

**"On the Status of the Integration of Complementary and
Alternative Medicine (CAM) and Cancer"
Statement of**

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Opening Statement

Good morning. I am pleased to be here today to talk with you about the National Cancer Institute (NCI) and the evaluation of complementary and alternative medicine in cancer. I am pleased because we recognize that this is an important and challenging issue, and we have been taking steps to significantly alter our approaches to complementary and alternative medicine.

I am also pleased to be able to say unequivocally that this Nation is experiencing real progress against cancer. This is evident in our cancer incidence and death rates, which are declining. Between 1990 and 1995, these rates dropped for all cancers combined and for most of the top 10 cancer sites, reversing an almost 20-year trend of increasing cancer cases and deaths in the United States.

After increasing 1.2 percent per year from 1973 to 1990, the incidence rate for all cancers combined declined an average of nearly 1 percent per year between 1990 and 1995. The rates declined for most age groups, for both men and women, and for most racial and ethnic groups. The exceptions were black males, when the rates continued to increase, and Asian and Pacific Islander females, when the rates were level. The overall death rate declined an average of 0.5 percent a year from 1990 to 1995, with the declines greater for men than for women. The only racial and ethnic group not included in the downturn was Asian and Pacific Islander females.

We realize that these declines, while encouraging, must be accelerated and extended so that all of our population benefits.

Recent Advances in Understanding Cancer

As we understand the nature of cancer, we understand that it is a unique set of diseases, and that the answers to cancer are related to the most fundamental mysteries of life itself. We know that cancer is not one disease, but at least 100 different diseases that share

certain features. Because of this it is unlikely that one magic bullet will solve the problem.

The most remarkable progress in the past 25 years has been in our knowledge of cancer biology. We are dramatically extending our understanding of what is required to turn a normal cell into a cancer cell. Cancer arises when a single cell changes so that it divides continuously, released from the controls that constrain the replication of normal cells. This transformation results from changes in the function and activity of genes. Of the approximately 100,000 genes found in the human genome, the altered activities of only a relatively small number of genes are responsible for transforming a normal, well-behaved cell into a cancer cell. Identifying these cancer genes defines the central scientific hunt in cancer biology, and opens an unprecedented window into the nature of cancer. Up until now, our detection tools have lacked the sensitivity and the specificity that we must demand if early detection is to be useful and successful. Our interventions, despite their success, have, by and large, been the result of guesswork. But now, we are at a point where we can transform our approach to cancer.

We also are learning to understand the causes of cancer. Research on cancer risk---the probability that the disease will occur in a given population---is identifying populations with a significant probability of developing cancer. Because cancer is a multistage process, analysis of risk factors leads to the development of prevention and control strategies, as well as early detection methods, and in some cases more precise treatments. Epidemiologic research has identified many factors that increase cancer risk. Most of these are related to environment and lifestyle, while others are part of a person's genetic makeup. With the exception of a few genetic conditions, however, it is still not possible to predict with any degree of certainty that a person having one or more of these factors will develop cancer. This uncertainty is related to the very nature of cancer and the need for many specific alterations to accumulate in a single cell for that normal cell to be transformed into a cancer cell.

NCI Support of Complementary Treatments for Cancer - Links to CAM cancer research

Let me emphasize at the start that the basic tenet of the NIH is to employ rigorous methodologies to reach conclusions based on evidence and not on belief. It is through such methodologies that the intersection between so-called traditional medicine and so-called complementary and alternative medicine will be sought. Standards of evidence cannot be compromised and I am pleased that, on this crucial point, I and many colleagues in the complementary and alternative medicine community agree. 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, including 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.

Before I describe what the NCI is doing to alter both our approach to the evaluation of complementary and alternative therapies and our relationship with the complementary and alternative medicine communities, let me make a few underlying points. First, why is there so much complementary and alternative medicine in cancer? Let me propose two reasons:

First, is the near universal and quite ancient desire both to explain observations about health and disease and to contribute by turning those observations, beliefs and theories into interventions. Whether capturing folk traditions or individual contributions, these activities offer an often confusing but potentially rich storehouse of information.

Second, is the frustration that all of us have with the inadequacy of so many of our current therapies, especially for certain cancers and especially for far advanced cancer. Those of us dedicated to eradicating cancer have two reasons to be open to the evaluation of non-traditional therapies. However, under no circumstances can that replace the need to subject them to vigorous tests of efficacy that must be based on rules of evidence and not on anecdotes, beliefs or testimonials, no matter how compelling they may seem.

First, we will not be successful in alleviating cancer unless we are open to new ideas and new approaches. We have learned that anecdotes and folk traditions have often guided us to real and effective therapies.

Second, many people take complementary and alternative medicines and they reasonably ask who is providing evidence as to whether they help, do nothing or are harmful. The question is, how do we best go about both choosing which complementary and alternative medicines to evaluate through rigorous clinical trials and designing those trials so that they yield timely and credible answers.

Let me emphasize that an evidence-based approach to evaluating therapies must be imposed on every step that leads us to initiate a trial. There are thousands of potential therapeutics and that number multiplies with the nearly endless combinations that could be tested. The result is that only a tiny fraction of what is possible to test could possibly be brought to clinical trial. At every step of the way, the weight of evidence supporting an intervention and the rationale behind it must be evaluable and evaluated to prioritize which approaches to move forward with. The challenge before us is to assure that complementary and alternative approaches have real access to the same processes of evidence and review that all interventions must live up to.

NCI/OAM Collaborative Efforts to Evaluate CAM Cancer Research

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 Office of Alternative Medicine (OAM), the careful evaluation of CAM therapies, and the development of accurate CAM information for the public.

While it is true that the relationship between the CAM communities and the NCI has been distant at best, I feel we have finally and securely moved beyond this period. There exists a real commitment by the NCI to learn as well as to inform and to listen as well as to speak. We are in final stages of appointing an individual to be the Coordinator for CAM therapies at NCI, a position that has never before formally existed. This individual will be a member of the cancer research community whose primary interest and responsibility will be to develop relationships with the CAM community and to function as a liaison with the NCI research community on behalf of the CAM community to encourage collaboration and joint research initiatives.

We are also collaborating with OAM to implement the recommendations of the Practice Outcomes Monitoring and Evaluation System (POMES) report including the establishment of a Cancer Advisory Panel (CAP-CAM). A slate of potential members has been jointly developed by NCI and OAM to be presented to the OAM advisory board for their review in September. The CAP-CAM will be expected to meet 2 or 3 times a year and draw its 13 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 to the OAM and the NCI on whether and how these evaluations should be followed up, and, be available to observe and provide advice about studies supported by the OAM and NCI, and about communication of the results of those studies. We are enthusiastic that this group can work collaboratively in a new partnership between the conventional and CAM cancer research community. There already are two submissions from the homeopathy community for review and consideration once the panel is constituted. Rather than have NCI conduct Abest case series@ review independent of the CAM community, the CAP-CAM will facilitate the joint review of data using this model.

We are also moving ahead with a number of research efforts that involve the evaluation of CAM therapy.

Due to public interest in the potential anti-cancer activity of shark cartilage and its continued use despite the lack of definitive clinical evidence of efficacy, the NCI is collaborating with OAM to sponsor clinical trials in this area. The NCI issued a public request soliciting proposals to conduct randomized phase III clinical trials evaluating the clinical activity and efficacy of a shark cartilage product. Five proposals have been received and are in the process of being reviewed.

The NCI is working with OAM to begin an evaluation of Dr. Gonzalez's therapy at Columbia Presbyterian Medical Center, one of the NCI-designated Cancer Centers. Both NCI and OAM will be providing support for the trial and NCI is working with the Columbia clinical investigators to have the Investigative New Drug (IND) filed as quickly as possible. It is expected that funds will be in place and the IND approved by the end of September.

Another interesting area of potential research activity is the evaluation of green tea as a cancer prevention strategy. NCI staff in the Division of Cancer Prevention have met this

week to review the evidence that exists, make an assessment of the weight of this evidence, and then propose recommendations about the appropriateness of moving forward with future evaluations.

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 OAM 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 antineoplastins 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 shall establish 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.

We are discussing with Dr. Barnett Kramer, the Editor of the Journal of the National Cancer Institute, the possibility of instituting a regular feature on CAM and cancer. This would, in my view, be a very useful thing to do; the ultimate decision on how this ought to be implemented will rest with Dr. Kramer and his Editorial Board.

As Director of NCI, I have a strong commitment to improving relations and eliminating as best as possible the tension between the two research communities. Both communities share a common and admirable goal - to cure cancer. It is vital that we work together to that end.

I will be happy to answer any questions.