

"The Role of Complementary and Alternative Medicine in the Detection and Treatment of Women's Cancers"

**Statement of
Edward L. Trimble, M.D., Head
Surgery Section
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Department of Health and Human Services**

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Good morning. I am Ted Trimble, M.D Head of the Surgery Section, Division of Cancer Treatment and Diagnosis at the National Cancer Institute (NCI). I am pleased to be here today to talk with you about the NCI and the evaluation of complementary and alternative medicine in women's cancers. We at the National Cancer Institute recognize that this is an important and challenging issue, and we have taken steps to significantly alter our approaches to complementary and alternative medicine.

Our Nation is experiencing real progress against cancer. This is evident in our cancer incidence and death rates, which are declining. Between 1990 and 1996, these rates dropped for all cancers combined and for most of the top 10 cancer sites. After increasing 1.2 percent per year from 1973 to 1990, the incidence rates for all cancers combined declined an average of nearly 1 percent per year between 1990 and 1996. The peak year was 1992; from 1992 to 1996 the rate decreased 2.2 percent per year. This confirms the continued downward trend that was reported to the nation in 1998 for the period 1990 to 1995. The rates declined for most age groups, for both men and women. The overall death rate declined an average of 0.6 percent a year from 1990 to 1996, with the declines greater for men than for women.

Advances in Knowledge

While these declines are encouraging we continue to strive to accelerate and extend our progress so that all population groups may benefit. The National Cancer Institute is steadily building an environment that fosters the convergence of ideas from traditional and alternative approaches to the goal of eradicating cancer. The collective oncology research community has made exciting advances in understanding the biology of cancer and developing new ways to screen, diagnose, treat and prevent cancer.

- **Angiogenesis**

Particularly compelling is new information about the development of blood vessels, or angiogenesis, and the cancer cell's ability to exploit this natural process. A number of angiogenesis inhibitors, which arrest tumor expansion by curtailing the formation of new blood vessels and, subsequently, the delivery of oxygen and nutrients to the tumor site, are undergoing testing in clinical trials. One of the agents set to be evaluated this year in a phase III trial co-sponsored by NCI and the National Center for Complementary and Alternative Medicine (NCCAM) is Neovastat, a preparation of shark cartilage. For many years other preparations of shark cartilage have been available as dietary supplements and have been used widely in the United States and abroad for treatment of cancer. Other anti-angiogenic drugs are under investigation for the treatment of breast and ovarian cancers and NCI continues to support a broad range of research projects addressing angiogenesis inhibition in breast and ovarian cancers, among others.

- **Cancer Genetics**

The remarkable gains made in the area of cancer genetics have continued to direct progress in the screening and treatment of cancer and NCI has developed tools to maximize the benefit of this expanding collection of information. The Cancer Genetics Network is a group of family registries for breast and ovarian, as well as prostate cancers, enabling researchers to have access to information about inheritance patterns in these types of cancer. Researchers sponsored by NCI continue to study the tumor suppressor genes, BRCA1 and BRCA2. Mutations in these are sometimes present in inherited cancers, but not generally in spontaneous tumors or normal tissue. NCI has established the Genetic Annotation Index, a catalog of variations in cancer-related genes; and the Cancer Genome Anatomy Project, which has the goal of indexing all expressed genes in a given type of cancerous cell. To date, this database contains over 15,000 DNA sequences for breast cancer alone, of which more than 350 are novel genes. Also listed are around 600 unique genes in ovarian tissue, 3 of which have been linked to ovarian cancer. This type of information can be used to identify possible targets for molecular approaches to the diagnosis and treatment of cancer. In March, the NCI issued an invitation for applications for cooperative agreements to establish a national network that will have the responsibility for the development, evaluation, and validation of biomarkers: cellular, biochemical, molecular, or genetic alterations by which a normal or abnormal biological can be recognized or monitored. The NCI funds resources to make available breast cancer tissue specimens to researchers to study potential molecular markers.

- **Molecular Markers**

Advances in the identification of molecules unique to or overexpressed in cancerous cells have led to sophisticated new treatments for many types of cancers suffered by women. The cell surface molecule, HER2/neu, was originally valued as a prognostic factor for breast cancer. NCI continues to support clinical trials gauging the usefulness of a new drug, Herceptin, a monoclonal antibody

targeting HER2/neu for treatment of both breast and ovarian cancer in conjunction with chemotherapy. In addition HER2/neu is under consideration as a target for a cancer vaccine. Selective Estrogen Response Modulators (SERM) modify the effects of estrogen on breast tissue and have been prescribed as an alternative to hormone replacement therapy in women at high risk for breast cancer. The recent NCI-sponsored Breast Cancer Prevention Trial, which addressed the effectiveness of Tamoxifen in preventing breast cancer in high-risk patients, was stopped due to the obvious benefit to women who received the drug. This year the NCI expects to begin a highly anticipated comparison of Tamoxifen and another SERM, Raloxifene, which was approved for treatment of osteoporosis and has been shown preliminarily to reduce the risk of breast cancer.

CA125 is a molecule produced in normal uterine and ovarian tissue and is elevated in ovarian cancer cells. The NCI is sponsoring an important screening study, the Prostate, Lung, Colorectal, and Ovarian Cancer Trial (PLCO), that is, in part, an evaluation of a variety of techniques, including CA125 testing, for uncovering ovarian cancer.

Studies have revealed that approximately 90% of cervical malignancies are linked to infection with Human Papilloma Virus (HPV). NCI has a new study underway in which researchers are looking for ways to manage the mild cervical abnormalities that sometimes progress to cervical cancer. The project is designed to evaluate the usefulness of testing for certain types of HPV as a means to differentiate between abnormalities and determine which treatment would be most appropriate. Another important study supported by NCI is currently being conducted in Costa Rica where investigators have screened about 10,000 women to obtain data on the incidence and prevalence of HPV infection and co-factors that increase the risk of cervical cancer. NCI is sponsoring a phase II trial to determine whether or not a carotenoid – rich diet can be effective in reversing mild cervical lesions. Changes in HPV status will be concurrently monitored. In addition, scientists at NCI are leading the development and testing of two promising HPV vaccines: one that could prevent new infection with HPV and another that would treat existing HPV. Vaccines against HPV could be instrumental in significantly decreasing cervical cancer incidence.

Tumor vaccines, which may encourage the immune system to recognize cancer cells, may help the body reject tumors and also help prevent cancer from recurring. Vaccine therapy in the treatment of women's cancers is an area of intense research activity. NCI is supporting clinical trials investigating the safety and effectiveness of several different types of vaccine-based approaches for the treatment of breast, ovarian, and endometrial cancers, as well as cervical cancer.

- **Natural Products Research**

Since 1955, the NCI has screened samples of plant, marine and microbial origin for activity against cancer, and several clinically effective anticancer drugs,

including vincristine, vinblastine, etoposide, topotecan, adriamycin, actinomycin, bleomycin and paclitaxel (taxol), have emerged from this program. Taxol's antitumor activity was discovered in the 1960s during a largescale plant-screening. Interest in developing the drug increased in 1979 after scientists found that Taxol has a unique mechanism for preventing the growth of cancer cells: it affects the fiber-like cell structures called microtubules, which play an important role in cell division and other important cell functions. Taxol has been proven, through intensive NCI-sponsored testing, to be effective in treating both ovarian and breast cancers and NCI is supporting continuing efforts to apply use of Taxol to other types of cancer including many types of pelvic malignancies. Another promising alternative is docetaxel (Taxotere, Registered Trademark), a compound that resembles Taxol in chemical structure. The drug's manufacturer is conducting independent clinical trials and is cooperating with NCI to test its efficacy in treating a variety of cancers including ovarian and cervical cancers.

Since 1986, the NCI's Developmental Therapeutics Branch has performed collections of plants and marine organisms in over 30 countries located in tropical and subtropical countries worldwide. Over 50,000 plant and over 10,000 marine organism samples have been collected through contracts with botanical and marine biological organizations, working in close collaboration with qualified organizations in the source countries. In addition to testing for activity in the NCI anticancer screens, over 110,000 extracts of these samples are available for testing by investigators at other NIH institutes and in the extramural community for activity against the whole spectrum of human diseases, including cancer, AIDS and opportunistic infections, and diseases of concern to the source countries, such as malaria and other parasitic diseases.

- **Other Treatment Advances**

There has been real progress in successful management of cancers occurring in women. Chemotherapy or hormonal therapy administered prior to surgery has improved overall survival for many breast cancer patients. Women with invasive cervical cancer in five different randomized clinical trials benefited from the use of radiation therapy and chemotherapy given together; until now only one or the other was chosen.

NCI continues to support basic and applied research in many areas. We are moving ahead with a number of research efforts that involve the evaluation of CAM approaches to cancer-related problems. NCI, along with NCCAM, is supporting an evaluation of Dr. Nicholas Gonzalez's nutritional therapy at Columbia Presbyterian Medical Center, one of the NCI-designated Comprehensive Cancer Centers. At present, patients are being screened for the study. Another interesting area of potential research activity is the evaluation of green tea as a cancer prevention strategy.

By employing rigorous methodologies to studies in complementary and alternative medicine, NCI has awarded and continues to support many high quality CAM-related research projects. Among the many research efforts underway are projects examining the effects of dietary interventions in cancer treatment, projects examining the therapeutic value of vitamins and minerals in cancer treatment and prevention, studies in stress and pain management to enhance the quality of life for cancer patients, and studies examining the effect of natural inhibitors of carcinogenesis.

Complementary and Alternative Medicine

The NCI is moving very quickly in important directions to develop CAM information and expand research opportunities for CAM investigators. These activities are broad in scope and include strengthening our relationship with the NCCAM, the careful evaluation of CAM therapies, and the development of accurate CAM information for the public.

Recently, Requests for Applications (RFA) have been issued by NCI in conjunction with NCCAM and other Institutes. The intent is to establish Centers for CAM Research that would provide the resources necessary for the rigorous scientific study of CAM approaches, as well as Specialized Research Centers to investigate the biological effects of botanicals, including those that are available as dietary supplements.

We collaborated with NCCAM on the establishment of a Cancer Advisory Panel (CAP-CAM). The CAP-CAM meets 2 to 3 times a year and draws its 15 members from a broad range of experts from the conventional and CAM cancer research community. This group will review and evaluate summaries of evidence for CAM cancer claims submitted by practitioners, make recommendations on whether and how these evaluations should be followed up, and be available to observe and provide advice about studies supported by the NCCAM and NCI, and about communication of the results of those studies. There already are two submissions from the homeopathy community for review and consideration. Rather than have NCI conduct a best case series review independent of the CAM community, the CAP-CAM will facilitate the joint review of data using this model. We are enthusiastic that this group can work collaboratively in a new partnership between the conventional and CAM cancer research community.

Imaging Research

Medical imaging has experienced astounding advances in the last twenty-five years. X-ray and other techniques allow for the diagnosis of abnormalities of the bones, organs, and other body structures, often before they have caused irreversible damage. Cancers that were once too small to be detected by physical examination can be pinpointed by imaging and treated before they can spread. The early detection of breast cancer by x-ray mammography is an example of the advances made which saves the lives of many women.

Current imaging techniques include more than just the standard x-ray. X-rays can be collected, recorded and analyzed to produce plain images on film or computed tomography (CT) scans. Radioactive materials called tracers, when introduced into the body, seek out a particular organ or structure (such as a tumor) and can yield an image of the organ or structure when special sensing devices detect the decay of the tracer. The responses of tissue exposed to a changing magnetic field can be recorded as magnetic resonance images (MRI). Ultrasound are sound waves of high frequency which can pass through the body and produce images in real time of rapidly moving or stationary anatomical structures.

As a result of these developments, organs deep within the body can now be biopsied by long, thin needles guided safely to their targets by CT or ultrasound scanning, in many cases eliminating the need for general anesthesia and an open surgical procedure. Adaptations of MRI permit the refined visualization even of the arteries of major organs without the need for painful and potentially hazardous injection of contrast material into these vessels. The biggest impact that imaging research has had on women's health has been through the development of mammography.

- **Mammography**

After skin cancer, breast cancer is the most frequently diagnosed cancer in women in the United States. It is second only to lung cancer in cancer-related deaths. It is projected that approximately 175,000 new cases of breast cancer will be diagnosed in 1999, and about 43,300 women are expected to die from the disease this year.¹ A woman's risk for breast cancer increases with age and continues to increase over her lifetime. It is important to understand that most women who get breast cancer have no known risk factors, such as family history of the disease.

Mammography is an imaging process that uses low-dose x-rays to take a picture of the breast. Regular screening mammograms, though not perfect, are the best method available today to detect breast cancer early. Early detection of the disease may allow more treatment options. For most women, the National Cancer Institute recommends regular screening mammograms every one or two years starting in their forties.

The National Cancer Institute has developed information for doctors to help women who are between 40 and 50 years old decide when to begin having regular mammograms. There are six risk factors that doctors should be aware of that pose a high enough risk to warrant screening for a woman in her forties: previous breast cancer; specific alteration in a breast cancer susceptibility gene such as BRCA1 and BRCA2; a mother, sister, daughter with breast cancer; atypical hyperplasia (a condition where breast cells are both abnormal in appearance and increased in number) on previous breast biopsy; 75 percent dense tissue on mammogram at age 45-49; or, two or more breast biopsies, even if the results are benign. If none of these risk factors are present, three weaker factors still need to be considered: age of menarche; the number of previous biopsies (either zero or

one); and, age at their first live birth (the risk for breast cancer for women with no live births is the same as for women who had a child at ages 25-29).

While mammography has had a major influence on women's health in the past twenty-five years, the NCI continues to work on ways to improve imaging methods for cancer detection and diagnosis.

- **Improving Imaging Methods for Cancer Detection and Diagnosis**

The National Cancer Institute (NCI) funds numerous research projects to improve conventional mammography and develop alternative imaging technologies to detect and characterize tumors. For breast cancer screening, high-quality mammography, an X-ray technique to visualize the internal structure of the breast, is the most effective technology presently available. Efforts to improve conventional mammography center on refinements of the technology and quality assurance in the administration and interpretation of the X-ray films. To advance breast imaging, NCI is funding research to reduce the already low radiation dosage; enhance image quality; and develop and evaluate digital mammography as an improvement over the conventional, film-based technique; develop statistical techniques for computer-assisted interpretation of digitized images; and enable long-distance image transmission technology, or teleradiology, for clinical consultations. NCI also funds research on non-X-ray based technologies such as magnetic resonance imaging (MRI), and breast-specific positron emission tomography (PET) to detect the disease.

- **Digital Mammography**

Digital mammography is a computerized technique that captures the image with electronic sensors rather than film, and displays images using an infinite scale of gray tone. This area of research is of great interest. Mammography X-ray films can contain subtle information not easily discernible to the radiologist. Preliminary data indicate that digital mammograms enhance the quality of the image and even magnify the view of specific areas of the breast. This technology is expected to improve the sensitivity of mammography, especially in radiographically "dense" breast tissue, which renders visualization of cancer problematic, and to decrease the radiation dose per mammogram. Digital mammography also will allow advances to occur in computer-aided diagnosis and teleradiology. NCI funds many studies of this technology, including those of the National Digital Mammography Development Group. This multidisciplinary academic and industrial group is developing and evaluating digital mammography and related technologies such as image processing for improved lesion visualization, computer-aided diagnosis for enhanced image interpretation, and telemammography (electronic image transmission providing access to specialized clinical experts at remote sites). Currently, this group is testing the potential of digital mammography to serve as the next generation screening technology. NCI has also just released 2 new Program Announcements to alert the investigator

community and the small business community to the need for and NCI interest in a concerted effort to overcome the problems of display for digital mammograms.

- **Novel Non-Ionizing Radiation (Non-X Ray) Imaging**

Scientists are exploring novel non-ionizing imaging technologies including MRI, ultrasound, optical imaging, and other technologies. The NCI-funded studies encompass basic technology and instrumentation development through pre-clinical and clinical testing. There are currently 41 NCI-funded projects that aim to define the precise role of these technologies in detecting and characterizing breast tumors.

- **MRI, Ultrasound and Optical Technologies**

Of novel non-ionizing technologies, MRI and ultrasound have been the most studied as ways to improve the sensitivity of breast cancer detection and staging. Both have shown potential for improving differentiation between benign and malignant lesions and in detecting tumors in dense breast tissue. Furthermore, MRI appears unique in its ability to define local anatomic tumor extent, or staging, critical for treatment planning. NCI funds a Cooperative Group of 14 medical centers that is evaluating the use of MRI to improve diagnosis of breast abnormalities. Preliminary results are encouraging, and the Cooperative Group has begun to study the value of MRI in screening for early breast cancer in women at high risk, such as those with a strong family history, or who carry the BRCA1 or BRCA2 genes. The Group is now in the process of expanding the study to include women who received radiation for treatment of Hodgkins disease. Such women are at high risk for developing breast cancer several years after their therapy for Hodgkins disease.

MRI and ultrasound have their limitations, too. One disadvantage of MRI is its requirement for the use of injected contrast material. NCI is funding some projects to study MRI techniques that will enhance the natural tissue contrast between normal and abnormal tissue. Advances in such techniques could lead to cancer detection without injecting contrast material. NCI funds a Cooperative Group of eight centers exploring the value of magnetic resonance spectroscopy (MRS) in four different cancers, one of which is breast cancer. Another property of tissue which physicians have used for centuries is the difference in hardness of normal and cancerous tissue, measured now by palpation. An equivalent method for “palpating” tumors deep in tissue is to measure the tissue elastography (compressibility). This can be done with either MRI or ultrasound, and NCI funds projects evaluating both approaches.

About half of cancers detected by mammography appear as a cluster of microcalcifications. Ultrasound does not consistently detect microcalcifications, nor can it detect very small tumors. Another limitation of ultrasound is that is not an automated, reproducible procedure. NCI is funding two research projects on

two different techniques that detect calcifications by ultrasound. Several NCI-funded projects are improving the ability of ultrasound to detect very small cancers, and one project supports the development of an ultrasound device that produces images similar to a computed tomography scan, thus automating the procedure. Progress in all of these areas may come together to make ultrasound an alternative to mammography for breast cancer screening.

Recent technical advances in fiberoptic and laser technologies make optical imaging an exciting new area of potential for early cancer detection. NCI is funding eight projects exploring the use of optical techniques to improve breast cancer detection. Optical signals carry very specific information about the biochemical makeup of the tissue, but localization in space is not as good as with MRI or ultrasound. Therefore, some NCI-funded researchers are developing devices that combine optical techniques with ultrasound, for example, to combine the strengths of both approaches.

Optical technologies also show considerable potential for a variety of other tumors, most notably cancers of the cervix or ovary. Optical detection, diagnosis, and subsequent therapy of early cervical cancer are possible at a single visit, thus eliminating some of the problems associated with PAP smears. Optical technologies applied to the detection of ovarian cancer may bring some progress to this difficult medical problem which has eluded early detection despite advances in so many other areas.

- **Breast Biopsies**

Imaging is also being tested as an aid in performing biopsies. The majority of women in the United States (80 percent) who undergo surgical breast biopsies do not have cancer. As an alternative to surgical tissue removal, image-guided, needle breast biopsy is being studied for women with non-palpable lesions. (Women who have large, palpable lesions usually undergo needle aspirations to determine if their lesions are fluid-filled benign cysts). Image-guided needle biopsy offers the potential advantages of minimized tissue damage, reduced waiting time until diagnosis, and cost savings. A multi-institutional research program is now testing the efficacy and cost-effectiveness of the large-core and fine-needle biopsies compared with more extensive surgical biopsies. (See attached list).

- **Other Areas of Study**

In addition to research on imaging technologies, other research is developing methods to detect products of breast cancer (antigens) in blood, urine, or nipple aspirates, and to detect genetic alterations in women who are at increased risk for breast cancer. Once cancer is diagnosed, studies of these types contribute to characterization of breast tumors and can be useful in treatment planning. Still other NCI-funded projects seek to increase the utilization of mammography

among women in age groups for which mammography has proven benefit. An emphasis is increasing utilization among minority and medically underserved women.

Unconventional Innovations Program

In addition to current imaging research being planned the NCI recently created an Unconventional Innovations Programs (UIP) to spur development of daring technologic improvements in cancer treatment and detection in the 21st century. The five year, \$48 million program seeks to stimulate development of radically new technologies in cancer care that can transform what is now impossible into the realm of the possible for detecting, diagnosing and intervening in cancer at its earliest stages of development.

Envisioned are futuristic technologies that may sound like Star Wars medicine, but which are grounded in scientists' rapidly evolving grasp of how alterations in the molecules within our cells may lead to cancer. These technologies would enable physicians to scan the human body for molecular changes that foreshadow disease and, once detected, to intervene with minimally invasive procedures, including some that may seem like science fiction - such as injectable miniature robotic devices (nanorobots) capable of killing tumors or "smart" polymers that both detect cancer and deliver drugs.

To aid in identifying technology opportunities that could contribute to the stated goal and fundamentally change the way we detect, diagnose, and treat cancer, the NCI solicited input from the scientific community in the fall of 1998 in the form of white papers. Ideas and information submitted by investigators have contributed to the definition of scope for a Broad Agency Announcement (BAA) solicitation of contracts for the development of "Novel Technologies for Noninvasive Detection Diagnosis and Treatment of Cancer." Proposals were due April 15, 1999, and we are planning to make contract awards by September 1999.

The UIP will take a new management approach to the development of technology that will target quantum improvements in existing technologies or entirely new approaches, rather than incremental improvements to the state of the art. UIP management will actively recruit the interest and involvement of investigators from disciplines that have not traditionally received support from the NCI in taking on the defined technology challenge.

Survivorship

Although cancer remains among the worst fears of Americans, it is becoming increasingly clear that cancer is not the "death sentence" it once was. More than 8 million Americans alive today have a history of cancer. The past ten years have seen an explosion of new and effective treatments for cancer. The emergence of these treatments has enabled some researchers to turn their attention to developing treatments that are well-tolerated and effective, and to interventions that will help ameliorate the worst side effects of the treatment and the disease. Measurement of a patient's quality of life now is

included routinely as a component of most NCI-supported clinical trials. Some of NCI's primary quality of life activities and research areas cover several areas.

- **Supportive Care**

The side effects of cancer treatment can not only severely impair a patient's quality of life, but may also leave the patient unable or unwilling to continue with a recommended treatment regimen. NCI continues to pioneer studies on pain relief, fatigue intervention, and the alleviation of other problems that accompany a cancer's progression.

- **Access to Clinical Trials**

NCI believes that clinical trials offer excellent, state-of-the-art treatments for cancer patients and should be accessible to any patient diagnosed with cancer.

- **Rehabilitation**

Even when someone is successfully treated, effects of their disease may remain. Ongoing NCI-supported rehabilitation studies include research on a variety of interventions to aid in more normal functioning.

- **End of Life**

Despite our advances, more than 1,500 Americans die each day from cancer. NCI is actively studying end-of-life issues. In addition to ongoing research in this area, NCI, in conjunction with several offices and other institutes at the NIH, is now currently soliciting proposals for research on ways to ease the final days of cancer patients who can no longer withstand treatment.

- **Long-Term Survivorship**

As more people survive cancer longer, the needs of long-term survivors are gaining increased attention. Because recovering from cancer and living as a cancer survivor are new challenges, the National Cancer Institute (NCI) has established the Office of Cancer Survivorship (OCS) to explore the physical, psychological, and economic well-being of individuals who are cancer survivors. The OCS will support research covering the entire spectrum of issues facing cancer survivors. Areas in which there is opportunity for progress include:

- long-term medical and psychosocial effects of cancer treatment;
- factors that predispose survivors to second malignancies;
- reproductive problems following cancer treatment;
- insurance and employment issues unique to cancer survivors.

Information Resources

Communicating with cancer patients, individuals at high risk for cancer, the general public, and the health care community is a central component of NCI's mission and mandate. Our programs are based upon needs identified through epidemiologic studies and market research among specific population groups, resulting in programs that are relevant and understandable to each group. Our patient education program, leadership initiatives for special populations, and minority research networks are all actively involved in spreading state-of-the-art information about cancer prevention, detection, diagnosis, treatment, and care.

- **Public Information about CAM**

Of considerable importance to all of us is the public availability of accurate, up-to-date information about CAM therapies. NCI has taken steps to assure that this information receives the same consideration as conventional approaches in our evaluation and dissemination efforts.

Detailed CAM summaries are being prepared for cancer therapies identified by our Cancer Information Service and the NCCAM Clearinghouse as being of public interest. The development of these summaries will follow the same model as those for conventional therapies and include specific trial results and references to the published literature. They will be reviewed by the appropriate Physicians Data Query (PDQ) Editorial Board depending on whether the intervention is for the treatment or prevention of cancer or used as a supportive care intervention. In addition, these summaries will be sent to experts in the CAM community for review and comment before they are made available on the NCI web site. Reviews are in progress for shark cartilage and hydrazine sulfate; summaries for laetrile, Essaic, and antineoplastons will be drafted in the near future.

Several months ago, as a result of our own concerns and the constructive input from the CAM community, we removed from the NCI web site all previous CAM information and are creating new information that treats CAM dispassionately and fairly. We are in the process of completely rewriting all the NCI fact sheets that deal with CAM, with hydrazine sulfate and antineoplastons being the first therapies newly available on the web site.

We have established a lecture in CAM at the NCI as part of the medical grand rounds series in our Division of Clinical Sciences and open to all members of the NIH community interested in CAM approaches. The first CAM lecture will be presented by Dr. John Potter on July 20, 1999. The NCI has also initiated a Cancer Complementary and Alternative Medicine Research Interest Group. Dr. Eloy Rodriguez of Cornell University gave the first lecture in this series on April 2, 1999.

The primary avenues NCI uses to communicate with the public and the health care community are:

World Wide Web (<http://www.nci.nih.gov>): Currently NCI is redesigning its web site to increase its usefulness as a communication tool. The new web site will be organized so that clinicians, researchers, and the public can quickly and easily locate up-to-the-minute information that is relevant to their needs. A new addition to NCI's Web site is the CancerTrials site (<http://cancertrials.nci.nih.gov>). Through this site, patients, health care professionals, and the public can learn about ongoing NCI-sponsored trials, read about the most recent advances in cancer therapy, and explore other information resources related to cancer treatment. This web site was used by many patients and others who wanted information about treatment advances publicized over the past several months.

Cancer Information Service: The CIS provides accurate, up to date cancer information to patients and their families, the public, and health care professionals in every state through 19 offices located at NCI-funded Cancer Centers and other health care institutions. By dialing 1-800-4-CANCER, callers are automatically connected, free of charge, to the office serving their region. Information on specific cancer types, state-of-the-art care, clinical trials, and resources such as support groups or screening and smoking cessation programs is provided in English or Spanish by specialists who respond to more than 600,000 inquiries annually. The CIS regional offices are NCI's focal point for state and local cancer education efforts that target underserved, high risk, and low literacy populations. Thousands of patients and others called the CIS to get more information about recent treatment advances that were in the news. The system is experiencing a higher busy signal rate that NCI wishes and efforts are being made to address that problem.

Physician Data Query (PDQ): Patients and health care professionals want and need access to accurate, up-to-date, comprehensive information about ongoing clinical trials. Through PDQ, NCI provides information about NCI-sponsored trials. We are in the process of expanding the database, with the cooperation of patient advocates, the Food and Drug Administration, and the pharmaceutical industry, to include all cancer clinical trials approved by the FDA and to revamp the way information is presented. This system has served as a model for other institutes at the National Institutes of Health, and we want to ensure that it continues to be responsive to the needs of the communities we serve.

Medical choices are increasingly made on an individual basis, requiring that physicians and their patients have access to the resources needed to make an informed decision about their treatment and care. Communicating the importance of research findings to physicians and patients in a clear and understandable manner is central to making critical decisions about a patient's treatment and care. NCI is committed to improving public understanding of emerging science and will continue to work with its public and private partners to raise public awareness of key issues in the treatment and prevention of cancer. NCI will work with its partners to provide the public with accurate, useful, and timely information for physicians, cancer patients and their families.

I will be happy to answer any questions.