DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

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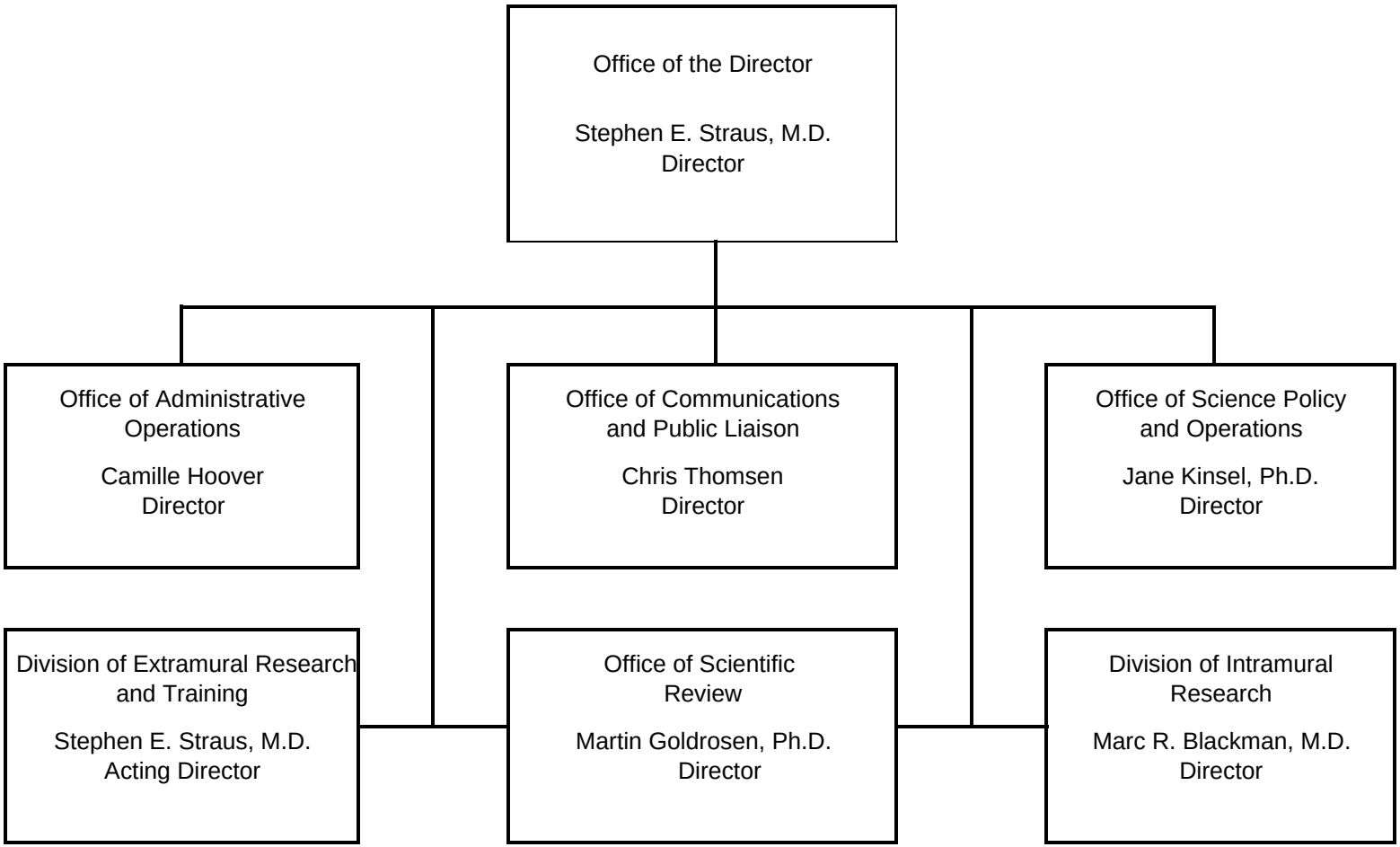

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

For carrying out section 301 and title IV of the Public Health Service Act with respect to complementary and alternative medicine, [$105,032,000] *$111,494,000.*

[Department of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act for Fiscal Year 2002 (P.L. 107-116)]

National Institutes of Health

National Center for Complementary and Alternative Medicine
Amounts Available for Obligation 1/

Source of Funding	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Appropriation	$89,211,000	$104,644,000	$110,920,000
Enacted Rescission	(54,000)	(52,000)	---
Subtotal, Adjusted Appropriation	89,157,000	104,592,000	110,920,000
Comparable adjustment for legislative proposal for accrued retirement costs	356,000	388,000	574,000
Real transfer to:			
Other HHS Agencies through Secretary's one-percent transfer authority	(17,000)	---	---
Real transfer to HHS for the Office of Human Research Protection	(19,000)	---	---
Comparative transfer from:			
National Cancer Institute for research activities	---	---	2,329,000
Subtotal	89,477,000	104,980,000	113,823,000
Unobligated Balance, start of year	1,000	---	---
Revenue	0	---	---
Unobligated Balance, end of year	0	---	---
Subtotal, adjusted budget authority	89,478,000	104,980,000	113,823,000
Unobligated balance, lapsing	2,000	---	---
Total obligations	89,476,000	104,980,000	113,823,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2001 - $240,000; FY 2002 - $3,000,000; FY 2003 - $3,000,000

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:

	2001 Actual	2002 Appropriation	2002 Current Estimate	2003 Estimate	Increase or Decrease
Current Law BA	$89,122,000	$104,644,000	$104,592,000	$113,249,000	$8,657,000
Accrued Costs	$356,000	$388,000	$388,000	$574,000	$186,000
Proposed Law BA	$89,478,000	$105,032,000	$104,980,000	$113,823,000	$8,843,000
FTE	45	80	80	80	0

This document provides justification for the Fiscal Year 2003 activities of the National Center for Complementary and Alternative Medicine (NCCAM), including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2003 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR)."

The President's appropriations request of $113,823,000 for this account includes current law adjusted by assuming Congressional action on the proposed Managerial Flexibility Act of 2001.

INTRODUCTION

NCCAM continues to capitalize on the many untapped opportunities to define the safety and effectiveness of complementary and alternative medicine (CAM) approaches and to disseminate research findings to the public and healthcare practitioners. Our portfolio has begun to demonstrate the breadth and complexity typical of work supported by the more established Institutes. For example, NCCAM has emphasized the expansion of investigator-initiated studies on the basic mechanisms of action and clinical applications for many different, widely used, CAM therapies. NCCAM maintains a Centers program to investigate, in-depth, a range of botanical products, cancer therapies, cardiovascular disease treatments, and women's health approaches, among others. Likewise, we support a substantive research training program, using each of the major training mechanisms supported by NIH. This program includes pre- and postdoctoral fellows, physicians and CAM practitioners, and individual as well as institutional training awards. Our Phase III clinical trials program has now enrolled thousands of research subjects into rigorous studies of the most promising CAM treatments.

Looking ahead, and in keeping with our Strategic Plan, we aim to build on this foundation. In FY 2003, we will expand our investigations into some of the most complex and sought after applications of CAM to human health, especially in such areas as: Neurosciences; Cancer; HIV/AIDS; International Health; and Women's Health at Mid-Life. The accompanying

narrative highlights the critical scientific foundations that have been established in these key areas, recent research findings, and our plans for advancing research on CAM therapies.

CAM AND THE NEUROSCIENCES

One of the largest components of the rapidly growing NCCAM research portfolio is directed to important public health needs and opportunities in the neurosciences. This includes studies focused on pain, mental health, stroke, addiction, and neurodegenerative disorders, as well as studies that are targeted to learning more about how the central nervous system responds to a variety of CAM therapies. Together, these studies promise not only to determine the range of vexing neurological conditions for which CAM therapies may be beneficial, but also to further elucidate the intricate processes of the brain and central nervous system.

Acupuncture: The Treatment of Pain and Beyond. Until recently, acupuncture has been poorly understood by standards of conventional medicine, even though it has enjoyed millennia of empiric development and widespread use in Asia. Currently, NCCAM investigators are learning more about acupuncture's mechanisms of action and its value for pain relief. Several different basic studies are applying powerful new imaging techniques to identify linkages between needle insertion sites, ancient acupuncture meridians, and functional and chemical changes in the brain. The first such studies have shown that placement of acupuncture needles into traditionally defined pain control points on the body leads to a dampening of activity in the very regions of the brain in which pain sensations are regulated. A considerable proportion of NCCAM's acupuncture studies are dedicated to investigating how effective acupuncture is at managing pain relative to other contemporary approaches. In collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NCCAM is sponsoring the largest and most rigorous trial to date of the safety and efficacy of acupuncture for the pain of osteoarthritis of the knee. In order to determine the broadest extent to which acupuncture may be an effective pain therapy, NCCAM is supporting smaller studies for other conditions including: carpal tunnel syndrome; temporomandibular disorder and postoperative dental pain; and back pain. We are also investigating other "traditional" applications of acupuncture for which many Westerners are less familiar. These studies include: treating drug addiction; ameliorating cardiovascular disease; relaxing muscle tension in children with cerebral palsy; treating depression; controlling nausea and other quality of life issues associated with advanced cancer and HIV/AIDS; treating hypertension; and reducing pain associated with endometriosis. Collectively, this is the largest compendium of contemporary acupuncture studies.

Experimental Animal Model Reveals Ability of Soy to Reduce Pain. Aspirin and morphine, as well as other conventional pharmaceuticals, are well-characterized and proven to treat pain. In addition to acupuncture, other CAM approaches such as meditation also promise to ameliorate pain. Dietary interventions have not been associated with such activity. Recently, however, NCCAM-supported investigators showed that rats fed a high soy diet *prior* to a nerve-injuring procedure experienced less pain following the procedure than cohorts fed a diet lacking soy. While pain reduction could not be demonstrated in rats fed a high-soy diet *following* the nerve-

injuring event, the study merits follow-up to explore more fully the connection between diet and pain sensation and the attendant opportunities for therapeutic advantage.

CAM Therapies for Neurodegenerative Disorders. Progressive degeneration of cells in the nervous system causes a number of debilitating and fatal illnesses. While these conditions, such as Alzheimer's disease, Parkinson's disease, and Huntington's disease are common and well-characterized, conventional treatment strategies remain of limited benefit. Currently, NCCAM is supporting innovative research into these areas with the goal of expanding treatment options and learning more about the processes underlying damage to vital neural tissues. For example, several NCCAM grantees are examining the antioxidant properties of a class of compounds derived from grapes, called polyphenols. It is hypothesized that damage to neural tissues is often a consequence of the accumulation of corrosive oxygen-containing molecules, a condition known as oxidative stress, and therefore, products that could protect against such stress might reduce neural damage. Following similar reasoning, one investigator has taken clues from the ancient practice of Traditional Chinese Medicine to identify botanical products with a range of antioxidant properties. Extracts of the Hemsley plant (*Cynanchum wilfordii*) protected cultured nerve cells from harmful substances that accumulate in aging or diseased brains. In accord with the results of smaller, preliminary studies, and in collaboration with the National Institute on Aging (NIA), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Neurological Disorders and Stroke (NINDS), NCCAM is supporting a key study of the efficacy of *Ginkgo biloba* in preventing dementia in the elderly.

Nutritional Supplement Shows Promise as Treatment for Huntington's Disease. Huntington's disease (HD) strikes in midlife. The genetic abnormality that underlies this condition causes progressive degeneration of crucial brain cells over a period of years before leading, ultimately, to death. There is a great need to identify an effective treatment for the disease; at present, there is none. Recently, researchers have tested the nutritional supplement creatine in a transgenic mouse model of HD and observed improvement in survival, body weight, and motor function. These results implicate the role of metabolic dysfunction in the mouse model of HD and suggest a novel therapeutic strategy to slow the disease process.

Role of Stressors. The NCCAM Intramural Research Program (IRP) was invigorated recently by the appointment of its first Director for Clinical Research and his development of a long-term research plan. The Program is intended to serve as a model for clinical, translational, and laboratory-based research, training, and clinical care related to several CAM modalities. In the near term, the IRP will focus on three of the body's cardinal communications systems: endocrine, immune, and neural. Significant to these studies is their interrelationship, especially with regard to the impact of life stressors, such as depression, cognitive decline, chronic pain, frailty, and sleep disorders. These stressors are disproportionately more common and problematic in the elderly; commonly co-exist in the same individual; and account for substantial usage of one or another CAM modality. Initial clinical studies will examine the use of acupuncture to control nausea associated with aggressive cancer therapy, and mind-body interventions and dietary supplements. A key feature of NCCAM's new IRP is its commitment to undertake its studies in conjunction with leading experts in other NIH Institutes and Centers.

Approaches to Mental Health Disorders. NCCAM currently supports several studies designed to expand treatment options for a wide range mental health disorders. For example, it has been hypothesized that patients with major mood disorders have experienced oxidative injury to their brains. NCCAM-supported researchers are investigating this concept by examining omega-3-fatty acids, which have antioxidant properties. In the first study, investigators are assessing omega-3 fatty acids for the prevention of bipolar disorder, type I, recurrences over one year. In the second study, researchers are examining the nutritional status of patients suffering major depression and supplementing their diet with omega-3 fatty acids. NCCAM investigators are also investigating binge eating disorder (BED). BED is marked by recurrent episodes of binging, accompanied by feelings of loss of control, and involves chronic dysregulation of physiological, emotional, and behavioral systems. Because meditation-based interventions have been used successfully to treat disorders with similar addictive and behavioral characteristics, NCCAM-supported investigators are evaluating the role of a mindfulness meditation-based intervention as a treatment component for BED in a six-month study. The results will be factored into a more comprehensive BED treatment program.

Additional Studies of St. John's Wort Initiated. A study of St John's wort (*Hypericum perforatum*) for the treatment of major depression of moderate severity was recently completed and is awaiting the formal reporting of results. The National Institute of Mental Health (NIMH), the NIH Office of Dietary Supplements (ODS), and NCCAM, cosponsors of this study, have again collaborated on another study of St. John's wort, this time for minor depression. This study of 300 patients evaluates the botanical against a standard antidepressant for an initial phase of twelve weeks. After 12 weeks, patients who do not respond to treatment will be reassigned to an active treatment arm. Patients who respond to treatment will continue to take their assigned medication for another 14 weeks. Another NCCAM-sponsored study is examining the use of St. John's wort for social phobia. A small business innovative research (SBIR) grantee is developing an improved St. John's wort product that can be manufactured in a standardized and reproducible manner.

Investigations of the Placebo Effect. The placebo effect is a physiological or psychological change in a patient's condition that occurs in response to administration of otherwise inert substances or participation in a psychophysiological activity, such as faith-based healing or hypnosis. It had been believed that the use of a placebo as an intervention would merely simulate medical therapy but had no specific action itself against a target disease. Research, however, has demonstrated that placebos do have effects on treatment outcome. In November 2000, NCCAM and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) co-sponsored a major international conference to examine social, psychological, and neurobiological contributions to the placebo effect, and ethical use and evaluation of placebo actions in clinical trials. In response to recommendations resulting from the conference, NCCAM has designed and will fund, in FY 2003, in collaboration with several other NIH Institutes and Centers, two new research initiatives. The first is aimed at elucidating the underlying mechanisms of the placebo effect by closely examining the underlying biological pathways. The second will support interdisciplinary studies involving social and behavioral

sciences, to reveal those factors that are important for eliciting placebo effects in a clinical practice setting. It is believed that together these initiatives will identify fundamental processes by which the mind and body communicate most effectively to improve one's health.

THE CHALLENGES OF BOTANICAL PRODUCTS IN MEDICAL RESEARCH

Labeling of Dietary Supplements May Differ from Actual Contents. Consumers of the dietary supplement ginseng believe that its use will increase their strength and energy. Ginseng-containing supplements are among the most popular medicines worldwide; however, because they can be prepared from a number of related plants, they are subject to botanical misidentification. With such a premise, an NCCAM-grantee examined 25 commercial products containing ginseng to determine if the amount and type of ginseng was consistent with the product labeling. The study showed that, although each product was appropriately labeled for the *type* of ginseng contained within, the *concentrations* of ginseng, as determined by analysis of marker compounds, differed widely from that stated on the label. These results suggest that careful characterization and standardization of herbal products is a necessary step in the design and evaluation of studies using those products. The lack of consistent and reliable botanical products represents a formidable challenge to conducting clinical trials, as well as basic research. Although many botanicals are widely used, most have not been sufficiently characterized or standardized for the conduct of clinical trials capable of adequately demonstrating safety or efficacy. Consequently, obtaining sufficient quantities of highly-characterized products for evaluation in clinical trials would be advantageous. Several issues regarding the choice of the clinical trial material require special attention, for example: (1) use of different parts of the plants (*e.g.*, roots, seeds, aerial parts, whole plant); (2) use of different cultivars and species; (3) optimal growing and harvesting conditions; (4) whether to use whole extract or a specific fraction; (5) the method of extraction (*e.g.*, alcoholic, tea, pressed juice); (6) chemical standardization of the product; (7) presentation of the medication (*e.g.*, extract, tablet, capsule); and (8) the dose and length of administration. Given the popularity of botanical products, NCCAM has taken several steps to ensure the development of well-defined product to conduct conclusive clinical trials.

NCCAM-Industry Colloquium. A critical step in ensuring that NCCAM can secure sufficient standardized botanical products is to build collaborative relationships with industry. On May 14, 2001, NCCAM, in conjunction with the NIH Office of Dietary Supplements (ODS), convened a colloquium to begin a dialogue regarding how NCCAM, ODS, and industry can work together to definitively evaluate CAM therapeutic products for composition, safety, and efficacy. The meeting involved two key groups: (1) industrial stakeholders that supply raw materials and manufacture and market CAM therapeutics (e.g., dietary supplements) and (2) organizations that develop and apply standards to determine the identity, quality and safety of these products. Having gained an understanding of the common interests and the complementary roles each group can play, a foundation has been laid for pursuing opportunities to develop collaborations, as they emerge.

Development of Standardized Echinacea. With the great need for standardized botanical products and apparent industry interest, NCCAM sought to encourage industry involvement through the use of the SBIR grant mechanism. For example, one SBIR awardee is attempting to identify the best source of crude Echinacea (*Echinacea angustifolia*), an herb used for treatment of common respiratory infections. The awardee is biochemically profiling "marker" compounds in the plant to determine the optimal conditions for cultivation relative to the yield of potentially medicinal components. Later work will focus on the isolation and characterization of the most biologically active components. Another SBIR grantee is examining the correlation between composition and bioactivity of Echinacea. She is using an *in vitro* model to determine the circumstances under which the liver activates specific Echinacea components possessing the kinds of immunostimulating effects that are thought to help speed the resolution of infections.

Echinacea in use in Clinical Trials. Currently, NCCAM investigators are using crude preparations of Echinacea in clinical trials in order to determine if there is a foundation to assertions that it is effective in preventing and/or treating upper respiratory and middle ear infections. Each study differs from the others in type of Echinacea preparation used, as well as duration of administration, patient population type and size, and outcome measurements. Together, however, they may demonstrate some applicability to these conditions, providing us with helpful clues concerning the best opportunities for conducting conclusive clinical trials employing a highly characterized and standardized product.

CANCER

Many cancer patients incorporate CAM modalities into their conventional prevention and/or treatment regimens to improve their prognosis and reduce side effects of conventional treatments; however, others may choose a CAM therapy as an alternative, especially for those cancers that are not very effectively treated by conventional therapies. NCCAM is working closely with staff of the National Cancer Institute and leading cancer specialists to examine both complementary and alternative therapies for cancer and its complications, palliative care treatment, and options for care at the end of life. We are also supporting studies on the integration of CAM cancer therapies within conventional medical practice. Together these studies provide a compelling base from which we plan to launch our future initiatives.

Exploring Herbal Products. Many cultures have a tradition of incorporating herbs into their healing practices, including those to control cancer and its related symptoms. For example, Native Hawaiians and other Pacific Islanders have employed an extract of the Indian mulberry (*Morinda citifolia*), known as noni, as a treatment for various ailments. Cancer patients commonly take noni, even though there is little scientific information available to support or refute claims of its usefulness. Investigators supported by NCCAM have initiated the first ever Phase I study of noni to determine its safety, anticancer activity, and under what circumstances, if any, it is effective. In another study, researchers are conducting *in vitro* and animal studies of skullcap (*Scutellaria baicalensis*), a widely used Chinese herb, to determine the mechanisms of action for its previously documented anticancer and anti-inflammatory properties. For years Central Europeans have employed mistletoe (*Viscum album*) in the treatment of various cancers; however, there is little compelling evidence of its efficacy. NCCAM investigators are conducting a Phase II clinical trial in advanced lung cancer patients who are also receiving conventional medical care to determine if mistletoe enhances key immune parameters and quality of life indicators. NCCAM is also supporting research on the characterization of active compounds in red wine extracts and their effects on tumor cell lines *in vitro*.

Combating Fatigue. Fatigue is the most frequently reported symptom in patients with cancer.[1] The causes of fatigue in cancer are numerous, including the disease itself, anticancer therapies, anemia, depression, and malnutrition. In an NCCAM-sponsored study, investigators are

[1] Miaskowski C, *et al.* Update on the assessment and management of cancer-related fatigue. Principles and Practice of Supportive Oncology Updates 1(2): 1-10, 1998.

examining the role of L-carnitine. L-carnitine is a key micronutrient involved in energy metabolism. Its deficiency is characterized by weight loss, fatigue, muscle weakness, decreased tolerance to metabolic stress, and cardiomyopathy. The study is designed to determine if L-carnitine supplementation reduces fatigue and the other signs of its deficiency. A separate study of cancer patients examines the effect of massage on fatigue and other quality of life issues.

Integrative Oncology. NCCAM is not only studying CAM cancer therapies, but also how those validated therapies are incorporated and used in evidence-based medical practice. One such study is examining the effectiveness of an existing CAM program within a unique multidisciplinary outpatient cancer clinic setting. It is expected that much will be learned about what CAM programs are used and how the patients use them, as well as factors that facilitate or dissuade cancer patients from availing themselves of CAM therapies.

PC SPES, Hope for Prostate Cancer? PC SPES is a mixture of Chinese herbs that is being carefully examined for its effects against prostate cancer. The name PC SPES is an amalgamation of English and Latin: PC, an abbreviation for prostate cancer; and SPES, the Latin word for hope. In addition to the first ever randomized, controlled clinical trial of PC SPES at one of NCCAM's Specialized Research Centers, additional studies are underway to further examine the biochemical properties of this herbal mixture. In one study, PC SPES is under evaluation, along with green tea, for the effect each might have on androgens, a class of male hormones, and their effects on the growth of human prostate cancer cells *in vitro* and in immunologically impaired mice. Another study is examining the influence that PC SPES exerts over androgen regulation in male rats and the implication for prostate cancer treatment.

Testing Experimental Therapies for Glioblastoma. Glioblastoma is a rapidly growing, malignant tumor of the brain. Although effectively treated with a combination of surgery and radiation, glioblastoma is eventually fatal in most patients. An NCCAM sponsored study is comparing the use of berberine, a relatively nontoxic substance isolated from Chinese medicinal herbs, to conventional drugs in order to determine its ability to decrease resistance of cancer cells to being killed by radiation. It has been shown that glioblastoma cells express a mutant form of the gene p53 that increases their resistance to radiation. Berberine has been shown to trigger apoptosis, or programmed cell death, in these glioblastoma cells. It is speculated that berberine's action will contribute to decreased radiation resistance of glioblastomas and other cancers harboring mutant p53 genes, hopefully improving the outcomes. In another glioblastoma study, investigators are examining the role of "distant healing" (DH) on patient survival time. Distant healing is a mental intention on behalf of one person, to benefit another at a distance. In the trial, healers from diverse backgrounds located in communities across the United States are assigned to patients by rotation, so that each patient in the DH group is treated for two weeks by 10 different healers over the 20-week intervention. Experienced healers are given photographs of subjects and send "mental intention for health and well being" to subjects for one hour daily, three times per week. The healing intervention will be performed at a distance, and patients and healers will never meet, nor will patients know their group assignment. Findings from this study will help determine whether this popular, but controversial, healing approach warrants a larger more definitive trial.

New Research Opportunities: Phase I/II Trials of Herbal and Biopharmacologic CAM Therapies for Cancer. Many CAM cancer therapies are claimed to extend life expectancy and improve quality of life, but the scientific literature provides limited or no evidence to confirm these claims. Rigorous Phase I/II studies of well-characterized products are necessary before more definitive studies of efficacy can be justified. Consequently, NCCAM plans to support the development and clinical testing of several unconventional cancer treatments that are widely used alone or in combination with conventional cancer therapies. These agents might include high-dose antioxidants (e.g. vitamin C or CoenzymeQ10), herbal mixtures (*e.g.* Flor-Essence, Essiac, PC-SPES, or Traditional Chinese Medicines), single whole plant extracts (*e.g.* mistletoe, oleander, or green tea), biopharmacologics (*e.g.* MTH-68, or 714-X), or complex regimens (*e.g.* Revici or Gerson therapies).

HIV/AIDS

People living with HIV infection often incorporate CAM modalities into their personal treatment strategy. The most frequently cited reasons for doing so include the need to counteract the side-effects of highly-active antiretroviral therapy (HAART), to boost the immune system, and to improve overall sense of well-being.[2] Consequently, NCCAM is building an innovative and broad-based research portfolio to determine the safety and efficacy of CAM modalities employed for the treatment of HIV/AIDS.

Antiretroviral Therapies. A few CAM therapies have demonstrated the potential for activity against the human immunodeficiency virus. NCCAM is currently supporting studies to examine the antiretroviral action of a number of such substances. In a clinical study, the dietary supplement dehydroepiandrosterone (DHEA) is being administered to patients to determine if it lowers HIV levels and what effects it may have on the patient's metabolic profile. In an *in vitro* HIV assay, an investigator is examining the potential of licorice (*Glycyrrhiza glabra*) and St. John's wort (*Hypericum perforatum*) to work in concert with the anti-HIV drugs AZT, nevirapine, and indinavir. Although well-documented studies show that patients St. John's wort concurrently with indinavir causes the antiretroviral to drop below therapeutic levels,[3] preliminary research shows that there is nonetheless an inherent antiretroviral activity in St. John's wort.[4] These circumstances underscore another challenge in working with whole or partially purified botanical products and the need for careful and well-designed studies of such products.

HAART-Induced Side Effects. HAART is the indicated treatment strategy for people with HIV/AIDS and has contributed greatly to the major decrease in AIDS-related deaths

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[2] Greene KB, *et al.* Most frequently used alternative and complementary therapies and activities by participants of the AMCOA study. J Assoc Nurses AIDS Care 10(3): 60-73, 1999.

[3] Piscitelli SC, *et al.* Indinavir concentration and St. John's wort. Lancet 355:547-548, 2000.

[4] Degar S, et al. Inactivation of the human immunodeficiency virus by hypericin: evidence for photochemical alterations of p24 and a block in uncoating, AIDS Res Hum Retroviruses 8(11):1929-36, 1992.

nationwide.[5] There are, however, some undesirable side effects to the HAART regimen, most notably significant changes in body composition and metabolism associated with abnormal serum lipid and glucose levels and the unusual deposition of fatty-tissues beneath the skin, a condition known as lipodystrophy. NCCAM has recently funded two new studies to address these consequences. In a Phase I/II clinical trial, investigators are comparing the use of a dried garlic product to placebo, to determine the product's effect on the patient's serum cholesterol, lipid, and glucose levels. In another study, supported under a small business innovative research (SBIR) award, researchers have developed a specialized clinical consultation service that combines dietary and nutrient supplementation with medication adherence strategies and a program of resistance exercise to improve quality of life, side-effect incidence, and biochemical profiles. In both studies, standard antiretroviral therapy is maintained.

Restoration of the Immune System and other Signs of Vitality. Successful HAART does not fully reconstitute the integrity of the immune system in people with HIV and failed therapy generally leads to a collapse of the immune system. Therefore, CAM therapies are being examined for their ability to restore the damage caused by HIV. In one study, patients receiving conventional AIDS treatment also receive the dietary supplement, alpha lipoic acid. It is theorized that this supplement increases the level of the antioxidant glutathione, which is vital to lymphocyte function. In another study, the supplement creatine is under evaluation to determine if people with HIV can improve skeletal strength, energy metabolism, work capacity, body composition, and immune function.

Care at the End of Life for People with HIV. While HAART has greatly improved the survival rate for people with HIV, 448,060 Americans died of AIDS and associated complications in the year 2000.[6] Because palliation is one of the purported benefits of many CAM therapies, NCCAM is supporting several research projects on improving the quality of life for people with advanced AIDS (parallel studies are being conducted with people who have advanced cancer). For example, NCCAM-supported investigators are assessing the usefulness of massage therapy for the treatment of depression and improvement in the quality of life in patients in the late stages of AIDS. Another study is examining the capacity of Reiki, a Japanese therapy in which a practitioner channels his/her vital energy to a patient (without touching). Patients are evaluated for changes in anxiety, depression, pain, and other quality of life measures. Other such studies examine alternative stress reduction approaches through cognitive behavioral coping and tai chi, and the role spirituality plays in sustaining one's will to live.

Uses of CAM in HIV/AIDS. There is increasing evidence that HIV-infected patients with drug-resistant virus are more susceptible to fatal complications of HAART, such as liver failure or lactic acidosis. Although these risks are uncommon, NCCAM plans, in FY 2003, to support

[5] Fauci, AS, et al. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. *HIV/AIDS Treatment Information Service*. http://www.hivatis.org/trtgdlns.html#Adult. August 13, 2001.

[6] Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report: 12(No.2): p. 29, 2000.

studies designed to identify roles for CAM in ameliorating the side-effects. These may include *in vitro*, animal models, and Phase I/II clinical studies.

International Research Activities. Recognizing that a global CAM research network would also enhance CAM research activities in the United States, NCCAM plans to solicit applications to develop an international site of CAM research excellence in FY 2003. Through scientific collaborations with U.S. investigators, the Center 's researchers would conduct studies and train new investigators. Providing access to CAM research in its native environment would uniquely position U.S. investigators to examine the effects of geographic and cultural changes on CAM practices by comparing those practices in their countries of origin and in the U.S.

WOMEN'S HEALTH AT MID-LIFE

Women are increasingly using herbal remedies to treat menopausal symptoms and other health conditions associated with mid-life, even though little is known about the efficacy or safety of these products. NCCAM supports studies on the underlying biochemical properties and health effects so that women may make more informed decisions concerning their health care choices.

The Role of Soy Phytoestrogens in Women's Health. Soybeans naturally contain a class of compounds called isoflavones, or phytoestrogens (PE) because of their biological properties that are similar to those of the hormone estrogen. While conventional estrogen replacement therapy (ERT) for women increases the risk of breast cancer, supplementation with PEs might seem to be an attractive alternative. However, little is known about the long-term safety and efficacy of PEs. Currently, NCCAM is supporting key studies to determine what benefit, if any, PEs have on women's health, and, more specifically, what impact they may have on breast cancer survivors. One study examines the basic and clinical effects of PEs on breast cancer and bone density in post-menopausal women, comparing those women on ERT and those that are not. Other studies examine the interaction of both mammalian estrogen and PEs on local estrogen production in the breast and on cancer risk markers in the breast and endometrium. Another study focuses on the interactive effects between PEs and tamoxifen, a first-line treatment for estrogen-dependent breast cancer. Study results can be used to educate the medical community and consumers on the safety of combining supplements with prescription regimens. Because it is unclear whether PEs may protect against breast cancer, or like conventional ERT could promote its emergence, NCCAM plans in FY 2003 to study these issues and assess the impact in a Phase II clinical trial of PE supplementation on the health of women after a breast cancer diagnosis.

Popular Botanicals used in the Treatment of Menopausal Symptoms Possess Estrogenic Activity. In a recent study, investigators evaluated eight of the botanical preparations most commonly purchased by women for the treatment of menopausal symptoms and found that three – red clover (*Trifilium pratense*), hops (*Humulus lupulus*), and chasteberry (*Vitex agnus-castus*) – showed significant estrogenic activity. This suggests that the three herbs might be popular remedies because they supplement the decreased estrogen in menopausal women. Additional studies are needed to determine whether the estrogen-like compounds work similarly to conventional estrogen replacement therapy or have different properties, and what effect those

differences might have on the health of menopausal women.

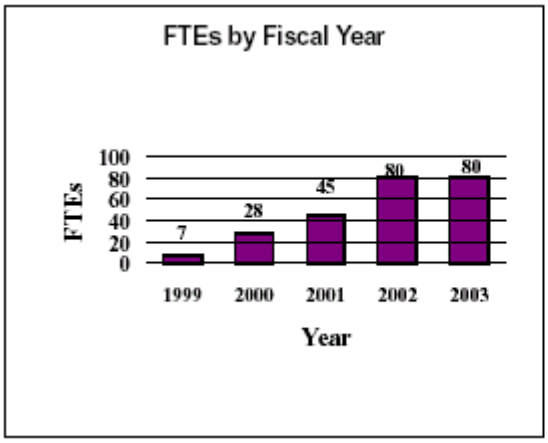
CONCLUSION

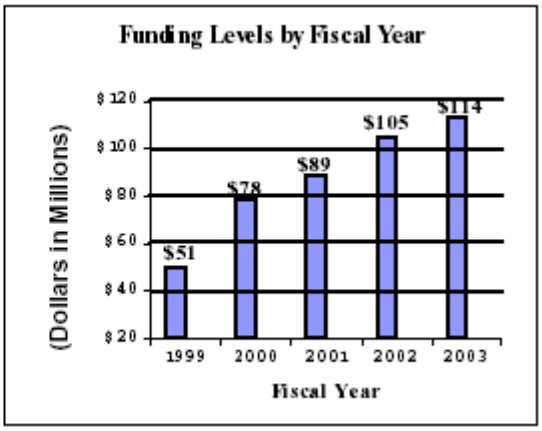
While many CAM remedies have been employed for centuries, we still have much to learn about them. By continuing our studies on their underlying mechanisms and clinical effects, we may succeed in determining which are safe and effective, and therefore suitable for incorporation into medical practice. Well-informed consumers will seek to reject those that are not.

Budget Policy

The Fiscal Year 2003 budget request for the NCCAM is $113,823,000, including AIDS, an increase of $8,843,000 and 8.4 percent over the FY 2002 level.

A five year history of FTEs and Funding Levels for NCCAM are shown in the graphs below. Note that Fiscal Years 2000 and 1999 are not comparable for the Managerial Flexibility Act of 2001 legislative proposal.





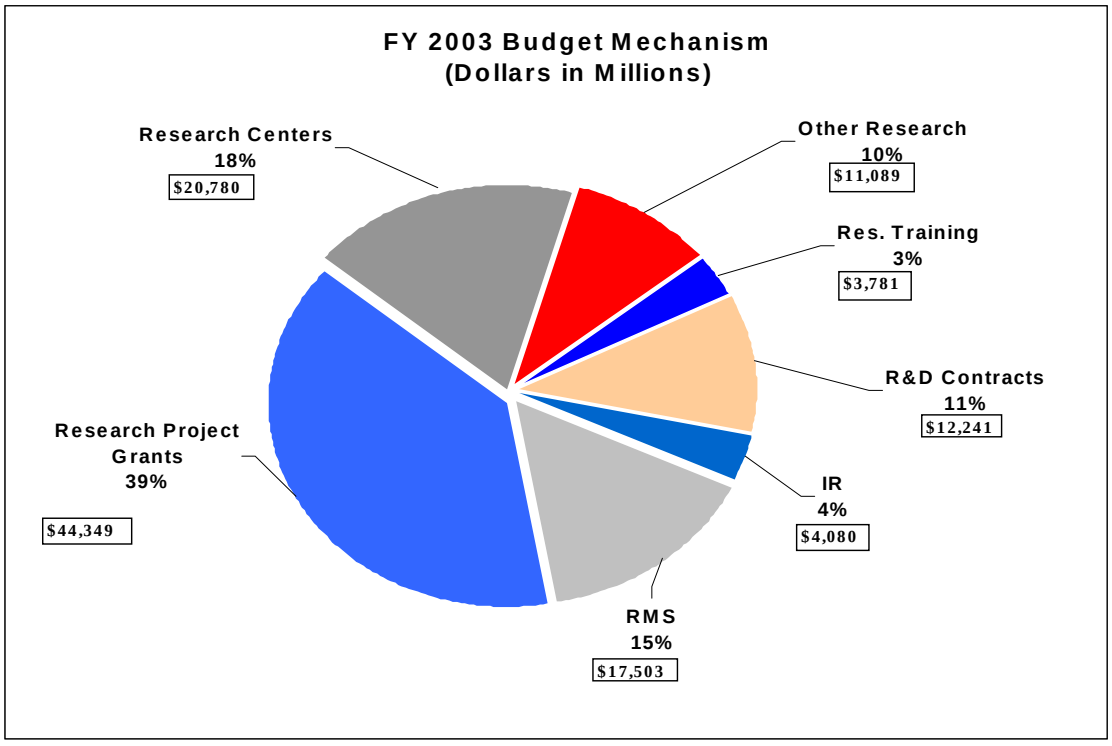
One of NIH's highest priorities is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while providing new research opportunities. The Fiscal Year 2003 request provides average cost increases for competing RPGs equal to the Biomedical Research and Development Price Index (BRDPI), estimated at 4.0 percent. Noncompeting RPGs will be funded at committed levels which include increases of 3 percent on average for recurring direct costs.

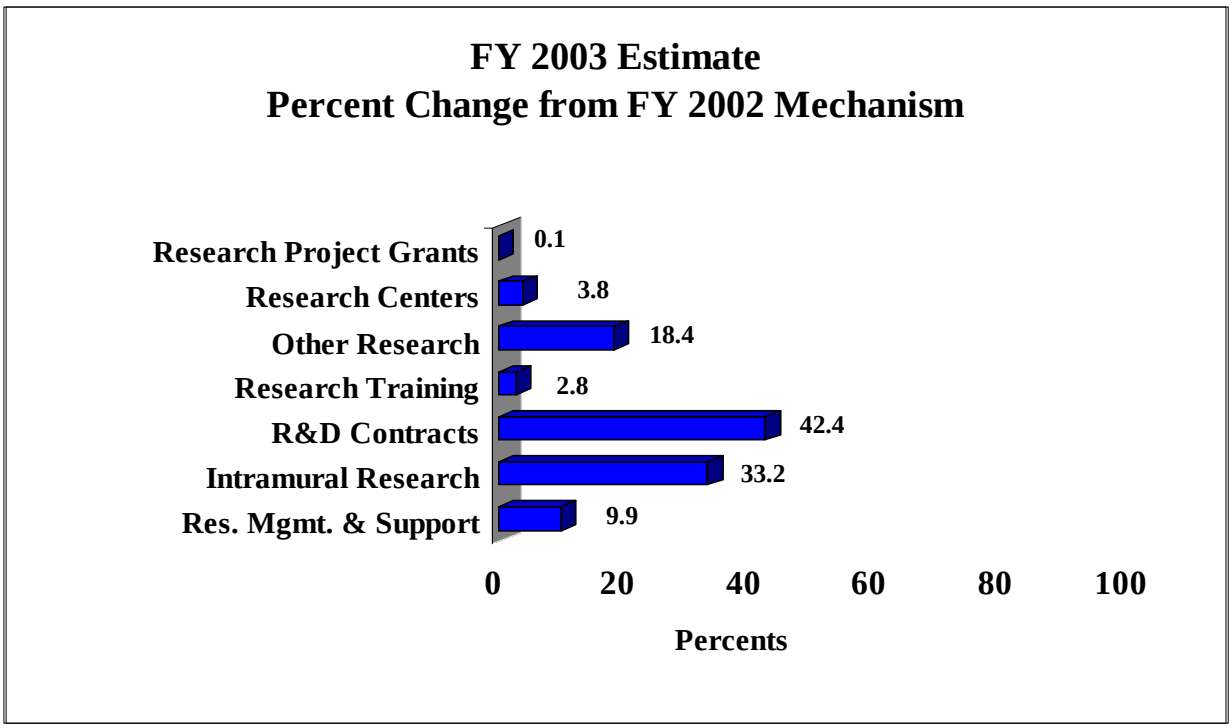
Future promises for advancement in medical research rest in part with new investigators with new ideas. In the Fiscal Year 2003 request, NCCAM will support 72 pre- and postdoctoral trainees in full-time training positions, the same number as in FY 2002. Stipend levels for

NRSA trainees will increase by 4 percent over Fiscal Year 2002 levels.

The Fiscal Year 2003 request includes funding for 23 research centers, 50 other research grants, which includes 7 clinical career awards, and 15 R&D contracts. Intramural Research and Research Management and Support receive increases of 33 and 9 percent respectively over FY 2002. The increase in the FY 2003 IR program over the FY 2002 reflects the development of 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 2003 Estimate
Percent Change from FY 2002 Mechanism
Research Project Grants
Research Centers
Other Research
Research Training
R&D Contracts
Intramural Research
Res. Mgmt. & Support
0.1
3.8
18.4
2.8
42.4
33.2
9.9
0
20
40
60
80
100
Percents

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
TOTAL - Current Law
Budget Mechanism

MECHANISM	FY 2001 Actual		FY 2002 Appropriation		FY 2002 Current Estimate		FY 2003 Estimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	49	$18,972,000	103	$31,257,000	103	$31,257,000	85	$31,877,000
Administrative supplements	(23)	205,000	(25)	250,000	(25)	250,000	(25)	260,000
Competing:								
Renewal	1	365,000	1	380,000	1	380,000	2	565,000
New	67	16,771,000	39	10,162,000	39	10,162,000	34	9,300,000
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	68	17,136,000	40	10,542,000	40	10,542,000	36	9,865,000
Subtotal, RPGs	117	36,313,000	143	42,049,000	143	42,049,000	121	42,002,000
SBIR/STTR	10	2,540,000	10	2,277,000	10	2,277,000	10	2,347,000
Subtotal, RPGs	127	38,853,000	153	44,326,000	153	44,326,000	131	44,349,000
Research Centers:								
Specialized/comprehensive	14	16,478,000	23	20,025,000	23	20,025,000	23	20,780,000
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	14	16,478,000	23	20,025,000	23	20,025,000	23	20,780,000
Other Research:								
Research careers	19	2,872,000	25	4,159,000	25	4,159,000	25	4,284,000
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	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	14	5,303,000	14	5,210,000	14	5,210,000	25	6,805,000
Subtotal, Other Research	33	8,175,000	39	9,369,000	39	9,369,000	50	11,089,000
Total Research Grants	174	63,506,000	215	73,720,000	215	73,720,000	204	76,218,000
Training:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual awards	17	504,000	20	681,000	20	681,000	20	695,000
Institutional awards	46	2,001,000	52	2,996,000	52	2,996,000	52	3,086,000
Total, Training	63	2,505,000	72	3,677,000	72	3,677,000	72	3,781,000
Research & development contracts	10	5,797,000	13	8,647,000	13	8,595,000	15	12,241,000
(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs	
Intramural research	2	2,053,000	15	3,000,000	15	3,000,000	15	4,000,000
Research management and support	43	15,261,000	65	15,600,000	65	15,600,000	65	17,009,000
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction		0		0		0		0
Total, NCCAM	45	89,122,000	80	104,644,000	80	104,592,000	80	113,249,000
(Clinical Trials)		(60,786,000)		(66,864,000)		(66,864,000)		(70,208,000)

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
TOTAL - Accrued Costs for Retirement and Health Benefits
Budget Mechanism

MECHANISM	FY 2001 Actual		FY 2002 Appropriation		FY 2002 Current Estimate		FY 2003 Estimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting								
Administrative supplements								
Competing:								
Renewal								
New								
Supplements								
Subtotal, competing								
Subtotal, RPGs								
SBIR/STTR								
Subtotal, RPGs								
Research Centers:								
Specialized/comprehensive								
Clinical research								
Biotechnology								
Comparative medicine								
Research Centers in Minority Institutions								
Subtotal, Centers								
Other Research:								
Research careers								
Cancer education								
Cooperative clinical research								
Biomedical research support								
Minority biomedical research support								
Other								
Subtotal, Other Research								
Total Research Grants								
Training:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual awards								
Institutional awards								
Total, Training								
Research & development contracts (SBIR/STTR)								
	FTEs		FTEs		FTEs		FTEs	
Intramural research		16,000		63,000		63,000		80,000
Research management and support		340,000		325,000		325,000		494,000
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction								
Total, NCCAM	0	356,000	0	388,000	0	388,000	0	574,000
(Clinical Trials)		(0)		(0)		(0)		(0)

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
TOTAL - Proposed Law
Budget Mechanism

MECHANISM	FY 2001 Actual		FY 2002 Appropriation		FY 2002 Current Estimate		FY 2003 Estimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	49	$18,972,000	103	$31,257,000	103	$31,257,000	85	$31,877,000
Administrative supplements	(23)	205,000	(25)	250,000	(25)	250,000	(25)	260,000
Competing:								
Renewal	1	365,000	1	380,000	1	380,000	2	565,000
New	67	16,771,000	39	10,162,000	39	10,162,000	34	9,300,000
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	68	17,136,000	40	10,542,000	40	10,542,000	36	9,865,000
Subtotal, RPGs	117	36,313,000	143	42,049,000	143	42,049,000	121	42,002,000
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Subtotal, RPGs	127	38,853,000	153	44,326,000	153	44,326,000	131	44,349,000
Research Centers:								
Specialized/comprehensive	14	16,478,000	23	20,025,000	23	20,025,000	23	20,780,000
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	14	16,478,000	23	20,025,000	23	20,025,000	23	20,780,000
Other Research:								
Research careers	19	2,872,000	25	4,159,000	25	4,159,000	25	4,284,000
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	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	14	5,303,000	14	5,210,000	14	5,210,000	25	6,805,000
Subtotal, Other Research	33	8,175,000	39	9,369,000	39	9,369,000	50	11,089,000
Total Research Grants	174	63,506,000	215	73,720,000	215	73,720,000	204	76,218,000
Training:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual awards	17	504,000	20	681,000	20	681,000	20	695,000
Institutional awards	46	2,001,000	52	2,996,000	52	2,996,000	52	3,086,000
Total, Training	63	2,505,000	72	3,677,000	72	3,677,000	72	3,781,000
Research & development contracts	10	5,797,000	13	8,647,000	13	8,595,000	15	12,241,000
(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs	
Intramural research	2	2,069,000	15	3,063,000	15	3,063,000	15	4,080,000
Research management and support	43	15,601,000	65	15,925,000	65	15,925,000	65	17,503,000
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction		0		0		0		0
Total, NCCAM	45	89,478,000	80	105,032,000	80	104,980,000	80	113,823,000
(Clinical Trials)		(60,786,000)		(66,864,000)		(66,864,000)		(70,208,000)

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Budget Authority by Activity 1/
(dollars in thousands)

ACTIVITY	FY 2001 Actual		FY 2002 Estimate		FY 2003 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research:								
Extramural Research and Training		$71,808		$85,992		$92,240		$6,248
Subtotal, Extramural Research		71,808		85,992		92,240		6,248
Intramural Research	2	2,069	15	3,063	15	4,080	0	1,017
Research Managament and Support	43	15,601	65	15,925	65	17,503	0	1,578
Total	45	89,478	80	104,980	80	113,823	0	8,843

1/ Please see the following tables for the crosswalk from current law to proposed law to reflect the administration's proposal for full accrued retirement and health benefits.

National Institutes of Health

National Center for Complementary and Alternative Medicine

2001 Crosswalk for Accrued Retirement and Health Benefit Costs
(Dollars in thousands)

	2001 Actual Current Law	2001 Additional Accrual Costs	2001 Actual Proposed Law
Extramural Research:			
Extramural Research and Training	$71,808	$0	$71,808
Subtotal, Extramural Research	71,808	0	71,808
Intramural Research	2053	16	2069
Research Management and Support	15261	340	15601
Total	89,122	356	89,478

National Institutes of Health

National Center for Complementary and Alternative Medicine

2002 Crosswalk for Accrued Retirement and Health Benefit Costs
(Dollars in thousands)

	2002 Current Estimate Current Law	2002 Additional Accrual Costs	2002 Appropriation Proposed Law
Extramural Research:			
Extramural Research and Training	$85,992	$0	$85,992
Subtotal, Extramural Resarch	85,992	0	85,992
Intramural Research	3,000	63	3,063
Research Management and Support	15,600	325	15,925
Total	104,592	388	104,980

National Institutes of Health

National Center for Complementary and Alternative Medicine

2003 Crosswalk for Accrued Retirement and Health Benefit Costs
(Dollars in thousands)

	2003 Estimate Current Law	2003 Additional Accrual Costs	2003 Estimate Proposed Law
Extramural Research:			
Extramural Research and Training	$92,240	$0	$92,240
Subtotal, Extramural Research	92,240	0	92,240
Intramural Research	4,000	80	4,080
Research Management and Support	17,009	494	17,503
Total	113,249	574	113,823

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Summary of Changes

2002 Estimated budget authority				$104,980,000
2003 Estimated budget authority				113,823,000
Net change				8,843,000
	2002 Current Estimate Base		Change from Base	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Within grade increase		$949,000		$17,000
b. Annualization of January 2002 pay increase		949,000		12,000
c. January 2003 pay increase		949,000		19,000
d. Payment for centrally furnished services		486,000		44,000
e. Increased cost of laboratory supplies, materials, and other expenses		1,565,000		33,000
f. Accrued costs for retirement and health benefits		63,000		17,000
Subtotal				142,000
2. Research Management and Support:				
a. Within grade increase		6,241,000		109,000
b. Annualization of January 2002 pay increase		6,241,000		75,000
c. January 2003 pay increase		6,241,000		118,000
d. Payment for centrally furnished services		1,366,000		123,000
e. Increased cost of laboratory supplies, materials, and other expenses		7,993,000		174,000
f. Accrued costs for retirement and health benefits		325,000		169,000
Subtotal				768,000
3. Cancer Prevention and Control:				
a. Within grade increase				
b. Annualization of January 2002 pay increase				
c. January 2003 pay increase				
d. Payment for centrally furnished services				
e. Increased cost of laboratory supplies, materials, and other expenses				
f. Accrued costs for retirement and health benefits				
Subtotal				
Subtotal, Built-in				910,000

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Summary of Changes--continued

CHANGES	2002 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	103	31,507,000	(18)	630,000
b. Competing	40	10,542,000	(4)	-677,000
c. SBIR/STTR	10	2,277,000	0	70,000
Total	153	44,326,000	(22)	23,000
2. Centers	23	20,025,000	0	755,000
3. Other research	39	9,369,000	11	1,720,000
4. Research training	72	3,677,000	0	104,000
5. Research and development contracts	13	8,595,000	2	3,646,000
Subtotal, extramural				6,248,000
	FTEs		FTEs	
6. Intramural research	15	3,063,000	0	875,000
7. Research management and support	65	15,925,000	0	810,000
8. Construction		0	0	0
Subtotal, program		104,980,000		7,933,000
Total changes	80		0	8,843,000

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Budget Authority by Object

	FY 2002 Appropriation	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease	Percent Change
Total compensable workyears:					
Full-time employment	80	80	80	0	0.0
Full-time equivalent of overtime and holiday hours	0	0	0	0	0.0
Average ES salary	$0	$0	$0	$0	0.0
Average GM/GS grade	10.9	10.9	10.9	0.0	0.0
Average GM/GS salary	$59,920	$59,920	$62,197	$2,277	3.8
Average salary, grades established by act of July 1, 1944 (42 U.S.C. 207)	$81,490	$81,490	$84,586	$3,096	3.8
Average salary of ungraded positions	$131,697	$131,697	$136,702	$5,005	3.8

	OBJECT CLASSES	FY 2002 Appropriation	FY 2002 Estimate	FY 2003 Estimate	Increase or Decrease	Percent Change
	Personnel Compensation:					
11.1	Full-Time Permanent	$4,717,000	$4,717,000	$4,867,000	$150,000	3.2
11.3	Other than Full-Time Permanent	873,000	873,000	939,000	66,000	7.6
11.5	Other Personnel Compensation	140,000	140,000	155,000	15,000	10.7
11.8	Special Personnel Services Payments	62,000	62,000	65,000	3,000	4.8
11.9	**Total Personnel Compensation**	**5,792,000**	**5,792,000**	**6,026,000**	**234,000**	**4.0**
12.1	Personnel Benefits	1,398,000	1,398,000	1,514,000	116,000	8.3
12.1	Personnel Benefits, Accrued Retirement Costs	241,000	241,000	424,000	183,000	75.9
13.0	Benefits for Former Personnel	0	0	0	0	0.0
	Subtotal, Pay Cost, Current Law	**7,190,000**	**7,190,000**	**7,540,000**	350,000	4.9
	Subtotal, Pay Cost, Proposed Law	**7,431,000**	**7,431,000**	**7,964,000**	**533,000**	**7.2**
21.0	Travel and Transportation of Persons	280,000	280,000	300,000	20,000	7.1
22.0	Transportation of Things	20,000	20,000	21,000	1,000	5.0
23.1	Rental Payments to GSA	0	0	0	0	0.0
23.2	Rental Payments to Others	65,000	65,000	70,000	5,000	7.7
23.3	Communications, Utilities and Miscellaneous Charges	115,000	115,000	122,000	7,000	6.1
24.0	Printing and Reproduction	40,000	40,000	42,000	2,000	5.0
25.1	Consulting Services	100,000	100,000	110,000	10,000	10.0
25.2	Other Services	2,109,000	2,109,000	4,096,000	1,987,000	94.2
25.3	Purchase of Goods and Services from Government Accounts	9,900,000	9,900,000	11,626,000	1,726,000	17.4
25.3	Accrued Retirement Costs	147,000	147,000	150,000	3,000	2.0
25.4	Operation and Maintenance of Facilities	400,000	400,000	450,000	50,000	12.5
25.5	Research and Development Contracts	6,267,000	6,215,000	8,000,000	1,785,000	28.7
25.6	Medical Care	30,000	30,000	40,000	10,000	33.3
25.7	Operation and Maintenance of Equipment	5,000	5,000	6,000	1,000	20.0
25.8	Subsistence and Support of Persons	0	0	0	0	0.0
25.0	**Subtotal, Other Contractual Services, Current Law**	**18,811,000**	**18,759,000**	**24,328,000**	**5,569,000**	**29.7**
25.0	**Subtotal, Other Contractual Services, Proposed Law**	**18,958,000**	**18,906,000**	**24,478,000**	**5,572,000**	29.5
26.0	Supplies and Materials	325,000	325,000	400,000	75,000	23.1
31.0	Equipment	400,000	400,000	500,000	100,000	25.0
32.0	Land and Structures	0	0	0	0	0.0
33.0	Investments and Loans	0	0	0	0	0.0
41.0	Grants, Subsidies and Contributions	77,397,000	77,397,000	79,925,000	2,528,000	3.3
42.0	Insurance Claims and Indemnities	0	0	0	0	0.0
43.0	Interest and Dividends	1,000	1,000	1,000	0	0.0
44.0	Refunds	0	0	0	0	0.0
	Subtotal, Non-Pay Costs, Current Law	**97,454,000**	**97,402,000**	**105,709,000**	**8,307,000**	**8.5**
	Subtotal, Non-Pay Costs, Proposed Law	**97,601,000**	**97,549,000**	**105,859,000**	**8,310,000**	**8.5**
	Total Budget Authority by Object, Current	**104,644,000**	**104,592,000**	**113,249,000**	**8,657,000**	**8.3**
	Total Budget Authority by Object, Proposed	**105,032,000**	**104,980,000**	**113,823,000**	**8,843,000**	**8.4**
	Total Accrued Retirement Costs	**388,000**	**388,000**	**574,000**	**186,000**	**47.9**

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Salaries and Expenses

OBJECT CLASSES	FY 2002 Appropriation	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
Personnel Compensation:				
Full-Time Permanent (11.1)	$4,717,000	$4,717,000	$4,867,000	$150,000
Other Than Full-Time Permanent (11.3)	873,000	873,000	939,000	66,000
Other Personnel Compensation (11.5)	140,000	140,000	155,000	15,000
Special Personnel Services Payments (11.8)	62,000	62,000	65,000	3,000
Total Personnel Compensation (11.9)	**5,792,000**	**5,792,000**	**6,026,000**	**234,000**
Civilian Personnel Benefits (12.1)	1,398,000	1,398,000	1,514,000	116,000
Accrued Costs of Retirement Benefits (12.1)	241,000	241,000	424,000	183,000
Benefits to Former Personnel (13.0)	0	0	0	0
Subtotal, Pay Costs, Current Law	**7,190,000**	**7,190,000**	**7,540,000**	**350,000**
Subtotal, Pay Costs, Proposed Law	**7,431,000**	**7,431,000**	**7,964,000**	**533,000**
Travel (21.0)	280,000	280,000	300,000	20,000
Transportation of Things (22.0)	20,000	20,000	21,000	1,000
Rental Payments to Others (23.2)	65,000	65,000	70,000	5,000
Communications, Utilities and Miscellaneous Charges (23.3)	115,000	115,000	122,000	7,000
Printing and Reproduction (24.0)	40,000	40,000	42,000	2,000
Other Contractual Services:				
Advisory and Assistance Services (25.1)	100,000	100,000	110,000	10,000
Other Services (25.2)	2,109,000	2,109,000	4,096,000	1,987,000
Purchases from Govt. Accounts (25.3)	4,542,204	4,542,204	4,668,204	126,000
Accrued Retirement Costs (25.3)	147,000	147,000	150,000	3,000
Operation & Maintenance of Facilities (25.4)	400,000	400,000	450,000	50,000
Operation & Maintenance of Equipment (25.7)	5,000	5,000	6,000	1,000
Subsistence & Support of Persons (25.8)	0	0	0	0
Subtotal, Other Contractual Services, Current Law	**7,156,204**	**7,156,204**	**9,330,204**	**2,174,000**
Subtotal, Other Contractual Services, Proposed Law	**7,303,204**	**7,303,204**	**9,480,204**	**2,177,000**
Supplies and Materials (26.0)	325,000	325,000	400,000	75,000
Subtotal, Non-Pay Costs, Current Law	**7,481,204**	**7,481,204**	**10,250,204**	**2,769,000**
Subtotal, Non-Pay Costs, Proposed Law	**7,628,204**	**7,628,204**	**10,400,204**	**2,772,000**
Total, Administrative Costs, Current Law	**14,671,204**	**14,671,204**	**17,790,204**	**3,119,000**
Total, Accrued Costs	**388,000**	**388,000**	**574,000**	**186,000**
Total, Administrative Costs, Proposed Law	**15,059,204**	**15,059,204**	**18,364,204**	**3,305,000**

National Center for Complementary and Alternative Medicine

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

FY 2002 House Appropriations Committee Report Language (H. Rpt. 56-101)

Item

EDTA Chelation Therapy – EDTA chelation therapy has long been used for improved circulation, but the potential benefits for use of this therapy for claudication or arteriosclerosis has not been studied. The Committee encourages NCCAM, in collaboration with NHLBI, to enhance efforts in this area through all available mechanisms, as appropriate, including clinical trials (p. 91).

Action taken or to be taken

A key area of public interest is the use of ethylenediaminetetraacetate (EDTA) chelation therapy to treat coronary artery disease (CAD), the leading cause of mortality for both men and women in the United States. In FY 2001, NCCAM, in collaboration with the NHLBI, released a formal solicitation for the first major, multi-site, clinical trial to investigate the efficacy and safety of EDTA chelation therapy in individuals suffering from CAD, using rigorous clinical trial design and validated outcomes measures. It is anticipated that in FY 2002, an award for a highly meritorious application will be made following appropriate peer review.

Item

Frontier Medicine – Frontier medicine includes the role of spirituality in healing, vibrational medicine, and subtle energies such as homeopathy, reiki, aromatherapy, Bach Flower Remedies, and Qi gong. Additionally, alternative diagnostic equipment using the human energy field may offer the potential for cost-saving opportunities in health care. The Committee urges NCCAM to enhance research in these areas through all available mechanisms, as appropriate (p. 91).

Action taken or to be taken

Frontier medicine can be defined as those CAM practices for which there is no plausible biomedical explanation. Examples include such interventions as magnet therapy, energy healing, homeopathy, and therapeutic prayer. In spite of the fact that the United States public uses these therapies extensively, little high-quality research has investigated their efficacy and safety. NCCAM currently supports multiple studies in this area under a variety of funding mechanisms including: R01 (research project); R21 (exploratory/developmental grant); F31 (predoctoral individual national research service award); and P50 (specialized center). In addition, we released a request for applications (RFA), “Exploratory Grants for Frontier

Medicine Research," using the P20 (exploratory center grant) mechanism. This program will involve collaboration between conventional and CAM institutions, practitioners and researchers. Projects will test novel hypotheses for which there is minimal preliminary data or lack of a conventional biological rationale. These hypotheses, if confirmed, could have a substantial impact on our current understanding of biology and medical science. Applicants will need to demonstrate strong institutional support, expertise in all relevant disciplines, rigorous study design, a tight thematic relationship between all of the subprojects, and the potential for close collaboration among experiences investigators. It is anticipated that awards will be made in FY 2002 for highly meritorious applications.

Item

Herbal Medicine – The Committee encourages the Center to enhance research to study the basic mechanisms of action and toxicity of herbal medicine through all available mechanisms, as appropriate, including requests for applications. The Committee also encourages the Center to enhance research on the risk of unanticipated and potentially dangerous interactions between botanical and prescription drugs and to continue to seek collaboration with other Institutes on research opportunities on botanical drugs that could lead to the development of new therapeutics (p. 91).

Action taken or to be taken

Botanicals, among the most popular CAM therapeutics, are relied upon by the public for treatment and prevention of a number of conditions. While some may prove to be beneficial to patients, others may be shown to be ineffective or even harmful when used in conjunction with conventional treatments. NCCAM funds more research related to botanicals than to any other form of CAM.

In collaboration with the NIH Office of Dietary Supplements (ODS), NCCAM funds four major Centers for Dietary Supplement Research, each with an emphasis on botanicals. The Centers identify and characterize botanicals, assess their bioavailability and activity, explore mechanisms of action, conduct pre-clinical and clinical evaluations, establish training and career development, and help select the products to be tested in randomized controlled clinical trials. NCCAM's plans include studying botanical-drug interactions and developing standardized botanical products.

In FY 2001, NCCAM funded numerous new projects involving key areas of botanical studies which came to NCCAM both in response to our focused RFAs and as investigator-initiated applications. NCCAM-supported researchers are investigating the varying interactions between popular herbal supplements and important prescription drugs used for chronic diseases, including the use of botanicals by diabetics and cancer patients. Other studies examine the interaction between botanicals and over-the-counter medications, prescription drugs, and other botanicals. In FY 2002, new RFAs will seek studies in complex botanical interactions, the effect of

cranberry on urinary tract infections, and interactions between botanicals and conventional drugs used by HIV patients. Also, NCCAM plans to issue an RFA to initiate further studies of the effect of phytoestrogens on breast cancer through clinical trials. Awards are expected in FY 2003. As these studies demonstrate, the dearth of credible scientific evidence on CAM practices provides unprecedented opportunity for determining the safety and efficacy of CAM modalities.

Item

Research Training Program – As required by the legislation creating NCCAM, NIH is encouraged to assist the Center in developing a research training program for complementary and alternative therapy professionals to improve opportunities for non-MD health care professionals to conduct or participate in high quality research evaluating the effectiveness and potential cost-savings of CAM therapies. NCCAM is also encouraged to establish a clinical research program within the Clinical Center in order to provide intramural research opportunities at NIH (p. 91).

Action taken or to be taken

Through several funding mechanisms, the NCCAM supports a full spectrum of pre-doctoral, postdoctoral and career awards to develop a cadre of skilled investigators in both the CAM and conventional communities. NCCAM is using the National Research Training Award (T32) mechanism to support pre- and post-doctoral trainees in CAM research at minority and minority-serving institutions. NCCAM also has made several of the major "K" awards that train young investigators and that afford more seasoned investigators the professional time to conduct research and serve as mentors. Included are Clinical Research Curriculum Awards to talented clinicians to pursue careers as investigators and to provide them with skills required for conducting rigorous research. The challenge is to train individuals to apply the tools of exacting science to CAM systems and modalities.

In addition, in FY 2000, NCCAM created a novel program to develop and study the effectiveness of model curricula to foster the incorporation of CAM information into medical, dental, nursing, and allied health curricula, as well as continuing medical education programs.

Finally, the creation of a vigorous research presence within the NIH intramural environment itself was deemed an important priority for NCCAM. To this end, in FY 2002, NCCAM appointed the first clinical director of its new Division of Intramural Research. Establishment of the new Division allows NCCAM to develop an intramural research program within the NIH Clinical Center. This intramural research program will stimulate collaboration with other NIH Institutes and Centers, interested Federal agencies, and will serve as a training ground for future CAM researchers. Its work focuses on CAM approaches to major life stressors that affect health in aging Americans, including cancer, depression, arthritis, and pain.

Item

Sickle Cell Disease – The Committee encourages NCCAM to support potential nutritional supplement and food additive research for sickle cell disease through all available mechanisms, as appropriate (p. 92).

Action taken or to be taken

NCCAM is committed to encouraging and supporting highly meritorious research on innovative applications of nutritional supplements and food additives to the treatment and prevention of disease and disability. The Center is aware of such studies specifically for sickle cell anemia, already supported by NHLBI, and is encouraging interested investigators in the field to submit new grant applications. NCCAM will exchange expert information with NHLBI to advance research in this field, whether supported by NHLBI alone, NCCAM alone, or jointly, as circumstances dictate.

FY 2002 Senate Appropriations Committee Report Language (S. Rpt. 107-84)

Item

Complementary and alternative therapies – The Center is charged with ensuring that complementary and alternative therapies be rigorously reviewed to provide consumers with reliable information (p. 174).

Action taken or to be taken

NCCAM is dedicated to exploring complementary and alternative therapies in the context of rigorous science. The Center is committed to building a research enterprise dedicated to examining and establishing, as appropriate, the safety and effectiveness of diverse complementary and alternative medical practices. To achieve this, NCCAM has identified four strategic areas: research investment; research training; proactive outreach; and facilitating a more integrated practice of medicine. Through these major areas of emphasis, NCCAM is committed to providing science-based information to practitioners and consumers. The information is disseminated through the regularly updated NCCAM website, Clearinghouse, Fact Sheets, newsletters, and town meetings.

Item

Funding for existing and new Centers and field investigations – 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 (p. 174).

Action taken or to be taken

Currently, NCCAM provides funding to a total of twelve centers. These CAM Specialized Centers include research in the areas of pediatrics, aging, minority health, cardiovascular diseases, neurological disorders, craniofacial disorders, and chiropractic. Also in collaboration with the NIH Office of Dietary Supplements, NCCAM is currently funding four centers for Dietary Supplement Research with an emphasis on botanicals. In conjunction with our frontier medicine initiative, NCCAM expects to make additional awards in FY 2002.

NCCAM uses a number of resources and has expanded its efforts to obtain and consider the results of alternative treatments provided by practitioners. For example, the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM), in effect, provides the Center with a field investigation function. CAPCAM members – CAM experts and conventional medical oncologists – collect and evaluate outcome data on promising alternative therapies for cancer. NCCAM has also called for the submission of compelling case histories from oncologists and CAM practitioners. This invitation, undertaken in collaboration with staff of the National Cancer Institute's Office of Cancer CAM, has been issued through advertisements in leading conventional and CAM periodicals, announced at multiple meetings, and personal letters sent to practitioners. One major study of an alternative approach identified by a CAM practitioner is under way, a second is in negotiations, a third is under review. To further enhance the efficiency of acquiring field data, NCCAM, through AHRQ, has contracted with the RAND Corporation to compile data history of best-case studies of CAM practitioners for subsequent review by CAPCAM. Two completed analyses will be presented to the CAPCAM in a forthcoming meeting. CAPCAM's members review and assess clinical data submitted through these various mechanisms to identify therapies worthy of more rigorous scientific study by NCCAM.

Item

NCCAM support of CDC field investigations program and AHRQ literature reviews and data analysis efforts – The Committee expects NCCAM to expand its support of CDC field investigations program and AHRQ literature reviews and data analysis efforts (p. 174).

Action taken or to be taken

NCCAM, in conjunction with the Centers for Disease Control and Prevention, has begun epidemiological investigations of the use of CAM within minority and underserved populations, emphasizing the use of traditional and folk medicine among immigrant populations and the rural poor. Information gained from these surveys will help to prioritize NCCAM research agendas for individual populations.

As part of literature review, NCCAM contracts with AHRQ to carry out systematic reviews though the Agency's evidence based practice program, which supports 12 evidence-based

practice centers in the United States and Canada. In addition, the Cochrane Collaboration, an international non-profit organization that emphasizes the need to rely on systematic reviews of scientific evidence, operates the Complementary Medicine (CM) Field, supported by NCCAM. The CM Field Group works to carry out systematic reviews related to complementary medicine.

Item

Fact Sheets – 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 (p. 174).

Action taken or to be taken

Fact Sheets are among the multiple information products that NCCAM makes available to the public. NCCAM has developed fact sheets to address such issues as information on CAM treatments, botanicals, vitamins, and CAM and bioterrorism. There are also fact sheets that address the use of CAM to treat a variety of diseases and disorders, including hepatitis C and cancer. The NCCAM Information Clearinghouse and the NCCAM website serve as principal vehicles for the dissemination of the fact sheets, as well as reports and publications. Both increase public understanding of CAM related topics and CAM research supported by the NIH. The NCCAM website has approximately 600,000 hits per month and has been recognized with numerous awards, including the following: Yahoo! Internet Life, Best Alternative Medicine Information on the Web Award (two years in a row) ; Lycos Top 5%; Eye on the Web Selected Site; The Password Best of the Web; and the Suite 101 Top 5 Best of the Web.

Item

White House Commission on Complementary and Alternative Medicine Policy – The Committee also expects the Center to transfer sufficient funds to the White House for the operations of the White House Commission on Complementary and Alternative Medicine Policy if funds provided in previous years prove insufficient (p. 175).

Action taken or to be taken

NCCAM will continue to provide the funds and resources to the Commission, such as appropriate administrative support and office and conference room space, so that it may continue its operation. The Center continues to work cooperatively with the Commission Executive Director and staff. The NCCAM Director has provided critical information concerning NCCAM's research activities in formal testimony before the Commission. The Commission's charter is set to expire in March 2002.

Item

Plant-based medicinal products – The Committee supports the need to accelerate the development and commercialization of plant-based medicinal products, and encourages the NCCAM to consider collaborating with plant scientists and companies in Hawaii to responsibly use that State's unprecedented biodiversity in developing new, health-enhancing products (p. 175).

Action taken or to be taken

NCCAM funds a large portfolio of studies of botanical products. Many of them are conducted under the auspices of the four major botanical research centers cofunded with the Office of Dietary Supplements. In addition NCCAM has made awards in areas, such as botanical-drug interactions that may be of specific interest to industry. The NCCAM Advisory Council has approved other concepts that may become formal solicitations, such as "Complex Botanical Interactions" and "Phase I/II Trials of Herbal and Pharmacologic CAM Therapies." One recent noteworthy solicitation, "Botanical Products Development: SBIR and STTR," was a solicitation under the aegis of the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (SITR) programs. In that solicitation, NCCAM targeted the development of standardized materials sufficient for the conduct of clinical trials for four botanicals: Echinacea, milk thistle, valerian, and feverfew.

NCCAM plans to collaborate with the producers of raw materials, manufacturers, and marketers of CAM therapeutics as well as groups involved in quality assessment. Also, NCCAM seeks to enhance collaborative opportunities with industry. Toward that effort, on May 14, 2001, NCCAM convened a colloquium to begin a dialogue with two key stakeholder groups: industrial representatives who produce, label, and market CAM therapeutics, and, organizations that develop and apply standards to determine quality and safety of these products. The meeting addressed how NCCAM and industry can work together to evaluate CAM therapeutic products for composition, safety, and efficacy, and to obtain input from the broad stakeholder community. As a result, NCCAM and CAM therapeutics industry have gained an understanding of the common interests and complementary roles each can play and the foundation for pursuing opportunities to develop collaborations has been set.

NCCAM is committed to increasing support to states, including Hawaii, that have not previously been full participants in NIH grants funding. NCCAM Director, Dr. Stephen Straus, Acting Deputy Director of NIH, Dr. Yvonne Maddox, and other NIH leaders, visited Hawaii in November 2001, to participate in an NIH research workshop, hosted by the University of Hawaii – Manoa. During this visit, Dr. Straus was able to promote research opportunities with NCCAM through meetings with top government, community health, traditional medicine and academic officials. Dr. Straus also reviewed the progress of NCCAM grantees at the University and encouraged their further efforts. NCCAM's goal is to make available funding for research projects that foster collaborations between scientists and industry in Hawaii so that the wealth of

biodiversity and indigenous health-enhancing products are of benefit to consumers worldwide.

Item

Traditional and indigenous medicine – The Committee is aware that knowledge of traditional and folk medicine is rapidly disappearing from areas such as the Appalachian region of the eastern United States, and it encourages NCCAM to fund studies that preserve indigenous knowledge of the uses of medicinal plants and investigate possible scientific bases for their efficacy. The Committee further recognizes that the moderated harvest of wild medicinal plants is important to their availability for future use and recommends that funding preference be afforded to those studies that incorporate a holistic approach of scientific investigation and resource management (p. 175).

Action taken or to be taken

NCCAM already funds a number of projects specifically aimed at studies of traditional healing practices in diverse communities. To expand this work through the program announcement (PA), "Traditional, Indigenous Systems of Medicine," NCCAM is currently seeking applications for developmental studies to establish the methodological feasibility and strengthen the scientific rationale for proceeding to full-scale, randomized, clinical trials on the use of traditional, indigenous systems of medicine (those in which the treatment practices are specific to local cultures) as practiced in the United States. Examples of these systems include Kempo, Native American medicine, Unani, and traditional Chinese medicine. The purpose of these studies is to: 1) investigate safety and efficacy; 2) identify and address difficult methodological and design issues particular to complex medical interventions; and 3) allow for the development of contextually and culturally sensitive research, more closely mirroring practice in the United States. Such trials will facilitate acceptance of proven alternative practices by conventional medical providers.

NCCAM is supporting studies of the epidemiology of CAM use in minority populations. These studies examine the emphasis placed on the use of traditional and folk medicine among immigrant populations and the rural poor. In collaboration with the CDC, an epidemiological survey instrument is under development and will be used in the field in 2002.

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2001 Amount Authorized	2002 Estimate	2003 Amount Authorized	2003 Budget Estimate 1/
Research and Investigation	Section 301	42§241	Indefinite	$101,303,000	Indefinite	$110,042,000
National Center for Complementary and Alternative Medicine	Section 417B	42§285	Indefinite		Indefinite	
National Research Service Awards	Section 487(d)	42§288	a/	3,677,000	b/	3,781,000
Total, Budget Authority				104,980,000		113,823,000

a/ Funding provided under the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2002 (P.L. 107-116).
b/ Reauthorizing legislation will be submitted.

1/ Reflects proposed transfer from the National Cancer Institute

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Appropriation 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	113,823,000			

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

National Center for Complementary and Alternative Medicine
Detail of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Office of the Director	5	7	7
Office of Administrative Operations	13	16	16
Office of Communications & Public Liaison	3	7	7
Office of Science Policy and Operations	6	9	9
Division of Extramural Research & Training	14	20	20
Office of Scientific Review	2	6	6
Division of Intramural Research	2	15	15
Total, NCCAM	45	80	80

Statutorily-ceiling exempt FTEs not included above

Funds to support these FTEs are provided by Cooperative Research and Development

FISCAL YEAR	Average GM/GS Grade
1999	12.9
2000	12.1
2001	10.7
2002	10.9
2003	10.9

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine
Detail of Positions

GRADE	FY 2001 Actual	FY 2002 Estimate	FY 2003 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	5	11	11
GM/GS-14	12	13	14
GM/GS-13	4	6	6
GS-12	3	12	13
GS-11	3	2	6
GS-10	2	4	4
GS-9	6	5	6
GS-8	0	3	3
GS-7	9	14	16
GS-6	2	2	2
GS-5	0	0	0
GS-4	3	2	2
GS-3	0	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	**49**	**75**	**84**
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General			
Director Grade	2	2	2
Senior Grade			
Full Grade			
Senior Assistant Grade			
Subtotal	2	2	2
Ungraded	17	32	36
Total permanent positions	49	80	80
Total positions, end of year	68	122	124
Total full-time equivalent (FTE) employment,end of year	45	80	80
Average ES level			
Average ES salary			
Average GM/GS grade	10.7	10.9	10.9
Average GM/GS salary	$57,230	$59,920	$62,197