancer Studies Initiated. NCCAM is broadly committed to conducting studies of CAM therapies used in the treatment of cancer. In FY 2002 we again expanded our portfolio of cancer research. An extract of pine cone has been shown to provide immunostimulatory effects. One NCCAM-supported researcher is using a mouse model of melanoma to determine if the pine cone extract enhances conventional chemotherapy. In a study of prostate cancer, investigators are studying extracts of Reishi (*Ganoderma lucidum*), a mushroom that has been characterized as possessing antitumor properties, to determine if tumor invasiveness and metastasis can be inhibited. A study initiated in NCCAM's Division of Intramural Research examines the dietary supplements carnitine and DHEA (dehydroepiandrosterone) to determine if either poses a risk to hormone-responsive tissues such as the prostate.

New Studies Suggest Cellular Mechanisms by which Ginkgo Could Prevent Dementia.

Extracts of the leaves of the *Ginkgo biloba* tree are commonly consumed because of their purported benefits to brain function, particularly in connection with age-related dementias and Alzheimer's disease. Evidence to date has pointed to a protective effect on neural tissue; however, the mechanism(s) of action remain unknown. Recently, in a trio of NCCAM-supported studies, investigators found that a standardized Ginkgo extract protects cells from oxidative stress and programmed cell death. Using well-established model systems to study the factors that regulate cell death, the investigators showed that the extracts increase the life-span of the worm *Caenorhabditis elegans*, protects cultured neural cells from undergoing programmed death, and hinders an early step in the biochemical processes leading to neurodegeneration. Together these experiments indicate that Ginkgo may provide multiple levels of protection to neural tissues, adding to the evidence from several small clinical studies that Ginkgo may be beneficial in preventing the onset of dementia.

Frontier Medicine Awards. To encourage research in understudied CAM domains, in FY 2002 NCCAM called for and made three new awards, two for exploratory research centers, and one research project grant, under our Frontier Medicine Initiative. Frontier Medicine can be described as those CAM practices for which there are no plausible biomedical explanation, such as magnetic therapy, biofield/energy healing, homeopathy, and therapeutic prayer/spiritual healing. Such high-risk studies are being supported to address the validity of these poorly understood practices. One of these centers is examining the potential role of Therapeutic Touch in healing bone fractures by studying the effect that the therapy has on markers of bone formation and resorption over time in women who have suffered a recent wrist fracture. The practice of Therapeutic Touch is an intentionally directed process of energy exchange during which the practitioner uses the hands as a focus to facilitate the healing of patients with "unbalanced energy fields." The other center is exploring the hypothesis that biofield therapies involve a common set of bioelectromagnetic and psychosocial mechanisms that together affect cellular functioning, thereby reducing pain and increasing wound healing. Specific projects include analysis of the effects of energy fields on the growth and motility of bacterial cultures and the application of energy therapies to surgical recovery. A separate individual research project grant award was made to an investigator seeking to determine if Qi Gong treatment can stimulate growth or death of cultures of human brain cells and human brain tumor cells.

Preparing for the Future

Building Critical Research Infrastructure and Intellectual Capital

Through our research centers program we are building a critical CAM research infrastructure. Likewise, through research training and career development programs we are developing the next generation of CAM researchers, thus growing our intellectual capital base. These efforts act synergistically to provide a firm foundation for the future of a vigorous CAM research community.

Centers. In FY 2002, we convened an expert panel of investigators, practitioners, and scientific administrators to assess the NCCAM Research Centers Program, which has been growing since NCCAM was established in 1999. The panel concluded that the Research Centers Program has played an important role in increasing the visibility of CAM research, building research infrastructure, and drawing investigators into the field. The existing Center's structure, however, did not adequately meet the need to deliver good research results across the investigator community. The panel recommended a more flexible approach to supporting future centers research. Consequently, in consultation with our Advisory Council, we will employ a mix of research mechanisms to expand participation among investigators with varying degrees of research expertise.

At the entry level, we will fund *planning grants* to groups of investigators in the CAM community with limited research experience to aid them in identifying their inherent strengths and to map a cogent research strategy for developing a future center application.

At the mid tier, we are introducing *developmental research centers* to strengthen the research capacity of CAM institutions. These centers are specifically intended to sharpen future grant applications by building research infrastructure and fostering partnerships between CAM and conventional investigators to conduct feasibility studies.

At the main tier, we are initiating *centers of excellence in CAM research*, for investigators with proven experience in hypothesis-driven studies to conduct studies of the mechanisms and clinical potential of CAM practices. The centers of excellence will conduct innovative, high quality, multi-project CAM studies with a well-defined central research focus.

We began implementation of this strategy in FY 2003 and will continue its roll-out through FY 2005.

Training and Career Development. NCCAM supports a spectrum of NIH training and career awards to develop a cadre of skilled investigators in both the conventional and CAM research communities. We now support dozens of mentored and independent trainees, from the pre-doctoral level through mid-career and senior faculty members. The research of these trainees is broad, covering the continuum of basic through clinical studies. In FY 2002, we made institutional training and clinical research career awards to CAM institutions, and joined the new NIH-wide loan repayment program with awards to two junior practitioner-investigators, marking a series of "firsts" for NCCAM.

Bringing it all Together

Evaluating CAM Therapies in Rigorous Clinical Trials

The rigorous evaluation of a therapy in clinical trials requires the confluence of a variety of research efforts. Dietary supplements used in the therapy must be well characterized to determine their composition and purity, and to identify the active component(s). The therapy's mechanisms of action must be examined objectively to document its effect on cell culture and animal models. These studies must be conducted by highly trained professionals in well-equipped research facilities. The initiation of clinical trials of dietary supplements is also dependant on the outcome of studies that assess how the supplement enters the bloodstream and is metabolized. Additional studies also identify supplement interactions with prescription drugs, and determine if the supplement is safe and at what dosage range. Together, the data from these studies greatly enhance our ability to address the central question: "Does it work?"

Ensuring Quality Clinical Trials. In FY 2002, NCCAM established the Office of Clinical and Regulatory Affairs, and hired its first director. The new office will help plan, coordinate, and monitor our clinical trials; serve as a resource for our clinical investigators; and help to ensure the safety of clinical trials by overseeing the NCCAM Data Safety and Monitoring Board and compliance with all Institutional Review Boards and Food and Drug Administration regulations.

First Intramural Trials Launched. NCCAM's Division of Intramural Research launched its first clinical trials in FY 2002. The first study is an evaluation of electroacupuncture in reducing delayed nausea experienced by pediatric cancer patients following chemotherapy. Unlike acute chemotherapy-induced nausea, delayed nausea does not respond well to medications. To manage delayed nausea, pediatric cancer patients are often prescribed steroids, which can lead to unwanted side effects, such as weight gain, growth retardation, or susceptibility to infection. It also appears that delayed nausea may contribute to stress in patients and the negative effects that stress can induce. Therefore, finding an effective alternative may help patients avoid the potential side effects of steroids and stress. The randomized trial will enroll 52 patients, aged 16 to 35 years, who have been newly diagnosed with osteosarcoma, a form of cancer that requires intensive chemotherapy. The second clinical trial initiated in the Division of Intramural Research is a phase I study of mistletoe (*Viscum album L.*) in combination with the conventional chemotherapeutic agent gemcitabine for a variety of solid tumors. Over the past 80 years mistletoe extracts have been used across Europe for cancer treatment. Preclinical data suggest that mistletoe extracts exert stimulatory and modulatory effects on the immune system. In clinical practice, mistletoe extracts have been used in cancer patients as a sole intervention or as an adjunct to conventional cancer therapies. The clinical efficacy of mistletoe in the treatment of cancer is an area of active investigation, with inconclusive results to date, due in large part to the use of varying preparations, concentrations, study populations and regimens. Moreover, little is known about the toxicity of mistletoe and the potential for botanical and drug interactions between mistletoe extract and standard chemotherapeutic agents. Through this study we intend to establish a model for investigating botanicals used in conjunction with conventional chemotherapy. The initiation of additional clinical trials will occur in FY 2003 and FY 2004.

Using a “Natural Medicine” Regimen to Reverse Atherosclerosis. Atherosclerosis, a condition characterized by the progressive accumulation of cholesterol-laden deposits in artery walls and obstruction to blood flow, is the major factor underlying cardiovascular disease (CVD), the number one cause of death among older Americans. It is believed that targeting multiple risk factors for progressive atherosclerosis may be more effective in preventing CVD than treating individual risk factors; however, few studies have attempted to modify several risk factors simultaneously. By employing a multi-modality treatment program derived from a traditional system of Indian natural medicine (Maharishi Vedic Medicine) involving aggressive dietary changes, exercise, anti-oxidant herbal food supplementation, and stress reduction approaches, a research team supported by NCCAM significantly reduced the extent of carotid artery wall thickness, as an indicator of atherosclerosis, in patients at risk for CVD by nearly 20 percent, over one year. It will be important to determine whether sustained adherence to this multifaceted treatment strategy in a larger number of subjects confirms the encouraging results of this preliminary study.

Trials for Prostate Diseases. NCCAM is collaborating on two clinical trials with the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) for benign prostate enlargement. The first is an ongoing phase II randomized, double-blind, placebo-controlled study of saw palmetto (*Serenoa repens*) on men with moderate-to-severe disease. The results from this and other studies will form the evidence base for a much larger trial whose foundation is already being laid. Together, NCCAM, NIDDK, and the NIH Office of Dietary Supplements (ODS), will evaluate, both saw palmetto and another botanical, african plum (*Prunus africanum*), in 3,100 men with benign prostate disease. NCCAM is also collaborating with the National Cancer Institute (NCI) on its large Selenium and Vitamin E Cancer Prevention Trial (SELECT) to determine if one or both of these dietary supplements prevents prostate cancer. The study will ultimately enroll over 32,000 men at over 400 sites and take from seven to 12 years to complete.

Studies of Popular Diets for Obesity. Prevention and treatment of obesity, diabetes, and coronary heart disease (CHD) are major public health goals. Reduction of risks for these diseases include making changes in diet and physical activity. There is a wide spectrum of nutritional practices that claim to prevent, treat or manage obesity, diabetes, and cardiovascular disease. They range from specific, well-researched, biochemically understood treatments on which national public health recommendations are based, to unstudied interventions advertised in the popular press. In spite of their wide use by adults with obesity, diabetes, and other CHD risk factors, NCCAM is supporting studies to answer persistent questions about the safety and efficacy of some of these popular diets. Currently, NCCAM is supporting studies to examine the Atkins (extremely low carbohydrate), Zone (low-carbohydrate, high protein), and Ornish (very low fat) diets, and compare them to diets with greater supporting scientific evidence, such as the USDA/Food Pyramid (high carbohydrate/moderate-low fat) and DASH -- Dietary Approaches to Stop Hypertension (high carbohydrate, low fat). Results of these studies could potentially justify additional, larger and longer-term investigations, but the public health significance of obesity certainly warrants our critical, but open-minded search for new and better ways to control the nation’s waistline.

Results of NCCAM's First Phase III Clinical Trial:

St. John's Wort Product Proves Ineffective

Background: Each year, 9.5 percent of the population, or about 18.8 million American adults, suffers from a depressive illness, ranging in severity from mild to life threatening. In the year 2000, this resulted in over 10 million physician office visits. Both psychotherapy and a variety of medications have been demonstrated to be effective therapy for this condition. A popular herbal remedy for the treatment of depression, St. John's wort (*Hypericum perforatum*), has been used extensively in Europe and the United States; however, little is known about its effectiveness. A number of studies employing various St. John's wort products and patient populations have been conducted, however results have been inconsistent, leaving the question of its potential for therapeutic benefit unresolved.

Advance: A randomized, double-blind, clinical trial compared one widely used St. John's wort product to placebo and sertraline, a prescription antidepressant drug, in the treatment of patients with well-defined major depression of moderate severity. It was the largest study of its kind, enrolling 340 adults, and long enough in duration to adequately assess whether the product could provide a meaningful therapeutic effect. Overall, the study's investigators found similar rates of response in patients taking the St. John's wort product and placebo according to primary and secondary measurement scales of depression. Although sertraline produced no greater effect than placebo on a primary clinical measure of depression, it fared better than placebo on a secondary measurement scale, yielding results consistent with its known benefits. The investigators concluded that the St. John's wort product employed in this study was not effective for the treatment of adults with major depression of moderate severity.

Implications: Additional studies, currently under way, should clarify whether other St. John's wort products have any therapeutic benefit for patients with less severe forms of this disease. In the interim, self-assessment and self-treatment for depression may pose public health risks and consequentially should be avoided. In contrast, licensed mental health professionals are equipped to provide the best possible evaluation of, and treatment for, depression.

Hypericum Depression Trial Study Group: Effect of *Hypericum perforatum* (St. John's wort) in Major Depressive Disorder - A Randomized Controlled Trial. JAMA 287: 1807-1814, 2002.

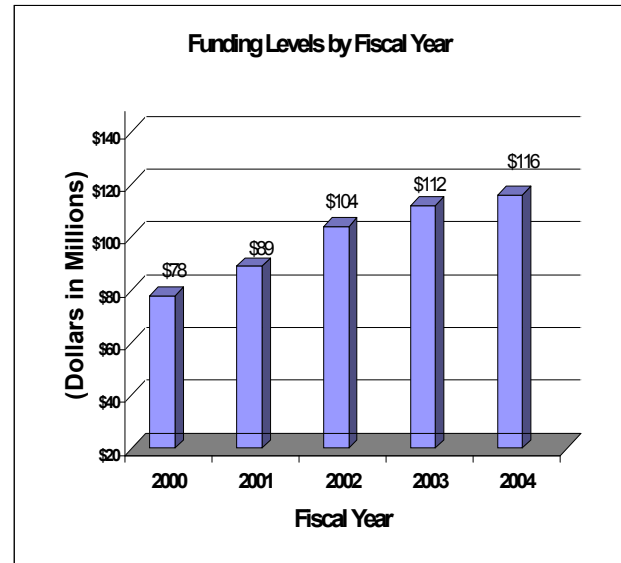
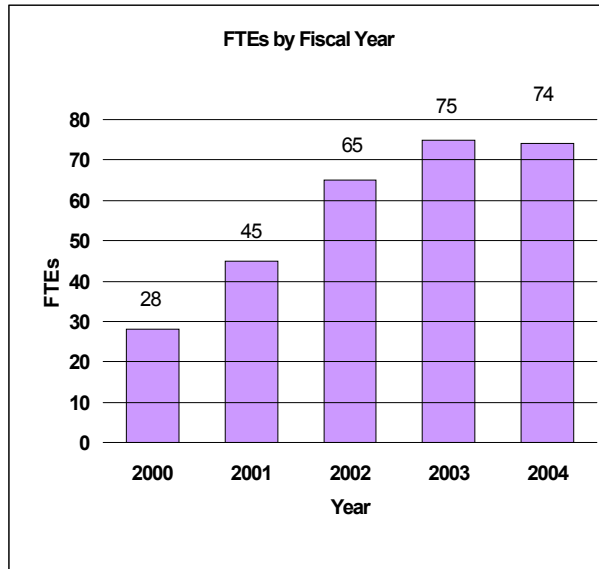
Conclusion

NCCAM's early research investments have begun to yield results. We continue to challenge the research community to design and conduct rigorous research, thus providing the promise of clear and compelling results that will guide consumers in making more informed healthcare decisions in the years to come.

Budget Policy

The Fiscal Year 2004 budget request for the NCCAM is \$116,202,000, including AIDS, an increase of \$3,760,000 and 3.3 percent over the FY 2003 amended President's Budget Request.

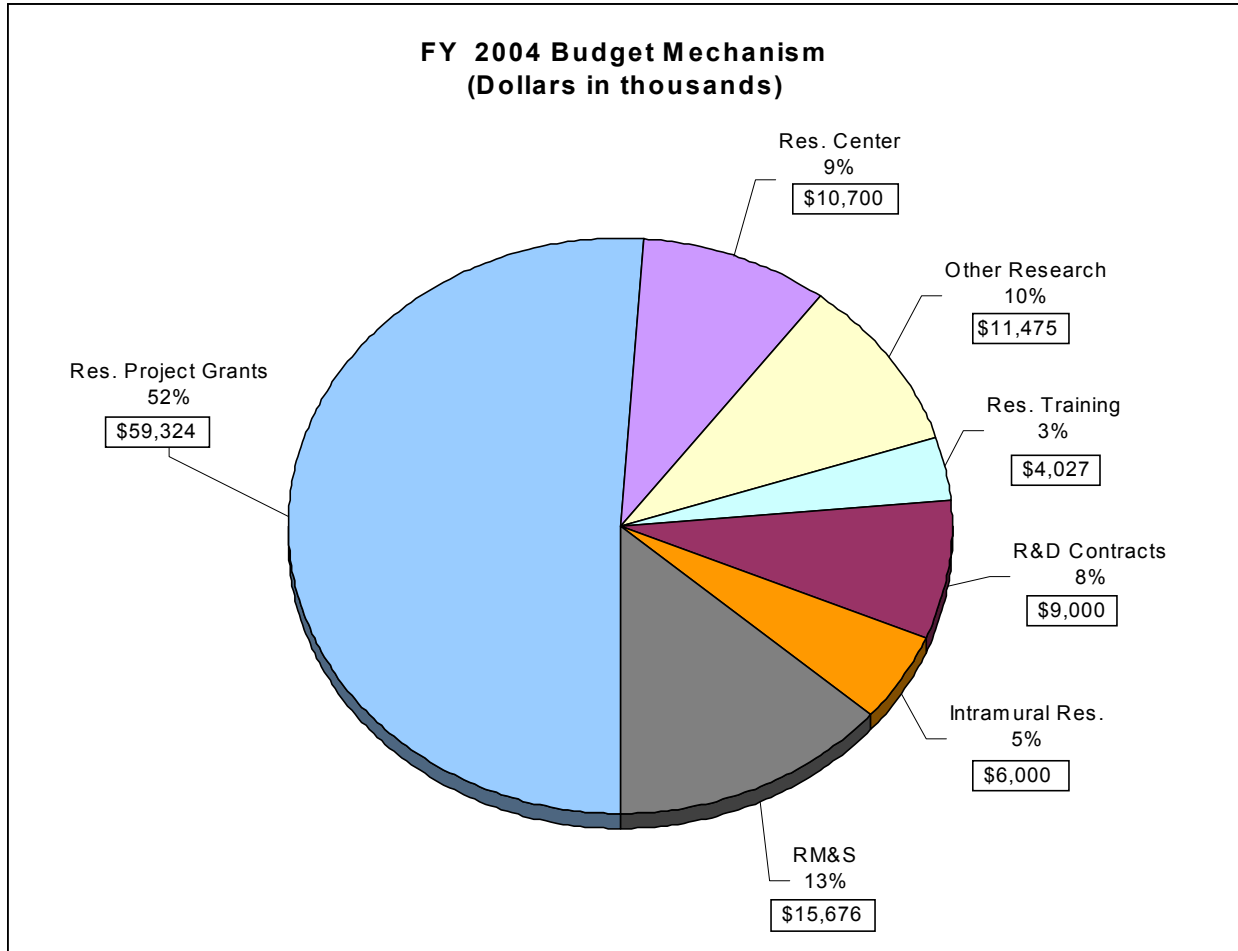
A five year history of FTEs and Funding Levels for NCCAM are shown in the graphs below. Note that Fiscal Years 2001 and 2000 are not comparable for the NIH Human Resources functional consolidation.



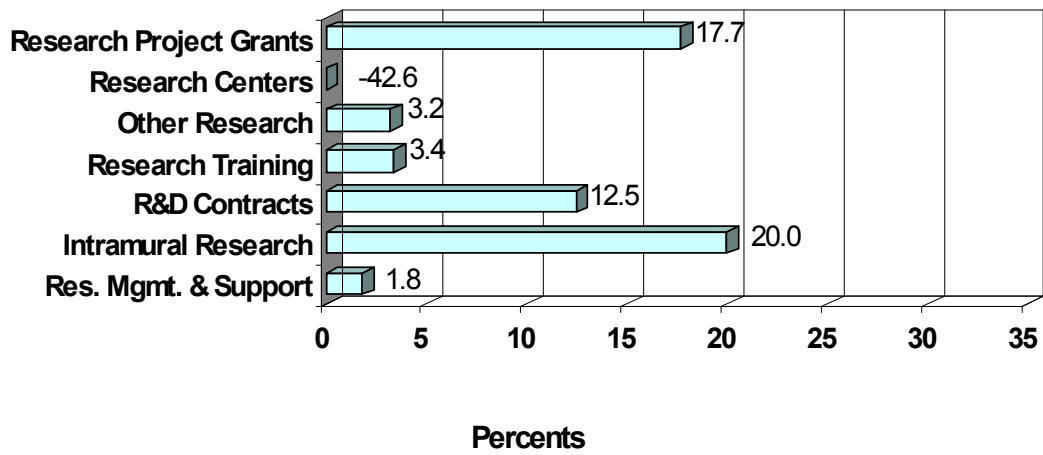
NIH's highest priority is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while providing new research opportunities. NCCAM will provide an aggregate average cost increase of 8.3 percent for Research Project Grants (RPGs).

Promises for advancement in medical research are dependent on maintaining the supply of new investigators with new ideas. In the Fiscal Year 2004 request, NCCAM will support 84 pre- and postdoctoral trainees in full-time training positions, the same number as in FY 2003. Stipend levels for NRSA trainees will increase by 4 percent over Fiscal Year 2003 levels for pre-doctoral fellows, and from 4-1 percent, based on years of experience, for postdoctoral fellows. The Fiscal Year 2004 request includes funding for 8 research centers, 51 other research grants, including 18 clinical career awards, and 7 R&D contracts. The FY 2004 request also includes \$25,000 to support the Best Pharmaceuticals for Children's Act (BCPA). Intramural Research and Research Management and Support receive increases of 20 and 1.8 percent respectively over FY 2003. The increase in the FY 2004 IR program over FY 2003 reflects the development in the IR infrastructure, specifically new laboratory research sections and staffing, retrofitting research space, and the purchase of laboratory equipment.

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



**FY 2004 Estimate
Percent Change from FY 2003 Mechanism**



NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Budget Mechanism - Total

MECHANISM	FY 2002 Actual		FY 2003 Amended President's Budget		FY 2004 Estimate	
	No.	Amount	No.	Amount	No.	Amount
Research Grants:						
<u>Research Projects:</u>						
Noncompeting	99	\$28,348,000	90	\$33,710,000	75	\$32,899,000
Administrative supplements	(6)	1,096,000	(10)	750,000	(10)	750,000
Full funded	0	0	0	0	0	0
Single year	43	13,720,000	41	13,599,000	68	23,141,000
Renewal	0	0	0	0	0	0
New	43	13,720,000	41	13,599,000	68	23,141,000
Supplements	0	0	0	0	0	0
Subtotal, competing	43	13,720,000	41	13,599,000	68	23,141,000
Subtotal, RPGs	142	43,164,000	131	48,059,000	143	56,790,000
SBIR/STTR	13	2,448,000	10	2,336,000	11	2,534,000
Subtotal, RPGs	155	45,612,000	141	50,395,000	154	59,324,000
<u>Research Centers:</u>						
Specialized/comprehensive	16	18,326,000	11	18,636,000	8	10,700,000
Clinical research	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0
Comparative medicine	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0
Subtotal, Centers	16	18,326,000	11	18,636,000	8	10,700,000
<u>Other Research:</u>						
Research careers	28	4,137,000	30	4,634,000	30	4,780,000
Cancer education	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0
Other	21	5,961,000	21	6,485,000	21	6,695,000
Subtotal, Other Research	49	10,098,000	51	11,119,000	51	11,475,000
Total Research Grants	220	74,036,000	203	80,150,000	213	81,499,000
<u>Research Training:</u>	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Individual awards	15	473,000	19	611,000	19	632,000
Institutional awards	60	2,937,000	65	3,284,000	65	3,395,000
Total, Training	75	3,410,000	84	3,895,000	84	4,027,000
Research & development contracts (SBIR/STTR)	8 (0)	8,677,000 (0)	6 (0)	8,000,000 (0)	7 (0)	9,000,000 (0)
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural research	5	3,989,000	8	5,000,000	8	6,000,000
Research management and support	60	14,129,000	67	15,397,000	66	15,676,000
Cancer prevention & control	0	0	0	0	0	0
Construction		0		0		0
Total, NCCAM	65	104,241,000	75	112,442,000	74	116,202,000
(Clinical Trials)		(27,955,000)		(30,100,000)		(31,100,000)

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Budget Authority by Activity
(dollars in thousands)

ACTIVITY	FY 2002 Actual		FY 2003 Amended President's Budget		FY 2004 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<u>Extramural Research:</u>								
Extramural Research & Training		\$86,123		\$92,045		\$94,526		\$2,481
Subtotal, Extramural research		86,123		92,045		94,526		2,481
Intramural research	5	3,989	8	5,000	8	6,000	0	1,000
Res. management & support	60	14,129	67	15,397	66	15,676	(1)	279
Total	65	104,241	75	112,442	74	116,202	(1)	3,760

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Summary of Changes

2003 Amended President's Budget				\$112,442,000
2004 Estimated Budget Authority				116,202,000
Net change				3,760,000
CHANGES	2003 Amended President's Budget Base		Change from Base	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Within grade increase		\$1,068,000		\$13,000
b. Annualization of January 2003 pay increase		1,068,000		8,000
c. January 2004 pay increase		1,068,000		16,000
d. One extra day of pay		1,068,000		4,000
e. Payment for centrally furnished services		529,000		11,000
f. Increased cost of laboratory supplies, materials, and other expenses		3,403,000		60,000
Subtotal				112,000
2. Research Management and Support:				
a. Within grade increase		6,298,000		109,000
b. Annualization of January 2003 pay increase		6,298,000		49,000
c. January 2004 pay increase		6,298,000		94,000
d. One extra day of pay		6,298,000		24,000
e. Payment for centrally furnished services		1,690,000		33,000
f. Increased cost of laboratory supplies, materials, and other expenses		7,409,000		159,000
Subtotal				468,000
Subtotal, Built-in				580,000

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Summary of Changes--continued

CHANGES	2003 Amended President's Budget Base			
	Change from Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	90	\$34,460,000	(15)	(\$811,000)
b. Competing	41	13,599,000	27	9,542,000
c. SBIR/STTR	10	2,336,000	1	198,000
Total	141	50,395,000	13	8,929,000
2. Research centers	11	18,636,000	(3)	(7,936,000)
3. Other research	51	11,119,000	0	356,000
4. Research training	84	3,895,000	0	132,000
5. Research and development contracts	6	8,000,000	1	1,000,000
Subtotal, extramural				2,481,000
6. Intramural research	<u>FTEs</u> 8	5,000,000	<u>FTEs</u> 0	888,000
7. Research management and support	67	15,397,000	(1)	(189,000)
8. Cancer control and prevention	0	0	0	0
9. Construction		0		0
Subtotal, program		112,442,000		3,180,000
Total changes	75		-1	3,760,000

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Budget Authority by Object

	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	75	74	(1)
Full-time equivalent of overtime & holiday hours	0	0	0
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	11.2	11.0	(0.2)
Average GM/GS salary	\$67,185	\$69,537	\$2,352
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$82,670	\$85,563	\$2,893
Average salary of ungraded positions	130,074	134,627	4,553
OBJECT CLASSES	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	\$4,175,000	\$4,304,000	\$129,000
11.3 Other than Full-Time Permanent	1,172,000	1,207,000	35,000
11.5 Other Personnel Compensation	150,000	156,000	6,000
11.7 Military Personnel	294,000	303,000	9,000
11.8 Special Personnel Services Payments	70,000	72,000	2,000
Total, Personnel Compensation	5,861,000	6,042,000	181,000
12.1 Civilian Personnel Benefits	1,405,000	1,448,000	43,000
12.2 Military Personnel Benefits	100,000	103,000	3,000
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	7,366,000	7,593,000	227,000
21.0 Travel & Transportation of Persons	195,000	205,000	10,000
22.0 Transportation of Things	23,000	25,000	2,000
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Miscellaneous Charges	190,000	200,000	10,000
24.0 Printing & Reproduction	17,000	18,000	1,000
25.1 Consulting Services	1,775,000	1,910,000	135,000
25.2 Other Services	4,743,000	5,205,000	462,000
25.3 Purchase of Goods & Services from Government Accounts	7,302,000	8,062,000	760,000
25.4 Operation & Maintenance of Facilities	1,107,000	1,153,000	46,000
25.5 Research & Development Contracts	4,810,000	5,340,000	530,000
25.6 Medical Care	155,000	170,000	15,000
25.7 Operation & Maintenance of Equipment	14,000	15,000	1,000
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	19,906,000	21,855,000	1,949,000
26.0 Supplies & Materials	460,000	505,000	45,000
31.0 Equipment	240,000	275,000	35,000
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	84,045,000	85,526,000	1,481,000
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	105,076,000	108,609,000	3,533,000
Total Budget Authority by Object	112,442,000	116,202,000	3,760,000

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Salaries and Expenses

OBJECT CLASSES	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-Time Permanent (11.1)	\$4,175,000	\$4,304,000	\$129,000	3.1
Other Than Full-Time Permanent (11.3)	1,172,000	1,207,000	35,000	3.0
Other Personnel Compensation (11.5)	150,000	156,000	6,000	4.0
Military Personnel (11.7)	294,000	303,000	9,000	3.1
Special Personnel Services Payments (11.8)	70,000	72,000	2,000	2.9
Total Personnel Compensation (11.9)	5,861,000	6,042,000	181,000	3.1
Civilian Personnel Benefits (12.1)	1,405,000	1,448,000	43,000	3.1
Military Personnel Benefits (12.2)	100,000	103,000	3,000	3.0
Benefits to Former Personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	7,366,000	7,593,000	227,000	3.1
Travel (21.0)	195,000	205,000	10,000	5.1
Transportation of Things (22.0)	23,000	25,000	2,000	8.7
Rental Payments to Others (23.2)	0	0	0	0.0
Communications, Utilities and Miscellaneous Charges (23.3)	190,000	200,000	10,000	5.3
Printing and Reproduction (24.0)	17,000	18,000	1,000	5.9
Other Contractual Services:				
Advisory and Assistance Services (25.1)	310,000	320,000	10,000	3.2
Other Services (25.2)	4,743,000	5,205,000	462,000	9.7
Purchases from Govt. Accounts (25.3)	3,937,000	4,492,000	555,000	14.1
Operation & Maintenance of Facilities (25.4)	80,000	90,000	10,000	12.5
Operation & Maintenance of Equipment (25.7)	14,000	15,000	1,000	7.1
Subsistence & Support of Persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	9,084,000	10,122,000	1,038,000	11.4
Supplies and Materials (26.0)	460,000	505,000	45,000	9.8
Subtotal, Non-Pay Costs	9,969,000	11,075,000	1,106,000	11.1
Total, Administrative Costs	17,335,000	18,668,000	1,333,000	7.7

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

SIGNIFICANT ITEMS IN SENATE APPROPRIATIONS
COMMITTEE REPORT

The following section represents FY 2003 Congressional requirements for reports and significant items derived from Senate Report 107-216. These actions discussed below are contingent on inclusion of similar language and funding in the final FY 2003 appropriation and related reports. Additional items may be transmitted at a later date as a result of the final Conference report.

Item

Centers - The Committee expects that funding for existing and new Centers supported by NCCAM will be maintained and directs the Center to undertake field investigations and a program for the collection and evaluation of outcome data on promising alternative therapies. **(Page 74)**

Action taken or to be taken

In FY 2002, NCCAM continued its strong support of its research centers program by adding two new centers as a result of its Frontier Medicine Initiative. The new centers will be examining CAM practices for which there is no plausible biomedical explanation, including bioelectromagnetic therapy, biofield/energy healing, homeopathy and therapeutic prayer/spiritual healing. Specifically, one center will be studying the potential role of therapeutic touch in healing bone fractures, while the other center will be exploring the hypothesis that biofield/energy field therapies involve a common set of bioelectromagnetic and psychosocial mechanisms that together impact cellular functioning, reduce pain, and increase wound healing.

In FY 2002, NCCAM convened an expert panel of investigators and scientific administrators to assess the centers program and make recommendations regarding its future. The panel concluded that the current centers program has played a major role in increasing the visibility and credibility of CAM research, building research infrastructure, and drawing investigators into the field. They recommended a more flexible approach to supporting future centers research. Consequently, in consultation with the National Advisory Council for Complementary and Alternative Medicine, NCCAM will use a mix of research mechanisms to support a wider variety of center activities to expand participation among investigators with varying degrees of research expertise. Increasing the selection of funding mechanisms available to applicants will

strengthen the research infrastructure and expertise in both CAM and conventional research institutions, and facilitate innovative, high quality, multi-project CAM studies with a well-defined central research focus. Implementation of this strategy will begin in FY 2003 and continue through FY 2005.

With respect to its field investigation activities, NCCAM continues to solicit innovative and promising treatments from practitioners in the field through a variety of venues. Among these venues remains- the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM), which provides advice and recommendations to the NCCAM Director and the National Cancer Institute (NCI) regarding current and future trials testing CAM interventions in cancer. In this forum, practitioners present scientific and outcome data to a panel of alternative medicine experts and conventional medical oncologists who evaluate promising CAM therapies. Beginning in FY 2003, this function will be more closely integrated with the National Advisory Council for Complementary and Alternative Medicine through the establishment of a new Council working group. NCCAM also solicits research proposals from the field through its extensive outreach activities that include advertisements in periodicals targeted to CAM practitioners, town meetings, a revised web site, and participation in professional meetings and workshops.

Item

CDC Field Investigations and AHRQ Literature Reviews - The Committee expects NCCAM to expand its support of CDC's field investigations program and of AHRQ literature reviews and data-analysis efforts. **(Page 74)**

Action taken or to be taken

As members of the NIH Transagency CAM Coordinating Committee, the Centers for Disease Control, Agency for Health Research and Quality, and NCCAM enjoy productive, collaborative relationships. In FY 2002, NCCAM and CDC collaborated on developing questions regarding CAM usage for inclusion in the 2002 National Health Interview Survey (NHIS). Since the NHIS over-samples minority populations, the survey will provide the most accurate description to date of CAM use in these groups. In December 2002, the final wave was completed. Results are expected approximately in December 2003. In the future, NCCAM will look for opportunities to collaborate on cost-effective research initiatives proposed by the CDC. NCCAM continues to jointly conduct literature reviews with AHRQ. The current contract will be reissued in FY 2003. As a result of this collaboration, five reports have already been published, one is awaiting publication and three are in production. The largest ever such review by AHRQ that is being co-funded by NCCAM is examining all available data on the efficacy and safety of ephedra-containing products.

Item

Fact Sheets on CAM Therapies - The Committee also expects the Center to allocate sufficient funds to develop and disseminate a comprehensive set of fact sheets on CAM therapies to inform the public and health professionals of the state of scientific knowledge about these therapies. **(Page 74)**

Action taken or to be taken

Providing the public and health care providers with authoritative information about CAM is a key element of NCCAM's mission. In FY2002, NCCAM conducted usability testing to solicit comments on the features of our website that needed improvement. In response, NCCAM upgraded its website greatly. More than 65 fact sheets and other information products on topics including CAM treatments, clinical trials for CAM, advice for consumers, and alerts and advisories are now available in print and electronic form. NCCAM has launched a series of fact sheets on botanical products in collaboration with the NIH Office of Dietary Supplements. The first fact sheet, on black cohosh for symptoms of menopause, was completed in October 2002; others in progress include an overview of botanicals and fact sheets on valerian, kava, and echinacea.

With the National Cancer Institute, NCCAM has a series of fact sheets on cancer and CAM and we are collaborating on formative research with cancer patients about what information they want and need about CAM. The results of this research will be used to improve the information both NCCAM and NCI prepare for cancer patients.

NCCAM's quarterly newsletter, *Complementary and Alternative Medicine at the NIH*, which contains articles on CAM research and NCCAM activities, reaches more than 7,000 subscribers.

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2003 Amount Authorized	2003 Amended President's Budget	2004 Amount Authorized	2004 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	\$108,547,000	Indefinite	\$112,175,000
National Center for Complementary and Alternative Medicine	Section 41B	42§285b	Indefinite		Indefinite	
National Research Service Awards	Section 487(d)	42§288	<u>a/</u>	3,895,000	<u>b/</u>	4,027,000
Total, Budget Authority				112,442,000		116,202,000

Amounts authorized by Section 301 and Title IV of the Public Health Act.
Reauthorizing legislation will be submitted.

**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	68,000,000	56,214,000	68,753,000
Rescission				(363,000)
2001	71,362,000	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			
2004	116,202,000			

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

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Detail of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2002 Actual	FY 2003 Amended Pres. Budget	FY 2004 Estimate
Office of the Director	11	12	12
Office of Administrative Operations	14	14	13
Office of Communications and Public Liaison	3	3	3
Office of Science Policy and Operations	7	7	7
Division of Extramural Research and Training	23	28	28
Office of Scientific Review	2	3	3
Division of Intramural Research	5	8	8
Total	65	75	74
FTEs supported by funds from Cooperative Research and Development Agreements			
	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2000	12.1		
2001	10.7		
2002	11.2		
2003	11.2		
2004	11.0		

NATIONAL INSTITUTES OF HEALTH
National Center for Complementary and Alternative Medicine

Detail of Positions

GRADE	FY 2002 Actual	FY 2003 Amended Pres. Budget	FY 2004 Estimate
ES-6	0	0	0
ES-5	0	0	0
ES-4	0	0	0
ES-3	0	0	0
ES-2	0	0	0
ES-1	0	0	0
Subtotal	0	0	0
Total - ES Salary	\$0	\$0	\$0
GM/GS-15	6	8	8
GM/GS-14	15	16	16
GM/GS-13	5	6	6
GS-12	7	10	10
GS-11	6	9	9
GS-10	0	0	0
GS-9	6	8	8
GS-8	3	4	4
GS-7	6	9	9
GS-6	3	4	4
GS-5	2	2	3
GS-4	1	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	60	77	78
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General			
Director Grade	3	3	3
Senior Grade	1	1	1
Full Grade			
Senior Assistant Grade			
Assistant Grade			
Subtotal	4	4	4
Ungraded	20	22	23
Total permanent positions	65	74	75
Total positions, end of year	84	103	105
Total full-time equivalent (FTE) employment, end of year	65	75	74
Average ES level	ES-4	ES-4	ES-4
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	11.2	11.2	11.0
Average GM/GS salary	\$65,165	\$67,185	\$69,537