# SOLVING THE CANCER CRISIS: COMPREHENSIVE RESEARCH, COORDINATION AND CARE

## HEARING

BEFORE THE

## COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

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# SOLVING THE CANCER CRISIS: COMPREHENSIVE RESEARCH, COORDINATION AND CARE

**FRIDAY, JULY 31, 1998**

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
*Washington, DC.*

The committee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Miller, Waxman, Maloney, and Kucinich.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; David A. Kass, deputy counsel and parliamentarian; Laurie Taylor, professional staff member/counsel; Judith McCoy, chief clerk; Teresa Austin, assistant clerk/calendar clerk; Will Dwyer, director of communications; Bill Hanka, deputy director of communications; John Williams, press secretary; Robin Butler, office manager; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Cherri Branson, minority counsel; Earley Green, minority staff assistant; and Ellen Rayner, minority chief clerk.

Mr. BURTON. The committee will come to order.

Before we start our hearing today, I would like to make mention of Officer Chestnut, who lost his life last Friday, along with Detective Gibson, who was buried yesterday at Arlington. We would have deferred the hearing today except that people were already on their way and had made plans, and so we do not want this to be seen as any disrespect whatsoever for Mr. Chestnut, whose funeral process will be starting shortly.

So I would like for everyone to bow their head for a moment of silent prayer in remembrance of these two great officers.

Thank you.

Today, we will continue a series of hearings begun earlier this year focusing on improving access to alternative medical treatments for millions of desperately ill Americans. Today, we will focus on a disease that we know will kill half a million Americans this year and will afflict many more Americans. That is cancer. Cancer is not choosy. It strikes people of all ages, races, and economic backgrounds. Cancer now strikes one in three and kills one in four, and that is up from an incidence on one in four and mortality of one in five in the 1950's. So the increase has been substantial since the 1950's.

It is with regret that I say again that more than 25 years have passed since President Richard Nixon first declared war on cancer.

He predicted a cure in 5 years. So far, cancer has won; and it has touched probably every family in America one way or another. He predicted a cure within 5 years. It has not happened. This despite the fact that the budget of the National Cancer Institute has increased over tenfold, from $223 million in 1971, to an estimated $2.2 billion in 1998. This rate of increase has occurred in the face of escalating cancer incidence rates and little improvement in survival rates. What is more, we seem to be making little progress toward a cure or even in developing promising treatments. This is a sad commentary, given the billions upon billions of dollars that have been spent by this Government in the last 25 years to fight this deadly disease.

There are growing numbers of cancer patients who want and need options other than that which current conventional medicine provides to them. There are growing numbers of cancer doctors who realize that they are not meeting the needs of their patients. We are going to hear testimony from a cancer doctor today who tired of signing the hundreds of death certificates which faced him in his practice over the years, he knew he had to begin searching for alternatives to save his patients or, at the very least, to salvage their quality of life. Today he treats cancer patients with a variety of treatments which are nontoxic and produce more positive results.

In recent years, the media has reported that polls of American citizens show an astounding 40 to 60 percent have used some form of alternative therapy. What qualifies as alternative medicine? Some define it as any kind of treatment that is not taught in conventional medical schools. Most often, it is some therapy that a patient uses in conjunction with his or her conventional treatment. Yet, the vast majority do not tell their physicians because they feel they will reject anything not considered "conventional medical treatment." Perhaps we need to address medical education and encourage progress and change in that arena also.

In our February hearings, we heard sworn testimony from patients who feel that alternative and complementary treatment saved their lives. We will hear more of that today from doctors who have been stricken with cancer. We will hear the National Cancer Institute trumpet the minor reduction in certain categories of cancer deaths in the last 5 years, but we must wonder if that is, in fact, tied to the increased use of alternative therapies.

In past hearings, our distinguished ranking member, Mr. Waxman, and others pointed out that no matter how successful some individuals might find these treatments, a crucial piece of the puzzle is still missing, and that is scientific research. Without well-documented data, anecdotes are still just anecdotes. But if research is properly performed on the therapies that show promise, American citizens will have the information they need to make intelligent choices.

And if that research is federally supported, as it should be, then it is much more likely that successful therapies will be more widely used by physicians across the country, more often reimbursed by insurance plans and, most importantly, will save more lives. The intention here is not to throw the baby out with the bath water. Conventional treatments for cancer have shown to be effective in

some cases. But more and more doctors are realizing that treating cancer must involve more than trying to eliminate the cancer cells with some form of surgery and toxic chemical regime. The use of complementary treatments, a complete protocol consisting of a number of therapies and approaches used together, often have more favorable results.

Finding ways to change life-styles, reduce stress, strengthen relationships with loved ones and create a fulfilling spiritual life can boost the immune system and provide a better quality of life and often a longer life. We will hear from a distinguished doctor this morning who founded a center for mind-body medicine, and he will tell us about the necessity of treating the whole patient instead of just the physical symptoms.

As well, we will hear from a highly respected surgeon with Memorial Sloan-Kettering Hospital, who used complementary medicine to treat his own cancer. In fact, three of the four members of our second panel are physicians, doctors who have suffered from cancer and bring an enlightened perspective of the necessity of research of these therapies.

Despite the growing popularity and success of alternative and complementary treatments, some of our government institutions have resisted that trend. It has been 8 years since the New England Journal of Medicine first reported an astounding increase in the use of alternative medicine, and the Federal Government is just now beginning to take steps needed to properly research these treatments.

The Office of Alternative Medicine began in 1992 with minuscule funding and still receives only a fraction of what is needed to conduct meaningful research. But some progress is being made. Last year, the Office of Alternative Medicine and the National Cancer Institute brought together approximately 80 experts across the medical spectrum who made recommendations for how to move forward with research on complementary and alternative treatments for cancer. Implementing these suggestions has been slow, but it must be done. And today we have the esteemed directors of both the National Cancer Institute and the Office of Alternative Medicine to provide us more information on how this research is going to move forward.

The title of today's hearing is, "Solving the Cancer Crisis: Comprehensive Research, Coordination and Care" because I believe that the American people have clearly voted with their feet by visiting alternative practitioners by the millions and by their wallets by spending on alternative treatments in the billions of dollars.

Comprehensive research is imperative to assist the public in their search for quality treatment. Coordination among agencies at the National Institutes of Health and among conventional and unconventional practitioners is necessary for this research; and, if done correctly, Americans stricken by cancer will begin to get the care they deserve.

With that, I yield to my colleague from California, Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Today's hearing comes on the heels of last week's hearing in the Commerce Subcommittee on Health and Environment regarding the state of cancer research. The best and brightest cancer re-

searchers in the United States testified about recent progress in new cancer treatments, prevention and research. The National Cancer Institute provided a global overview of our public portfolio of cancer research. It was a highly educational hearing.

Today's hearing examines just one thread of the fabric of research and care described last week. Alternative medicines and therapies are but one of many areas of investigation and are eligible for public funding.

Earlier this month, the Institute of Medicine released a report on priority setting in NIH research funding. The report recommended that NIH "more fully engage the public" in its priority-setting by establishing a council of public representatives and offices of public liaison at each institute.

In this respect, alternative medicines already enjoy substantial institutional representation at NIH. In the past, Congress has created an Office of Alternative Medicine and an Office of Dietary Supplements reporting directly to the NIH Director; and I would like to submit information regarding both offices following my statement for the hearing record.

More importantly, the Institute of Medicine emphasized that NIH should continue to use science-based criteria and robust analysis of health statistics to determine how to allocate its funding and which scientific opportunities to target to determine how to allocate its funding and which scientific opportunities to grant awards and contracts.

On this point, there is almost universal agreement. Science must decide how NIH invests our public dollars—not anecdote, not wishful thinking, but science.

In the realm of cancer research, that means alternative medicines must compete shoulder to shoulder on the basis of scientific scrutiny against Taxol, genetically tailored antibodies, recombinant breast cancer vaccines and the many other promising areas of research described last week by our country's leading cancer researchers.

I believe that NIH has done a good job of balancing our country's many health needs in defining our country's biomedical research portfolio, but clearly more can be done. And I encourage Dr. Klausner and Dr. Varmus to pay heed to the IOM's recommendation.

Before yielding back my time, I just want to make a comment. This week is the anniversary of the only tobacco legislation the Congress is going to pass, and that was a provision snuck into the Balanced Budget Act that gave the tobacco companies a $50 billion tax break.

The reason I point that out is that, if we had a serious effort to reduce smoking in this country, the cancer rates would plummet. We would be talking about the great success of the war on cancer. Yet the Congress has been unwilling to do anything to offend the tobacco companies—for good reason. The leadership in the House of Representatives has received millions of dollars from the tobacco companies, and they do not want to offend those contributors.

So the only bill that we saw passed was one that was snuck into law giving the tobacco companies this huge break. It is the kind of thing that a committee looking at campaign finance abuses

ought to be investigating. But this committee has not looked at that issue.

The reason I point that out is that it is easy to complain that research and science has not given us the ways to stop cancer, but we know ways that we could stop cancer and prevent it and not have to struggle with the very difficult problems of cures and control. So it seems to me we ought to put this in perspective.

We want more research. We are willing to spend taxpayers' dollars to try to give us the hope of the way to deal with this disease. But we know already a way to deal with the disease that would be very, very successful, and the Congress of the United States has refused to act.

I welcome Dr. Klausner and the rest of our witnesses. I look forward to their testimony. And I yield back the balance of my time.

Mr. BURTON. I thank the gentleman.

[The prepared statement of Hon. Henry A. Waxman follows:]

**STATEMENT OF CONGRESSMAN HENRY A. WAXMAN**
**HEARING ON "SOLVING THE CANCER CRISIS: COMPREHENSIVE RESEARCH, COORDINATION AND CARE"**
**2154 Rayburn House Office Building**
**Friday, July 31, 1998**

Mr. Chairman, today's hearing comes on the heels of last week's hearing in the Commerce Subcommittee on Health and Environment regarding the state of cancer research. The best and brightest cancer researchers in the United States testified about recent progress in new cancer treatments, prevention and research. The National Cancer Institute provided a global overview of our public portfolio of cancer research. It was a highly educational proceeding.

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I believe that NIH has done a good job of balancing our country's many health needs in defining our country's biomedical research portfolio. But clearly, more could be done. I encourage Dr. Klausner and Dr. Varmus to pay heed to the IOM's recommendations.

I welcome Dr. Klausner and the rest of our witnesses, and look forward to their testimony.

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# Scientific Opportunities and Public Needs

## Improving Priority Setting and Public Input at the National Institutes of Health

Committee on the NIH Research Priority-Setting Process

Health Sciences Policy Program

Health Sciences Section

INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1998

## Executive Summary

The National Institutes of Health (NIH) is the leading federal agency supporting research related to improving the nation's health. The scientists and clinicians whom it has helped train and support have consistently been at the forefront of research discoveries that have advanced fundamental knowledge of human biology and of better ways to treat or prevent disease and promote good health. Over the past 50 years, NIH as an institution has played a major role in the explosion of knowledge that has amounted to a revolution in biology.

NIH's success has earned it steadily increasing budgets even when the overall federal budget has been tight, as it has been in recent years. Although the NIH budget for the current fiscal year (1998) is more than $13 billion and both the administration and the U.S. Congress have promised a substantial increase for 1999, it will never be large enough to meet every need or fund every promising lead. Choices must be made and priorities must be set.

Concerns about priority setting in the allocation of NIH research funding come from several sources. First, some members of Congress believe that there should be more of a correlation between the allocation of funding by disease and the distribution of disease burdens and costs in the population. Second, more and more disease-specific interest groups have begun campaigning for increases in NIH funding related to particular diseases. Additionally, many of these groups do not feel that NIH listens or responds to their inputs. Finally, the leadership of the health committees in Congress has become increasingly uncomfortable with intervening in research priority setting at NIH, for example, by mandating specific funding set-asides, new programs or institutions focused on specific diseases, or the use of particular research mechanisms or by trying to

push research advances in specific areas in other ways. For these reasons, this [illegible]nittee has been asked to evaluate the processes for setting priorities at NIH, particularly NIH's mechanisms for obtaining public input and the role of Congress in directing the allocation of funding among areas of research.

In setting priorities, NIH must also adapt to a changing policy environment. Despite having a growing budget, scientific research opportunities have grown even more rapidly, as has awareness of health problems as the population ages and as globalization exposes the U.S. population to emerging or reemerging infectious diseases.

To meet the expectations of the American people and fulfill the agency's mission, NIH's leaders must pursue many objectives. Two of the most important are (1) to identify the public's health needs, reducing the burdens of illness by developing better methods of prevention, diagnosis, treatment, and rehabilitation, and (2) to extend the basic knowledge base to lead to even better methods in the future. These two objectives are complementary and must be pursued with equal intensities if NIH is going to be successful. A third important objective is to communicate to the public and health providers the current state of scientific knowledge and the implications of research advances for improving the nation's health. Box 1 describes some of NIH's constituencies.

**BOX 1 NIH Constituencies**

NIH interacts with various external constituencies who have a stake in research priority setting. These include:

- research scientists in universities, colleges, medical centers, and other research institutions outside NIH who conduct most of the research funded by NIH;
- patients who apply research results and who can help identify research needs to [illegible], including specialized physicians, nurses, dentists, pharmacists, social workers, psychologists, public health practitioners, and other allied health practitioners;
- organized voluntary groups and individuals active in advocating for those with specific diseases or medical conditions;
- organizations and individuals who represent population groups with special health problems (members of particular ethnic groups, low-income populations, women, elderly people, children, etc.);
- Congress, which provides NIH with the authority and funding to carry out its mission, which oversees its effectiveness, and with which NIH must maintain good communication about priorities; and
- media who communicate research results and NIH activities and who thus play an important role in helping the public understand the research enterprise.

Identifying the burden of illness, however, is not a straightforward [illegible]. As indicated in the NIH booklet "Setting Research Priorities at the [illegible]ional Institutes of Health" (National Institutes of Health, 1997b) (referred to hereafter as Setting Research Priorities), there are many ways to measure the burden of disease because the problem can be analyzed and interpreted from many different perspectives. These are all relevant because the concept of the burden of disease is very broad.

> When applied to illness, the burden includes the heavy load borne by society in providing services to prevent, cure, and care for the sick. It also includes the substantial losses of output to the economy due to disease, disability, and death. The burden on the family in caring for and accommodating a sick member of the household can also be severe. Finally, there is the burden of pain, discomfort, and suffering of each sick person and that of anguish and grief of relatives and friends (Institute of Medicine, 1976:2).

Assessing the burden of disease takes into account the fact that the benefits of past research have not reached everyone, indicated by significant differentials in disease rates and outcomes among different socioeconomic and ethnic groups. Also, about half the nation's health care costs result from unhealthy behaviors and environments, which pose major research challenges. In addition, state-of-the-art screening, diagnostic procedures, and treatments are not reaching everyone, resulting in unnecessary burdens of undetected or poorly treated diseases, and patient and provider knowledge could be improved through education. All of these factors must be weighed and balanced in the priority-setting process.

The committee assessed NIH's priority-setting process in light of the agency's mission and objectives and the changing policy environment. Are the criteria adequate? Is the process for implementing them working? Given the objective of responding to health needs as well as scientific opportunity, in conjunction with the expansion of organized disease-specific interest groups, are the mechanisms for public input adequate, or can they be changed to increase the complementarity between NIH's goals of responding to health needs and scientific opportunity? Can Congress, the holder of the public purse strings, be assured that NIH has a rigorous process for priority setting in which the full range of considerations is taken into account in planning programs and allocating funding?

The committee concludes that NIH's system for setting priorities has generally served NIH and the nation well in supporting research to improve human health, but some changes would strengthen it, especially in mechanisms for exchanging information and concerns with interested individuals and groups. The process by which NIH sets its research priorities should more fully engage the public (i.e., the public should have greater opportunity to learn about and provide input into the priority-setting process) in a process that is led by the director, guided by reasonable criteria, and well informed by robust analyses of health statistics. The process should be open and understandable, include multi-

strategic planning, and give appropriate consideration to the competing needs of scientific opportunity and disease burden. Effective implementation of such a process would improve public access to the process and limit the need for congressional directives.

## CRITERIA FOR PRIORITY SETTING

The committee reviewed the major criteria that NIH uses in its overall priority setting. These criteria were explicitly laid out in Setting Research Priorities, and the committee concluded that they are generally reasonable and useful both for allocating research resources and for enabling organized interest groups, members of Congress, and members of the public to understand and evaluate NIH's program. The criteria are

- public health needs,
- scientific quality of the research,
- potential for scientific progress (the existence of promising pathways and qualified investigators),
- portfolio diversification along the broad and expanding frontiers of research, and
- adequate support of infrastructure (human capital, equipment and instrumentation, and facilities).

The committee wants to be sure, however, that the conceptualization of the first criterion, public health needs, be broadened beyond the medical model implied in the discussion of the criterion in the booklet to include the preservation and maintenance of health and function.

***Recommendation 1.*** **The committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.**

To enhance the legitimacy of and support for its priority-setting and resource allocation processes, NIH should work to increase the level of understanding of its criteria by the general public and of how they are implemented and should engage in regular evaluations of how the criteria are used and of their impacts. The Setting Research Priorities booklet and other documents are not as effective at gaining public understanding as they could be, for example, in informing citizens who are concerned about health and particular diseases about how they can become involved (an issue addressed more fully below in the section Mechanisms for Public Input).



***Recommendation 2.*** **NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.**

The committee found that some of the information needed for priority setting, especially data on disease burden and costs, is obtained rather informally and concluded that NIH should be more systematic in obtaining and analyzing such data. It should be kept in mind, however, that there is no simple metric for the use of these data, and the relationship between such data and allocations of research funding will not be simple because health problems are not equally ripe for research advances.

***Recommendation 3.*** **In setting priorities, NIH should strengthen its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.**

Individuals and groups concerned about specific health problems or health research often use NIH-generated data on spending by specific diseases or area of research to assess the overall research portfolio. The data are not of the quality that they could be, however, and NIH should work to improve the data and to better explain the data to the public. Calculations of spending by disease should include not only all research directly related to the disease but also research projects on fundamental areas indirectly related to that disease. Users of the data should know that such calculations reflect the best estimates of all NIH spending in particular areas and that fundamental science is essential to understanding the etiology and progression of disease.

NIH should also collect and analyze data on health research spending by others, such as other federal agencies, industry, nonprofit health organizations that fund research, foundations, or other countries. This should help identify gaps, overlaps, and opportunities for joint efforts and ensure that NIH invests wisely in areas and approaches that no one else is funding, provides the appropriate coordination, and supports the training of personnel and the other infrastructure needed in the national research enterprise.

***Recommendation 4.*** **NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.**

## PRIORITY-SETTING PROCESSES

Priority setting is decentralized at NIH, which is appropriate for a research organization in which those closest to a problem are in the best position to de-

cide on approaches and in which expertise is highly specialized. The priority-setting processes also vary from institute to institute and from area to area within institutes. Some such variation is appropriate, because the institutes vary in their missions, histories, leadership, sizes, and complexities. The committee did find that some institutes and programs have priority-setting processes that incorporate a broader range of inputs and views, including those of nonresearchers and nonclinicians.

More recently, NIH has been making decisions on priorities and funding allocations that are more centralized than in the past; that is, NIH is looking across traditionally independent institutes and centers and focusing on certain crosscutting needs and opportunities where joint or unified action is desirable. This trend stems from the growing realization that common biological processes underlie diseases that were previously seen as different or that important diseases and other health problems are more complex than was previously thought, affect more organs and processes than was previously realized, and happen to be addressed in more than one institute.

The committee concluded that the Office of the Director of NIH needs an increased capacity to analyze such crosscutting needs and opportunities and to interact with the public (the latter process-related issue is addressed separately below). Improvement requires a more central role for the NIH director and more uniformity in the data and analyses presented to the Office of the Director.

> ***Recommendation 5.*** **In exercising the overall authority to oversee and coordinate the priority-setting process, the NIH director should receive from the directors of all of the institutes and centers multiyear strategic plans, including budget scenarios, in a standard format on an annual basis.**

In any organization, change toward centralization raises concerns about accountability. As the authority of the director is strengthened, greater accountability of the director's office could be achieved through a strengthened Advisory Committee to the Director, one that is more actively engaged in the NIH priority-setting process and that has a broader base of membership, especially among its public members.

> ***Recommendation 6.*** **The director of NIH should increase the involvement of the Advisory Committee to the Director in the priority-setting process. The diversity of the committee's membership should be increased, particularly with respect to its public members.**



## MECHANISMS FOR PUBLIC INPUT

Although a major criterion in research priority setting is public health needs, the committee found that NIH's interaction with various kinds of publics is generally weak compared with NIH's interaction with the research community. This is especially true for the Office of the Director of NIH, which does not have adequate channels through which members of the public can express their concerns to NIH or through which they can receive information about the broad scope of effort being made in the fields with which they are concerned.

This structural weakness has important complications: first, because patient advocacy groups have become better organized and more proactive on behalf of their interests and have greatly increased their appeals to Congress to intervene to adjust NIH research priorities; second, because congressional leaders have expressed a strong desire to avoid mandates and earmarks in favor of particular diseases and to let NIH set research priorities; and third, because the NIH director has increased his role in priority setting (partly by exercising additional authorities granted to him by Congress). This confluence of events highlights the need for improved communication between the public and NIH.

NIH should engage the public to a greater extent in informing the process by which NIH sets its research priorities. The following three recommendations are intended to provide the public with more opportunities to present their views regarding research needs and to receive information about research and the priority-setting process at NIH.

> ***Recommendation 7.*** **NIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The director's Office of Public Liaison should review and evaluate these mechanisms and identify best practices.**

The Offices of Public Liaison are meant to serve several purposes: (1) they provide an easily identifiable point of contact for individuals and groups who have an interest or concern; (2) they are a place where members of Congress can refer constituents who want to obtain information or to raise concerns; and (3) they conduct an active program of outreach to and interaction with constituency groups. The NIH director's Office of Public Liaison will oversee and coordinate the institutes' Offices of Public Liaison, serve as a point of contact for individuals or groups who are dealing with crosscutting issues or who do not have a specific institute to contact, and staff the Director's Council of Public Representatives (discussed below).

*Recommendation 8.* **The director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH director, to facilitate interactions between NIH and the general public.**

The Director's Council of Public Representatives—an advisory group made up of citizens who are either patients, family members of patients, or advocates for patients—serves to elevate public input into the priority-setting process to the highest level of NIH in a systematic and periodic manner. Importantly, the Council will not set priorities regarding the NIH budget or its research programs. That is, it is not intended to serve as a forum for advocacy groups to lobby the NIH director for research dollars. Rather, it is intended to serve as a mechanism for NIH to receive valuable and thoughtful perspectives on its research programs from those who are in some way affected by disease and disability and who are therefore advocates for a healthy NIH and for NIH to provide information about its research and priority-setting process as part of a two-way exchange of information.

Together with the Offices of Public Liaison, the Director's Council of Public Representatives would permit continual interaction between NIH and the public. The Council would allow the NIH director to hear periodically from representatives of a spectrum of interest groups; the Offices of Public Liaison, which would be staff offices that function on a daily basis, unlike the Council, would provide information to and receive input from interested groups and congressional offices and would staff the Council in the Office of the Director. Figure 1 shows the proposed placement of the Offices of Public Liaison and the Director's Council of Public Representatives within the current organization at NIH.

*Recommendation 9.* **The public membership of NIH policy and program advisory groups should be selected to represent a broad range of public constituencies.**

NIH has long-standing mechanisms by which to include public or lay members on top-level advisory bodies. In the Institutes, these councils provide advice and guidance on their research programs and funding decisions by providing the second layer of review (the first being peer review through the study sections). Thus, public representatives play a role in the priority-setting process and provide advice on funding decisions. NIH also reserves slots for public members on the Advisory Committee to the Director. It does not appear, however, that advocates for patients or special populations are regularly considered for these advisory committee memberships, despite numerous examples of cases in which such arrangements have been constructive and positive. Not using this mechanism to receive public input is a missed opportunity and has resulted in the perception of some groups that NIH does not encourage public input at the highest levels of its advisory processes.

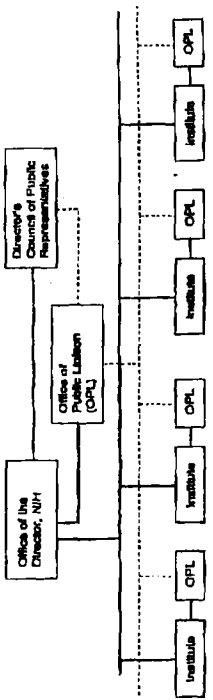


**FIGURE 1** Proposed placement of the Offices of Public Liaison and the Director's Council of Public Representatives within the current organization at NIH.

These recommendations are not intended to replace the existing criteria for priority setting. They are intended to enhance and reinforce existing NIH mechanisms through which the voices of the public can be heard in a constructive and open manner. The committee believes that public input, which has been important in sustaining the growth and stature of NIH, is an important component of the priority-setting process and, if used wisely by NIH when setting research priorities, will make for a stronger and more responsive NIH. It also believes that although implementation of these recommendations will not supersede or remove the potential for appeals to Congress, their enactment will reduce the need for such appeals.

The new organizational mechanisms proposed to improve public input have the potential to increase, in the short term, organizational costs and complexity. In the long run, however, the committee believes that the contribution made by these offices and the Council will prove to be cost-effective in terms of carrying out NIH's mission to improve health through research and will contribute to overall goodwill on the part of the public and Congress toward NIH.

## CONGRESSIONAL ROLE

Congress has always taken a special interest in NIH and has usually provided for larger budgets than administrations request. Congress has also often directed NIH in fairly specific ways, requiring the establishment of research programs, setting aside specific amounts of funding for research on designated problems, mandating the creation of research centers, institutes, or other specific mechanisms, and so forth.

Congress has the authority and the responsibility to intervene if it thinks that NIH is neglecting an opportunity or is not responsive to a need. Members of Congress recognize that it would be better for NIH to make the detailed decisions on how to approach problems.

The committee believes that if NIH revises its priority-setting system in the ways recommended above, Congress will be more likely to grant NIH (which, it is hoped, will be informed by stronger public input) the primary role in setting its research priorities. The text of the report includes some guidelines first offered by an Institute of Medicine committee in 1984 for Congress to use in deciding whether to mandate major organizational changes.

***Recommendation 10.*** **The U.S. Congress should use its authority to mandate specific research programs, establish levels of funding for them, and implement new organizational entities only when other approaches have proven inadequate. NIH should provide Congress with analyses of how NIH is responding to requests for such major changes and whether these requests can be addressed within existing mechanisms.**



If NIH is to have more autonomy in organizing and managing its r[illegible]ch programs, it is incumbent on the agency to engage in periodic reviews of its organizational structure and planning and budgeting systems and to explain the results to Congress and the public.

***Recommendation 11.*** **The director of NIH should periodically review and report on the organizational structure of NIH, in light of changes in science and the health needs of the public.**

The committee questions whether NIH, especially the Office of the Director, has adequate resources to operate an effective priority-setting system. Providing the Office of the Director of NIH with adequate resources for analysis and interface with the public would make research priority setting more effective.

***Recommendation 12.*** **Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.**

**BOX 2 The Committee's Recommendations**

**Criteria for Priority Setting**

Recommendation 1. The committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.

Recommendation 2. NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.

Recommendation 3. In setting priorities, NIH should strengthen its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.

Recommendation 4. NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.

**Priority-Setting Processes**

Recommendation 5. In exercising the overall authority to oversee and coordinate the priority-setting process, the NIH director should receive from the directors of all of the institutes and centers multiyear strategic plans, including budget scenarios, in a standard format on an annual basis.

Continued

BOX 2 Continued

Recommendation 6: The director of NIH should increase the involvement of the Advisory Committee to the Director in the priority-setting process. The diversity of the committee's membership should be increased, particularly with respect to its public members.

Mechanisms for Public Input

NIH should engage the public to a greater extent in informing the process by which NIH sets its research priorities, as illustrated by the following

Recommendation 7: NIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each Institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The director's Office of Public Liaison should review and evaluate these mechanisms and identify best practices.

Recommendation 8: The director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH director, to facilitate interactions between NIH and the general public [illegible]

Recommendation 9: [illegible] increasing of NIH policy and program advisory groups should be selected to represent a broad range of public concerns [illegible]

Recommendation 10: [illegible] authority to establish levels for funding for [illegible] approaches [illegible] provide [illegible] with analyses of NIH research [illegible] for such major changes and whether [illegible] be [illegible] while [illegible]

Recommendation 11: [illegible] should periodically review and report on organizational structure of NIH in light of changes in science and the health needs of the public.

Recommendation 12: Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.

# 1

# Introduction

The Institute of Medicine (IOM) was asked by the National Institutes of Health (NIH) "to conduct a comprehensive study of the policies and processes used by NIH to determine funding allocations for biomedical research" in accordance with a congressional provision (U.S. Congress, 1997a). The U.S. House and U.S. Senate authorization and appropriations committees requested that IOM present findings, conclusions, and recommendations "for improvements in the NIH research funding policies and processes and for any necessary congressional action." Specifically, the congressional committees asked that IOM "assess:

- the factors or criteria used by NIH to determine funding allocations for disease research,
- the process by which research funding decisions are made,
- the mechanisms for public input into the priority-setting process, and
- the impact of statutory directives on research funding decisions."

IOM was asked to conduct the study and submit a report in time to inform congressional consideration of reauthorization legislation in 1998 as well as of fiscal year (FY) 1999 appropriations (that is, during the second session of the 105th Congress). To comply with this request, IOM agreed to deliver the report by July 1, 1998, 5 months after the study began. The committee process is described below, after the following review of the background of issues concerning research priority setting at NIH.

**ABOUT THE OAM**

**OFFICE OF ALTERNATIVE MEDICINE**

**General Information**

History | Purpose | Mission
Program Advisory Council Charter | Fiscal Year Budget 1992-1997 | OAM Program Areas

## History

The Office of Alternative Medicine (OAM) was initiated through Congressional mandate under the 1992 National Institutes of Health (NIH) Appropriations Bill. The NIH is one of eight health agencies of the U.S. Public Health Service and is part of the U.S. Department of Health and Human Services (DHHS).

The NIH is one of the world's foremost biomedical research institutions, and the Federal focal point for biomedical research in the United States. It comprises 24 separate Institutes, Centers, and Divisions. The OAM is organized under the Associate Director of Disease Prevention within the Office of the Director of the NIH.

## Purpose

The Congressional mandate establishing the OAM stated that the Office's purpose is to "facilitate the evaluation of alternative medical treatment modalities" to determine their effectiveness. The mandate also provides for a public information clearinghouse and a research training program. The OAM *does not* serve as a referral agency for various alternative medical treatments or individual practitioners. The OAM *facilitates and conducts research*. The Office is located on the NIH campus in Bethesda, Maryland. The OAM Clearinghouse is located in Silver Spring, Maryland.

## Mission

The NIH Office of Alternative Medicine (OAM) facilitates research and evaluation of unconventional medical practices and disseminates this information to the public.

## Alternative Medicine Program Advisory Council Charter

The NIH Revitalization Act of 1993 provided for the establishment of a Program Advisory Council to provide advice to the Director of the OAM. The Secretary of DHHS approved a charter for the Council in November 1993, and the 18-member Council was officially formed in the summer of 1994. Council members are appointed by the DHHS Secretary. The first meeting was held in September 1994. The Council meets three times a year.

## Fiscal Year Budget

| FY1992 | FY1993 | FY1994 | FY1995 | FY1996 | FY1997 |
|---|---|---|---|---|---|
| $2M | $3.5M | $3.5M | $5.4M | $7.4M | $12M |

## OAM Program Areas

The OAM has six functional areas. The following paragraphs describe the activities within those areas.

**Extramural Affairs (Grants)**

*Sponsored Research*
The Office issued its first Request for Applications (RFA) in 1993, for grants of up to $30,000 each to fund exploratory pilot projects to identify promising areas of future research. The RFA was unusual in allowing any practitioner, with or without the backing of a conventional research institution, to apply.

Collaboration between orthodox research investigators and alternative medical practitioners was encouraged. More than 800 letters of intent were received, and 452 applications were reviewed – the *largest response* to a single RFA in NIH history. Thirty awards were made in September 1993 and another 12 in September 1994.

The OAM continues to co-fund research grants as appropriate applications for research into complementary and alternative medicine are received and reviewed through the NIH peer review process. Please contact the OAM Clearinghouse to obtain the Research Information Package for more information.

*Alternative Medicine Specialty*
*Research Center Grants*
The OAM has funded 10 Specialty Research Centers to study complementary and alternative treatments for specific health conditions.

The Centers form the foundation for conducting ongoing complementary and alternative medical research through the NIH.

The Centers will develop a prioritized research agenda, provide technical assistance, provide mechanisms for research development, and conduct collaborative research. Average funding for each Center is approximately $850,000 over 3 years. The OAM Specialty Research Centers are located at:

Bastyr University
Seattle, WA
*Specialty:* HIV/AIDS

Beth Israel Hospital, Harvard Medical School
Boston, MA
*Specialty:* General Medical Conditions

Columbia University College of Physicians and Surgeons
New York, NY
*Specialty:* Women's Health Issues
*Co-funding:* The Office of Research on Women's Health, NIH

Kessler Institute for Rehabilitation
West Orange, NJ
The University of Medicine & Dentistry, Newark, NJ
*Specialty:* Stroke and Neurological Conditions
*Co-funding:* The National Institute of Child Health and Human Development, NIH

Hennepin County Medical Center/University of Minnesota Medical School
Minneapolis, MN
*Specialty:* Addictions

Stanford University
Palo Alto, CA
*Specialty:* Aging

University of California at Davis
Davis, CA
*Specialty:* Asthma, Allergy, and Immunology

University of Maryland School of Medicine
Baltimore, MD
*Specialty:* Pain
*Co-funding:* The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

University of Texas Health Science Center
Houston, TX
*Specialty:* Cancer
*Co-funding:* The National Cancer Institute, NIH

University of Virginia School of Nursing
Charlottesville, VA
*Specialty:* Pain
*Co-funding:* The National Institute of Dental Research, NIH

**Research Database and Evaluation**

The Research Database Program provides an infrastructure for identifying and organizing the scientific literature on complementary and alternative medical practices.

Its goal is to establish a comprehensive electronic bibliographic database of this literature. This effort entails examining and further developing the classification system used to categorize information about complementary and alternative medical practices, maintaining a comprehensive list of journals that publish research on these practices, and expanding the terminology used to classify this research.

The literature identified from the database will serve as an ongoing source of information for scientists, researchers, practitioners, and the public. The OAM has an internal research database with more than 100,000 specific citations on complementary and alternative medical topics.

The Evaluation Program develops rigorous evaluation methods and applies them to the appraisal of complementary and alternative medical scientific literature. The Program will detail systematic evaluation methods appropriate for studies of complementary and alternative medical practices. These methods will be applied to evaluate bodies of scientific evidence on these practices. The Program is implementing a process for developing systematic reviews and meta-analyses of complementary and alternative medical scientific literature.

**OAM Clearinghouse and Media Relations**

The OAM Clearinghouse disseminates information to the public, media, and health care professionals to promote awareness and education about complementary and alternative medicine research.

The Clearinghouse provides several fact sheets and information packages. The Clearinghouse also provides a toll-free telephone service for public inquiries about OAM research and general information about complementary and alternative medicine. This toll-free number is (888) 644-6226. The

service does not provide medical referrals to individual practitioners of alternative medicine. The Clearinghouse is located in Silver Spring, Maryland.

The Media Relations area facilitates accurate coverage and follow-up of relevant stories with the news media, and provides information about the OAM and its current activities to mass media audiences.

**International and Professional Liaison**

The International and Professional Liaison Program supports and facilitates cooperative efforts in research and education in complementary and alternative medicine approaches worldwide, and with professional organizations across the United States. The OAM was recently designated as a World Health Organization Collaborating Center in Traditional Medicine. The OAM is 1 of 19 established research centers that are active worldwide in all phases of traditional, alternative, and complementary medicine.

**Research Development and Investigation**

The Research Development and Investigation Program screens, prioritizes, and provides technical support to the most promising domestic and international research opportunities in complementary and alternative medicine. It provides technical assistance in research education, networks experts in complementary and alternative medicine and research methods, and brings together researchers to prepare for grant applications.

**Intramural Research Training**

The Intramural Research Training Program provides a foundation for scientists to conduct basic and clinical research in complementary and alternative medicine at the NIH. Three to 5-year post-doctoral training positions gives researchers the opportunity to execute basic and clinical research in complementary and alternative medicine at the NIH. Initially, the program is limited to clinicians who are board certified in the United States (Individuals with a Ph.D. are also eligible).

**Other OAM Activities**

A major function of the OAM is to facilitate the evaluation of various alternative treatment modalities through Institutes and Centers within the NIH.

This cooperation is based on well-established expertise and encourages collaboration on projects of mutual interest. The OAM has established a network of coordinators in the NIH Institutes, Centers, and Divisions to assist in problems related to the evaluation of alternative medicine practices. Government agencies with which the OAM works include:

- Agency for Health Care Policy and Research
- Department of Defense
- Food and Drug Administration
- Health Care Financing Administration Agency
- Centers for Disease Control and Prevention

The OAM holds regular meetings with the FDA to enlist its cooperation in re-evaluating current rules and regulations governing research on and use of devices, acupuncture needles, herbs, and homeopathic remedies. The OAM also has corresponded with many alternative medical organizations providing them with information about research support and development.

# About ODS





The ODS is a Congressionally mandated office in the Office of the Director, National Institutes of Health (NIH). As an NIH office, the ODS embraces the overall mission of NIH:

*"...to uncover new knowledge that will lead to better health for everyone."*

NIH works toward that mission by:

*"...conducting and supporting research, helping to train research investigators; and fostering communication of biomedical information."*

The goal of NIH research is:

*"...to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold."*

The ODS supports research and disseminates research results in the area of dietary supplements. The ODS also provides advice to other Federal agencies regarding research results related to dietary supplements. Each of the links below provide more detailed information about the ODS.

- Why was the ODS started?
- What is the Congressional mandate for the ODS?
- What does the ODS do?
- What does the ODS not do?
- What activities does ODS have planned for the future?
- What is the ODS strategic plan?
- How was the ODS strategic plan developed?

For more information about the ODS and its activities, please contact the office at the following address:

Office of Dietary Supplements
National Institutes of Health
Building 31, Room 1B25
31 Center Drive, MSC 2086
Bethesda, Maryland 20892-2086
Tel: (301) 435-2920

Fax: (301) 480-1845
E-mail: ods@nih.gov

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Select a destination Go

# About ODS





## Why was the ODS started?

Dietary supplements can have an important impact on the prevention and management of disease and on the maintenance of health. Dietary supplements in the United States are usually defined as comprising plant extracts, enzymes, vitamins, minerals, and hormonal products that are available without prescription and may be consumed in addition to the regular diet.

Considerable research on the effects of dietary supplements has been conducted in Asia and Europe where plant products, in particular, have a long tradition of use. However, the overwhelming majority of supplements have not been studied scientifically. It is important to conduct objective research to determine the benefits and risks of promising dietary supplements and to interpret data for the public.

Recognizing these issues, Congress in November 1994 passed Public Law 103-417, the Dietary Supplement Health and Education Act (DSHEA). This bill amended the Food, Drug, and Cosmetic Act and focused on further defining aspects of that law that related to the definition, regulation, and labeling of dietary supplements. DSHEA included authorization for the creation of the Office of Dietary Supplements (ODS) at the NIH and a Presidential Commission on Dietary Supplement Labels. The ODS was formally established on November 27, 1995 within the Office of Disease Prevention, Office of the Director, at the National Institutes of Health. Bernadette M. Marriott, Ph.D. was appointed Director of the ODS.

# About ODS



## What is the Congressional mandate for the ODS?

In the Dietary Supplement Health and Education Act (DSHEA) Congress stated specific activities or mandates for the ODS and the Director of the office.

- Explore the role of dietary supplements to improve health care.
- Promote scientific study of dietary supplements in maintaining health and preventing chronic disease.
- Conduct & coordinate research on dietary supplements at NIH.
- Collect & compile databases of federally funded research & scientific papers on dietary supplements.
- Coordinate funding for research on dietary supplements at NIH.
- Provide advice to other HHS agencies related to dietary supplements.

# About ODS



## What does the ODS do?

To explore the role of dietary supplements in the improvement of health care, the ODS plans, organizes, and supports conferences, workshops, and symposia on scientific topics related to dietary supplements. The ODS can initiate such activities but more often the ODS works in conjunction with other NIH Institutes and Centers, other government agencies, professional organizations, and public advocacy groups. The specific goals and outcomes of these convening activities vary with the scientific topic.

Occasionally, the ODS will sponsor large conferences to provide an overview of a scientific area and to bring together scientists and professionals from different disciplines with the goal of identifying gaps in research and joint directions for future endeavors.

As an example, on June 3-4, 1996 a major two-day workshop, *The Role of Dietary Supplements for Physically Active People*, was sponsored by the ODS in conjunction with the American Institute of Nutrition and the American Society for Clinical Nutrition. This workshop was also cosponsored by 11 of the NIH Institutes and presented a state-of-the-art scientific review of dietary supplements as they may enhance the health of people who actively engage in exercise or recreational sports. The proceedings of this workshop will be published as a supplement to the American Journal of Clinical Nutrition. A Program with Abstracts and Bibliography of published articles was prepared for this workshop.

More typically the ODS sponsors or co-sponsors small workshops to promote scientific study of dietary supplements in a specific scientific area of dietary supplement research. In 1996 and 1997 for example, the ODS co-sponsored two workshops that were initiated by the National Institute on Aging: Melatonin and Sleep and Melatonin and Aging. The ODS is also co-sponsoring 15 similar conferences or workshops in 1998 that were initiated by various NIH Institutes and Centers in response to a request from the ODS. These conferences are described in more detail in Accomplishments.

As an office in the Office of the Director at NIH, the ODS does not have the authority to directly fund investigator-initiated research grant applications. Instead the ODS conducts research either

through contracts such as the Public Information Center Needs Assessment Survey (link) that was initiated by the ODS and is being conducted on contract and in collaboration with the USDA, or by funding grants to scientific investigators in cooperation with the Institutes and Centers at NIH, such as the Research Enhancement Awards Program (REAP).

To coordinate research and coordinate funding for research on dietary supplements at NIH, the ODS has established a Dietary Supplements Liaison Group, which consists of members appointed by the directors of the Institutes and Centers at NIH. This group meets periodically throughout the year and is in the process of developing a workable mechanism for trans-NIH research coordination on Dietary Supplements.

The ODS also serves as a member of the NIH Nutrition Research Coordinating Committee (NCC) that is managed through the NIH Division of Nutrition Research Coordination. The NCC serves to coordinate all nutrition research at NIH and provides a regular forum for Institute and Center dialogue about scientific issues related to nutrition, diet and health. Dr. Van Hubbard directs the Division of Nutrition Research Coordination. In addition, the NCC staff provides the link to the Department of Health and Human Services interagency Nutrition Policy Board, which coordinates nutrition research among the public health agencies and the Interagency Committee on Human Nutrition Research (ICHNR), which coordinates nutrition research at the federal level. The ICHNR functions as a subcommittee of the Committee on Health, Safety and Food of the National Science and Technology Council in the Office of the President.

To fulfill the Congressional directives to collect and compile databases of federally funded research and scientific papers on dietary supplements the ODS is developing the two databases--CARDS and IBIDS.

To provide advice to other HHS agencies and Congress related to dietary supplements the ODS answers inquiries, writes reports, makes presentations, and participates in interagency committee activities on a regular basis.

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Mr. BURTON. We will recognize the chairman of the International Relations Committee, Mr. Gilman.

Mr. GILMAN. Thank you, Chairman Burton, for bringing these talented people together. These panels before us are so important in this critical issue.

Studies have found that, as you have indicated, more than 40 percent of all Americans have been trying complementary and alternative medical treatments and have been seeking out the advice of physicians with regard to these treatments. And many individuals who have suffered through the agonizing effects of traditional cancer treatments, such as chemotherapy and radiation, are now turning to the complementary and alternative treatments like herbal therapy, meditation and nutritional therapy.

It is regrettable that research and studies that are done in our Nation do not focus on complementary and alternative forms of medicine enough. This collaboration between the National Cancer Institute and the Office of Alternative Medicine is the perfect opportunity, I think, for the medical world to take important strides in conquering the problems that we are confronted with as a result of cancer.

It is clear that straightforward attempts to cure cancer can and do work. Yet alternative forms of treatment can help our patients in conjunction with more commonly used remedies.

There are many nations that accept alternative medicine and rely on it regularly. But our Nation has always put a stigma on alternative medicine; and, as a result, funding for alternative studies has been difficult to acquire.

Significant achievements are being made in the cure for cancer that are occurring overseas, in Europe and Asia. And it is long overdue I think for our Nation to work together with its foreign counterparts sharing information, sharing strategies, and looking for better treatment.

Some cancer patients in our Nation have the ability to travel overseas to receive alternative treatments, but we should be able to offer all Americans that opportunity to access all forms of treatment both traditional and alternative, and we should pool our resources to create affordable, beneficial alternatives to common cancer treatments and alternative from which all cancer patients could benefit from.

We need to commit to a joint effort between NCI and OAM and pledge to commit a percentage of NIH's budget to this cooperative venture. Both organizations can benefit by working together, and the cancer patients in our Nation will receive the best of care and treatment that today's physicians and scientists have to offer.

I thank the gentleman for yielding the time, and I look forward to hearing the testimony today.

Mr. BURTON. Thank you, Mr. Chairman.

We will have other Members, I presume, that will come in from time to time. I ask unanimous consent that all Members and witnesses' written opening statements be included in the record; and, without objection, so ordered.

[The prepared statement of Hon. Christopher Cox follows:]

JULY 31, 1998

OPENING STATEMENT OF REP. CHRISTOPHER COX
VICE-CHAIRMAN, COMMITTEE ON
GOVERNMENT REFORM AND OVERSIGHT

HEARING ON NCI RESPONSE TO ALTERNATIVE TREATMENTS FOR CANCER

Mr. Chairman, thank you for holding this hearing today.

The question before us today is: what is the National Cancer Institute doing to advance research in the area of complementary and alternative medicine?

An increasing number of severely-ill patients are turning to alternative forms of medical treatment, after finding more traditional medicine to be unsuccessful. In fact, the New England Journal of Medicine has reported that more than one out of every three Americans have at some time relied on an alternative form of medical treatment.

At this Subcommittee's hearing in February of this year, Rep. DeFazio discussed H.R. 746, the Access to Treatment Act, legislation he has introduced and of which I am an original sponsor.

As introduced, the Access to Medical Treatment Act would ensure that individuals are free to choose to be treated by any legally authorized health care practitioner with any method of medical treatment--provided that there is no evidence that the treatment causes harm, and that the patient is fully informed about any possible side effects.

However, in order for doctors to know for sure that an alternative treatment does not cause harm and to then inform patients about possible side effects, agencies like the National Cancer Institute must research the treatments. I look forward to hearing from the Institute's representatives about why that is not happening.

Thank you Mr. Chairman.

Mr. BURTON. I also ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record; and, without objection, so ordered.

Would you gentlemen please rise? We have a habit of swearing everyone in.

[Witnesses sworn.]

Mr. BURTON. Do you have an opening statement, Dr. Klausner or Dr. Jonas?

## STATEMENT OF RICHARD KLAUSNER, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE, NIH

Dr. KLAUSNER. Good morning, Mr. Chairman, Mr. Gilman. Thank you for giving us this opportunity. I am pleased to be here today on behalf of the National Cancer Institute to talk about the evaluation of complementary and alternative medicine in cancer.

I am particularly pleased because a lot is happening, a lot is changing along the lines of what both you and Mr. Gilman have talked about; and that is the need to work together across these communities.

Let me emphasize at the start that the basic tenet at the NIH is to employ rigorous methodologies to reach conclusions based on evidence and not on belief. That is what we owe our patients. It is through such methodologies that the intersection between so-called traditional and so-called alternative and complementary, or CAM, medicine must be sought. Standards of evidence cannot be compromised. And I am pleased that on this crucial point I and my colleagues in the CAM community agree.

NCI has been and is awarding more grants to support high-quality, CAM-related research projects, examining the effects of dietary interventions and treatments in prevention; projects examining the therapeutic effects of vitamins and minerals; and studies in stress and pain management to enhance the quality of life of cancer patients, in addition to the question about the length of survival. Also, to look at natural inhibitors of carcinogenesis.

Now those of us who are dedicated to eradicating cancer have at least two reasons to be open to the evaluation of nontraditional therapies: First, we will not be successful in alleviating cancer unless we are open to new ideas. We have learned through history that anecdotes and folk traditions have often guided us to real and effective therapies.

Second, as you have pointed out, many people avail themselves of complementary and alternative medicine, and those people reasonably ask who is providing evidence as to whether they help, whether they do not do any good, or even whether they harm. The challenge is, how do we best go about choosing which complementary and alternative medicines to evaluate through rigorous clinical trials and, importantly, how do we design those trials that they yield timely and credible results to all communities involved?

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 therapies for these hundreds of diseases we call cancer, and that number multiplies in the nearly endless combinations that could be tested. The result and the reality is only a tiny fraction of what is possible, whether from

traditional or nontraditional approaches, can be brought to clinical trial; and, therefore, at every step we need mechanisms to evaluate the weight of evidence supporting an intervention. The rationale behind it must be evaluated to prioritize which approaches we move forward with.

The challenge before us, which I think we can meet, is to assure that complementary and alternative approaches have real, credible and fair access to the same processes of evidence and review that all interventions must live up to.

The NCI is moving quickly to develop CAM information and expand research opportunities for CAM investigators. The activities have broadened in scope and include increased collaboration with Dr. Jonas and his office, the careful evaluation of CAM therapies and, importantly, the development and dissemination of accurate 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 are truly and finally moving beyond that. There is a real commitment by the NCI to change that, to listen and to inform, as well as to speak.

We are in the final stages of appointing for the first time an individual at the NCI to be the coordinator for CAM therapies and evaluation, a position that has never before existed. This individual will have the responsibility and primary interest of developing relations with the CAM community and to function as a liaison between the Institute and the NCI research community on behalf of the CAM community to encourage collaboration and joint research initiatives.

As you know, we are also working with the OAM, the Office of Alternative Medicine, to implement the recommendations of the practice outcomes monitoring evaluation system through the development of the Cancer Advisory Panel, CAP, for complementary and alternative medicine; and I think Dr. Jonas will talk about that.

What we think this is going to do is provide us with a group of experts in both complementary and traditional medicine to work together, to learn to work together, to be an open door, to bring in ideas, to look at the literature, to make sure that individuals with ideas and interventions feel welcome to come in to learn to present those interventions in a way that the evidence can be evaluated so that we can make decisions about moving on to test those evaluations.

There are multiple examples of that. We do not have the time to go through all of them. But I will point out one that the NCI and OAM have moved quickly to support, and that is the evaluation at the Columbia Cancer Center of Dr. Gonzalez's therapy. I point that out because we will be hearing more about that later.

Of real importance to us is that the public has available accurate and up-to-date information about CAM therapies as well as about traditional therapies, and NCI has recently taken steps to assure that this information receives not blanket negative judgment but the same open consideration as conventional approaches both in our evaluation and dissemination.

Detailed CAM summaries are now being prepared for cancer therapies identified by the Cancer Information Service, along with the OAM clearinghouse, as being of public interest. The develop-

ment of these summaries will follow the exact same model that goes for conventional therapies, including specific trial results, the references to the published literature, and review by the appropriate editorial boards that we have for reviewing all of our approaches to therapy, prevention, as well as supportive care.

The PDQ Editorial Board will now be supplemented with individuals from the CAM community, and we have been provided with a list of names of recommendations of individuals from Dr. Jonas and Dr. Chung at the OAM.

Several months ago, as a result of my own concerns as well as the constructive input from the CAM community directly to me, we removed from the NCI web site all previous CAM information that we really felt was very judgmental and did not represent the openness that we are striving for, creating new information that treats CAM dispassionately and fairly.

We will establish at the NCI a prominent lecture as part of the medical Grand Rounds series in our Division of Clinical Sciences open to all members of the NCI and NIH community about CAM approaches. We think this is important as a way to disseminate information but very important as a statement of the importance of inviting individuals from that community to work with us.

We are discussing, as we have talked about 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. In my opinion, this will be very useful. This is an independent entity, even though it is called the JNCI, and the decision about how this ought to be done will have to rest with Dr. Kramer and his editorial board, although I am very supportive.

As the Director of the NCI, I have a strong commitment to improving our relations and to eliminating as best as possible the tension between the research communities. But in research communities, tensions will remain, arguments will continue. I think that ought to be done on a healthy and mutually respected level. Both communities share a common and admirable but extremely difficult goal: to cure cancer. We will only get there through rigorous objective and dispassionate accumulation of evidence, not through anecdote, belief and philosophy.

I believe that the NCI and the OAM are working together in a way that will successfully bring the power of science to alleviate the suffering of cancer. It is vital that we work together to that end.

If I could just add, I actually fully agree with you. And the reason NCI exists is not to defend the treatments we have but because we all agree our treatments are inadequate, not for all cancers. I think actually we have made real progress. It is frustrating to all of us that it is not fast enough. They are too toxic. They are not specific.

My explicit goal as Director of the NCI is to have us move from a real understanding of science to not guesswork and empiricism about the development of therapies, be they traditional or nontraditional, but to therapies that are specific, that are targeted, that we know will work the way we expect our cars to be fixed. We go after the specific machinery. And we are doing that. We have many examples.

There has been a lot of progress. Much of that progress has been hard to see because we have had to invest in understanding these diseases which are so complex. And I would be delighted to answer questions about that and how we are moving forward.

Thank you very much.

Mr. BURTON. Thank you, Dr. Klausner.

[The prepared statement of Dr. Klausner follows:]

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 "best 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.**

Mr. BURTON. Dr. Jonas.

**STATEMENT OF WAYNE JONAS, M.D., DIRECTOR, OFFICE OF ALTERNATIVE MEDICINE, NIH**

Dr. JONAS. Thank you. Good morning.

It is my pleasure to come before the committee today to summarize the activities of the Office of Alternative Medicine at the National Institutes of Health regarding unconventional cancer therapies.

As has been mentioned, cancer is one of the most devastating conditions faced by Americans today. Unconventional approaches abound and are extensively used by the public; and yet, at the same time, there is very little research on these treatments so that there are few guidelines to help the public make informed and evidence-based choices about their use. It is the purpose of the OAM to facilitate research for discovering what is safe and effective in unconventional medicine and provide that information to the public.

There are three main challenges that must be addressed in pursuing research and CAM cancer therapies. The first is the need for resources and an infrastructure that is committed to rigorous research in CAM cancer therapies. I agree wholeheartedly that choices in health care must be based on evidence and not simply belief.

The second is the need to develop trust and collaborative relationships between the cancer researchers and those practitioners who are providing CAM cancer therapies; and the third, to help the prioritization process that Dr. Klausner mentioned, is to obtain expert advisory input in deciding on which projects can and should be researched first. The OAM is moving forward in all of these areas.

In order to address the first issue, rigorous research, we recognized very early that we would need cooperation and collaboration with the NCI. The reason is very simple. The NCI has all the requisite resources to execute appropriate research, including in-house expertise for conducting clinical trials, conducting preclinical research, reviewing protocols, working with the Food and Drug Administration for investigation on new drug applications. The NCI is also able to provide linkages to non-NIH researchers with detailed knowledge about specific cancers.

The OAM is successfully using this model in a number of other areas with other institutes. For example, we have a large clinical trial on the treatment of depression with St. John's Wort with the National Institute of Mental Health. We have a trial that is going to start soon on acupuncture and osteoarthritis with the Arthritis Institute; and we are going to fund some studies in nutritional therapy for heart disease through the centers that are supported by the National Heart, Lung, and Blood Institute.

By working closely with the NCI, the OAM is developing similar projects for CAM cancer therapies.

To address the second issue, building collaboration and trust, we have begun a series of activities to bridge CAM practitioners with the conventional research community. This includes funding exploratory grants, a number of them on cancer; conducting over 40

site visits to practitioners, two-thirds of which deal with cancer; soliciting the CAM community for preliminary research information, conducting workshops, and providing technical assistance to hundreds of CAM practitioners, and having several contracts established to do summaries of the science and specific CAM areas.

We have also funded a Center for Unconventional Cancer Research at the University of Texas Health Science Center in Houston. This center has collected and summarized the current research on over 25 of the main CAM cancer therapies used by the public and identified possible and promising cancer research areas in need of further evaluation.

In order to address the third issue, obtaining a wider advisory input, the OAM has held a series of meetings to examine how to execute CAM cancer research more effectively and how to build better collaborative bridges between communities. Several meetings were held on communication processes in CAM cancer research. We were cosponsors for the Center for Mind-Body Study's Comprehensive Cancer Care Conference, of which you will hear about a little later. And we also held, in conjunction with the NCI, a large meeting in August 1997, that you mentioned that brought together many representatives from the CAM and conventional cancer communities.

The purpose of this latter meeting was to discuss how the OAM and NCI could best develop the research infrastructures and the collaborative processes needed to clinically test CAM interventions. A plan was developed called the Practice Outcome Monitoring and Evaluation System, or POMES for short, and a basic consensus of these groups was achieved.

One of the main recommendations from this meeting was the development of an advisory group. Such an advisory panel that Dr. Klausner has mentioned is now being formed. It will have the following functions: it will assist the NIH is evaluating claims of efficacy in CAM. It will make recommendations to the NIH on whether and how further research on these should be pursued. It will advise the NIH on the conduct of clinical trials. And it will develop opportunities for improving communication between the CAM and the conventional communities in the cancer area.

The purpose and the responsibility, the operation of this panel is designed specifically so that both conventional and CAM communities will be well represented. After the POMES meeting, the NCI and the OAM have been working to implement its recommendations within the context of existing administrative and scientific structures. If identified CAM cancer treatments are deemed to have sufficient data to warrant further research; and upon recommendations of the Cancer Advisory Panel, clinical trials can be funded by the OAM using appropriate NCI mechanisms.

Let me illustrate a couple of these that are already about to occur. We will be supporting two large clinical trials in specific CAM cancer therapies this year. These will be implemented through the NCI using recommendations from the POMES.

The first is the use of shark cartilage for the treatment of solid tumors. Shark cartilage is one of the most frequently used single unconventional interventions for cancer, and it is one of the most frequently requested from our OAM clearinghouse to get informa-

tion about. Protocols to conduct a rigorous test of shark cartilage are currently under review by the NCI and funds have been transferred for this project.

Diet and nutritional supplements are the most frequently used unconventional approaches to cancer. A second study will test the use of diet and nutritional supplements for the treatment of pancreatic cancer, an often rapidly fatal disease, using the program developed by Dr. Gonzalez as previously mentioned.

This particular project I think is an example of how CAM practitioners can go through a series of evaluation steps and get their practices properly evaluated, starting with the best-case series, going on to a practice outcomes evaluation, and then on to a controlled trial.

The OAM currently supports a cancer research center. It is our intent to increase commitment to CAM research centers significantly. And depending on budget and programming issues, the OAM has the option of funding more than one CAM cancer center.

Finally, there is a tremendous demand for CAM cancer-related information by the public. The OAM has three activities that address this issue. First, a public information clearinghouse was established in mid-1996 with a toll-free number available to the public. Last year, 65 percent of its inquiries were cancer related. The OAM is working closely with the Cancer Information Service of the NCI to develop fact sheets in areas such as shark cartilage, hydrazine sulphite, antineoplastons, just to name a few.

The OAM has been working with the National Library of Medicine to develop data bases of CAM citations. There is currently a data base of over 90,000 citations that are catalogued and can be found on the OAM home page. A search of the word "cancer" yields over 16,000 citations.

For the future, the OAM plans to intensify its efforts in research, clinical trials, data evaluation, and information distribution. The basic background for all these activities is solidly in place, and there is a growing and mutually beneficial interaction between the CAM and conventional cancer communities.

The Office of Alternative Medicine and the National Institutes of Health have a strong commitment to seeing complementary and alternative medicine practices evaluated in a scientifically rigorous and in a publicly relevant manner. By working together, we can make better and more informed choices about the treatment of cancer.

That concludes my statement. I would be happy to answer any questions.

Mr. BURTON. Thank you very much. I appreciate the work that is being done, the coordination that is taking place so far.

[The prepared statement of Dr. Jonas follows:]

## I. OPENING STATEMENT

Good morning. It is my pleasure to come before you today to summarize the activities of the Office of Alternative Medicine (OAM) of the National Institutes of Health (NIH) regarding research and public information on unconventional cancer therapies. Cancer is one of the most devastating afflictions faced by Americans. Unconventional approaches to cancer abound and are extensively used by the public. There is little research on unconventional cancer treatments and so there are few guides for the public for making informed and evidence-based choices. It is the purpose of the OAM to facilitate research for discovering what is safe and effective in unconventional medicine and provide that information to the public.

## II. BACKGROUND

The Office of Alternative Medicine (OAM) was established by statute in 1993 (P.L.103-43) to "facilitate the evaluation of alternative medical treatment modalities...." The Office developed its mission statement based upon this to facilitate research and evaluation of unconventional medical practices and disseminate these results to the public.

Within this broad scope, the OAM is interested in all clinical conditions and diseases that potentially lend themselves to treatment with complementary and alternative medicine (CAM) interventions. Cancer is one of the major diseases for which the OAM has concentrated resources. Over 60% of public inquiries that come into the OAM clearinghouse are related to cancer, and cancer patients frequently seek out and use unconventional therapies.

## III. DEVELOPING RIGOROUS AND RELEVANT CAM CANCER RESEARCH

There are three main issues that must be addressed in pursuing research on CAM cancer therapies. The first is the need for resources and a research infrastructure committed to rigorous research of CAM cancer therapies. The second is the need to foster trust and collaborative relationships between cancer research centers and practitioners who provide CAM cancer therapies. The third is the need for expert advisory input for prioritizing projects in CAM cancer areas. The OAM and NCI have been moving forward in addressing all of these issues.

### Rigorous Research

In order to address the first issue, rigorous research, the OAM recognized very early that significant inroads into research on use of CAM cancer interventions would require cooperation and collaboration with the NCI. The OAM was established as a coordinating office within the Office of the Director, NIH. As such, its role is to examine available scientific background for specific interventions, be cognizant of the needs of the cancer patient groups, and work with the NCI to implement selected studies in CAM areas.

There are many good reasons for taking this approach. First, research on CAM cancer therapies, like all other CAM research, must be conducted using rigorous methodologies to reach conclusions based on evidence and not on belief. The NCI has all the requisite resources to execute appropriate research - both in clinical trials as well as basic research. It has in-house scientific expertise in designing clinical studies, conducting pre-clinical and clinical research, reviewing research proposals, and working with the Food and Drug Administration on Investigational New Drug Applications. The NCI also is able to provide linkages to extramural researchers and clinicians who may have detailed knowledge about specific cancers that can augment in-house expertise.

Using the research expertise and infrastructures from existing Institutes and Centers is proving to be an efficient and successful model for conducting clinical trials in many CAM areas. Examples include a large clinical trial testing the herb St. John's Wort for the treatment of depression being conducted in collaboration with the National Institute on Mental Health; a test of the effectiveness of acupuncture for the treatment of osteoarthritis conducted with the National Institute of Arthritis and Musculoskeletal and Skin Diseases; and, a request for studies of nutritional therapy of heart disease to be done through research centers supported by the National Heart, Lung and Blood Institute. In his testimony, Dr. Klausner has provided a summary of the significant progress being made at NCI to develop and execute research on CAM cancer therapies using a similar cooperative approach between OAM and NCI.

Building Trust and Collaboration

To address the second issue, building collaboration and trust, the OAM began a series of activities to build bridges between CAM practitioners and the research community and to begin to identify research opportunities. Between 1993 and 1995, the OAM funded 42 "exploratory" grants. These were small awards designed to determine whether certain specific CAM interventions, modalities and systems, when used against some clinical conditions, showed signs of promise and therefore warrant larger, more in-depth studies. Of the 42 awards made, 10 were related to cancer.

From December 1995 to the present, an oncologist from NCI was detailed to the OAM on a part-time basis to assist with bridging activities and assisting in the evaluation of CAM cancer practices. This NCI oncologist, along with OAM staff made site visits to over 40 CAM practices, two thirds of which deal primarily with cancer treatments. Next steps for the evaluation of these therapies have been identified. In addition, OAM and NCI staff have

solicited the CAM community for preliminary research information, such as "Best Case Series," (a procedure for presenting cases successfully treated), conducted workshops and technical assistance to hundreds of CAM practitioners on how to collect research information, and issued several contracts to obtain scientific summaries of CAM cancer areas.

Also during this time, the OAM funded a grant to the University of Texas Health Sciences Center in Houston to begin collecting and developing research projects in CAM and developing links between the CAM and research communities. This center is administered through the NCI and is dedicated solely to cancer. The Texas center is now in their fourth and final year of award. Preliminary information coming from the Texas center has identified possible promising interventions in cancer such as the use of mistletoe extracts for the treatment of several types of cancer. In addition, the center has summarized the current research on over 25 of the main CAM cancer therapies and made this information available to the public over their website and at conferences and meetings.

In 1993, the OAM transferred funds to the NCI to conduct a study of anti-neoplastons, a controversial cancer therapy developed by a practitioner in Houston. This study failed to obtain sufficient recruitment and was stopped in 1995 after disagreements over protocol design. After evaluating the issues around this attempted trial, and on advice from the OAM advisory council, the OAM sought to increase advisory input and develop opportunities for more dialogue between the CAM and conventional communities.

Obtaining Advisory Input

In the summer and fall of 1995 and spring of 1996, the OAM and NCI held a series of meetings both internally and with outside consultants to examine how to execute research projects more effectively in CAM cancer areas and build better collaborative bridges between the

communities. This resulted in several meetings on communication processes in CAM cancer research and ended with a large meeting in August 1997 with both the CAM and conventional cancer communities.

The purpose of the meeting was to discuss how the OAM, working with the NCI, can develop the research infrastructure to clinically test CAM cancer interventions. A plan was developed, called the Practice Outcome Monitoring and Evaluation System (POMES), and basic consensus of the groups was achieved. As a result of this meeting, a Cancer Advisory Panel (CAP) is being formed which will assist the NIH in evaluating claims of efficacy relating to CAM, make recommendations to the NIH on whether and how further research on these claims should be pursued, advise the NIH on the conduct of clinical trials of CAM cancer therapies and identify opportunities for improved communications between the CAM and conventional communities.

This panel, along with OAM and NCI staff, will provide a mechanism to address the third issue in CAM cancer research, advisory input for prioritizing research opportunities. The purpose, responsibilities, operations and membership of the CAP is designed such that both conventional and CAM communities are well represented. The concept, functions and membership categories of the CAP have been developed with outside expert consultation and are now agreed upon by the NCI and the OAM. The concept has been distributed for comment to the OAM's Alternative Medicine Program Advisory Council and, upon Council approval, will be convened, most likely before the end of the calendar year.

Implementing POMES

Since the POMES meeting, the NCI and the OAM have been working to implement the POMES concept within the context of existing administrative and scientific structures.

Additionally, if any CAM cancer treatment is deemed to have the requisite background of data and upon recommendation by the CAP, clinical trials can be funded by the OAM, using NCI mechanisms as appropriate to do definitive trials.

## IV. OTHER CURRENT OAM RESEARCH ACTIVITIES IN CANCER

Several examples below illustrate other current CAM cancer research activities supported by the OAM and NCI.

### Surveillance Epidemiology End Results (SEER) Program

The Surveillance Epidemilogy End Results (SEER) Program at the NCI is unique in its two-decade plus tracking of diagnosed cancer patients. The willingness of the NCI to allow the OAM to tap into this rich resource allows the OAM a potential wealth of information on CAM use by cancer patients.

In 1997, the OAM participated with the SEER program by funding a contract modification statement of work to the University of Hawaii SEER contract to study "Ethnic Differences in Attitudes and Experiences Related to Alternative Cancer Treatments." This research examines the use of alternative cancer therapies by cancer patients, compares the quality of life of these patients, describes experiences with its use and determines factors which influence the adoption of alternatives therapies.

There is insufficient detail on the use of CAM cancer therapies by cancer patients and special populations. In 1998, a contract was made to the Fred Hutchinson Cancer Research Center in Seattle entitled "Use of Alternative Medicine by Cancer Patients." The purpose of this study was to describe more fully the magnitude and patterns of complementary and alternative medicine use among cancer patients in the general population through extensive telephone

interviews. This study was jointly funded by OAM and NCI. Finally, also in 1998, the University of Southern California SEER contract was also modified to include a "Special Study of Use of Complementary/Alternative Medicine by Cancer Patients for Selected Cancers and Population Subgroups." This is supported entirely by the NCI.

Future plans may include a study of the effectiveness of specific CAM cancer interventions over long periods of use as they relate to cancer outcomes, quality of life and mortality.

Current Clinical Trials. Because of the existing clinical trials infrastructure of the NCI, including cancer centers and cooperative groups, and the willingness of NCI to contribute the use of these centers, clinical studies will require minimal start up time. It is the aim of the OAM to perform more definitive clinical trials and make any results available to the public. There are two currently planned studies to be implemented with the NCI, using the recommendations of POMES and through NCI clinical trial mechanisms.

Shark Cartilage. The first is the use of shark cartilage for the treatment of some solid tumors. Protocols to conduct a rigorous test of shark cartilage on cancer through NCI supported cancer centers are currently under review by the NCI. A process for solicitation and selection of an appropriate product to test is also underway. Funds have been transferred to the NCI for this project.

Diet and Supplement Therapy. A second project is the use of diet and nutritional supplements for the treatment of pancreatic cancer (using a program developed by Dr. Nick Gonzales). This project is an example of how CAM cancer practices can go through a progressive series of research steps starting with a best case series, to practice outcome evaluation, to a controlled trial. The OAM has been providing technical assistance throughout

this process. The program is now ready for a randomized controlled trial at the Columbia Cancer Center in New York. When funding for this project was withdrawn by Proctor and Gamble, the OAM was quick to fill in the void and provide support for the proposed study using funds already budgeted for cancer trials.

OAM CAM Cancer Center. A request for applications for a grant to support a large CAM cancer research center will be issued at the end of August 1998. The plan is to use the standard funding mechanism for NIH research centers (the so-called P50 mechanism), which requires several viable peer-reviewed research projects at the time of funding. This way, there will be a minimum of research start-up time, and research could begin almost immediately. The intent is also to increase the OAM commitment to this center significantly. An award is anticipated by the summer of 1999. Budget and programmatic issues permitting, the OAM has the option of funding more than one CAM cancer center.

## V. OAM PUBLIC INFORMATION DISSEMINATION

There is a tremendous demand for CAM related cancer information by the public. To that end, the OAM has three activities dedicated to this need.

### Public Information Clearinghouse

A public information clearinghouse has been maintained by the OAM since mid-1996. Most of the calls to this clearinghouse are cancer-related. From July 1997 to July 1998, nearly 21,000 calls were received by the clearinghouse of which 65% , or 13,000+, were cancer related. The most frequently asked questions are about common types of cancers such as breast, colon and lung; what CAM interventions are available to treat them; and questions on specific CAM modalities, such as shark cartilage or hydrazine sulfate.

Fact Sheets

The OAM is also working closely with the Cancer Information Service of the NCI to produce "fact sheets" designed to provide information to both practitioners and to the lay public on various forms of CAM cancer interventions. Fact Sheets are being developed on specific modalities such as shark cartilage, hydrazine sulfate and antineoplastons, to name a few. These fact sheets are being written by professional science writers engaged by the NCI after reviewing the available literature. The style is such that it can be easily understood by the public, yet also be useful to a practitioner or researcher since references will be given.

A panel of experts on the topic, representing scientists and practitioners from both the conventional and CAM communities, will review each fact sheet and make recommendations on accuracy, bias, content and style. The OAM has provided the NCI with a list of over 50 potential reviewers with varying expertise. It is anticipated that these fact sheets will be disseminated through the OAM Clearinghouse, its web page and by the NCI through its extensive cancer information services. The process is similar to that usually done to disseminate other non-CAM information on a routine basis.

Database

Given the broad base of worldwide scientific literature on CAM and CAM related topics, the OAM began working with the National Library of Medicine databases to develop a database of CAM citations. As of August 1997, over 90,000 citations were catalogued and can now be found on the OAM home page. These citations can be searched in a variety of modes, some still under development. One search mode is by clinical condition. A search of "cancer" yielded 16,000 citations.

This database is continually updated and maintained. The goal is to eventually catalogue most of the world's useful scientific information on CAM and make it available to researchers, practitioners and the lay public.

VI. FUTURE PLANS

For the future, the OAM plans to continue current activities and relationships. Activities may intensify in basic research, clinical trials, data evaluation and information retrieval and distribution. The basic groundwork for all of these activities is already in place and there is a demonstrated mutually beneficial synergy developing between the CAM and conventional communities in cancer research.

The Office of Alternative Medicine and the National Institutes of Health have a strong commitment to seeing that complementary and alternative medicine practices are evaluated in a scientifically rigorous manner. In addition, the topics selected and research methods used in such investigations must provide the public with information that is useful for making reliable decisions in health care. It is essential that all communities work together to assist the public in making informed choices about the best options available for the treatment of cancer.

This concludes my statement. I will be happy to answer any questions.

Mr. BURTON. You may recall from our previous hearings we had some horror stories from people who had cancer and had children that had cancer and there were alternative treatments that they wanted to utilize and they were denied those alternative treatments even though it was a life-or-death situation, and that was very disturbing to me and to some of my colleagues.

We are not really trying to pick on you, Dr. Klausner or Dr. Jonas and your offices. It appears to me as a nondoctor, a layman, that there has always been an institutional bias against new scientific change. Louis Pasteur was vilified and yet later proven to be one of the great scientists.

Barry Marshall, who is a friend of mine, he is a friend of mine because he cured me of a stomach problem that I got when I was in Africa. Barry Marshall went before a symposium of stomach doctors, experts, in Belgium and he told them that he thought that ulcers in most people was caused by a bacteria and they literally laughed him off the stage. He went home and drank the bacteria and cured himself and proved it. It is kind of like what Louis Pasteur did, and it is kind of sad that doctors have to risk their lives to prove their point sometimes. But, nevertheless, now millions and millions of people are going to be able to be helped by Barry Marshall's procedure; and I think the guy ought to get the Nobel Prize. But that is the problem we have. There is an institutional bias.

Dr. Linus Pauling. When I was a State legislator, I called him about Laetrile. Dr. Linus Pauling got two Nobel Prizes for scientific research. He was not some guy from the backwoods. He knew what he was talking about. And Dr. Pauling told me that he thought there was some promise with Laetrile. And then he went off on a tirade about Vitamin C and said, you should take at least 4,000 or 5,000 milligrams a day, which I do. Because I think he must know something or must have known something.

And then we come to my wife. I read an article in Life magazine about a fellow who was having some remarkable results with breast cancer tumors, Dr. Springer, who just passed away recently up in Highland Park, IL. And I called him up and was able to get my wife in the program. She has been almost 5 years cancer free, and her prognosis was not good. And we attribute that in large part to Dr. Springer and his program. But FDA tried to close it down.

Those are the kinds of things that really bother people. Because if they feel they are in a life-and-death situation, they want to have every opportunity to save their lives or their loved ones' lives. And you and I have talked about this in my office privately; and I think it is really incumbent upon the medical profession, NIH, Alternative Medicine Office to do everything they can to accommodate people, especially those who are judged to be terminally ill.

I think somebody who is terminally ill, rather than say there is no hope, they ought to give them every opportunity. And that is why, I did not mean to go off on this speech, but I wanted to talk about a couple of things that I think are very important.

Mr. Horn is also here. Mr. Miller is here, and Mr. Kucinich is here, and we will let them ask questions in just a few moments.

We had testimony from Dr. Ralph Moss. I think he worked at Sloan-Kettering, and he is a well-respected source of information

on cancer in the medical community. He was an invited participant at the POMES meeting last year, and he served on the Advisory Panel for the Office of Alternative Medicine. I am sure you are aware of that, Dr. Jonas.

He testified that he saw firsthand the results of the first Laetrile trials at Memorial Sloan-Kettering in the 1970's, and that they showed that Laetrile caused tumors to shrink dramatically in laboratory mice. This is not somebody off the street. He worked at Sloan-Kettering. He saw the test results. He saw the mice. And he said that it dramatically reduced the tumors in laboratory mice, Laetrile.

He says that the subsequent trials both at Sloan-Kettering and at the Mayo Clinic were intentionally constructed so as to show that Laetrile was worthless. Now I do not understand that, and I think that is something that should be looked into, and I would like to ask you if you would take a look at running some more trials on that. Maybe it is worthless. I do not know. But why would a man of his caliber say that he saw firsthand dramatic results from Laetrile at Sloan-Kettering and it was later demeaned and called quackery? I think there should be another review of that to find out if there was anything to what Dr. Moss said.

This magazine, I do not know if you have seen this or not. It says, "Meet the Mouse that Beat Cancer." They are talking about, I guess, something similar to Laetrile.

Dr. KLAUSNER. These are new potential drugs to prevent the blood supply that nourishes tumors, yes.

Mr. BURTON. In any event, I wish you would take a look at that, if you could.

Let me get on to some questions. In 1990, the New England Journal of Medicine published an astounding study that showed a third of all Americans use alternative therapies. Why didn't the NCI immediately begin gathering data on the most promising therapies and allocate money for clinical trials right away?

Dr. KLAUSNER. Well, of course, I was not at the NCI then. I do know what happened around 1990, in response to the recognition of how many individuals take complementary and alternative medicine, which, of course, represents a tremendously broad range of definitions of what individuals are doing. We developed a best-case series approach to provide a mechanism for practitioners to approach the NCI to bring that information or any information, observations they had to see which would be amenable to clinical trials.

I actually think that since that time there has been a significant increase in both the openness to and evaluation of especially complementary approaches, the types of approaches that we will hear about from Dr. Gordon and I think Dr. Fair.

So I cannot exactly describe what was going on at NCI in 1990, in response to that New England Journal article. But actually I think what we have seen over this decade is an increasing amount of literature, an increasing amount of discussion and an increasing amount of research about complementary and alternative medicine for symptom control, for quality of life, and I think the majority of what individuals avail themselves of is not necessarily alternative medicine but complementary medicine.

So I think there was a response to it. And one could always ask, was it enough, was it appropriate, and it is very difficult for me to judge that. We are working hard now.

Mr. BURTON. In my opening statement, I said 40 to 60 percent of the people who have cancer are still going outside the normal medical remedies to find alternative therapies, and they need to be researched and looked at to find out if they are credible.

Exactly how much money has the NCI spent on funding clinical research and alternative cancer therapies for each of the last 7 years? And this excludes the botanical project the NCI has been funding for years where they are collecting potential active ingredients from plants around the world.

Dr. KLAUSNER. I do not know the number for each of the last 7 years. The funding last year, by our calculation using the criteria from OAM, was about $16 million excluding the types of evaluation of natural products, which we do. And you see from this that in many ways it is very difficult to set a clear boundary. Many of the alternative medicines relate to herbals and natural products; and, in fact, many of the "traditional medicines" are exactly that.

I think the boundary is not as crisp and clear in terms of the research and the practice and the science perhaps as the cultural differences, which I think we need to work on. So we calculate about $16 million directly and indirectly in this past fiscal year for the areas of complementary alternative medicine as provided to us in the definitions by the Office of Alternative Medicine. For direct clinical trials, about $2.6 million.

Mr. BURTON. Dr. Jonas, to what do you attribute the much-publicized reduction in cancer deaths? Do you think the increased use by cancer patients of CAM is a factor?

Dr. JONAS. Probably not, sir. I think Dr. Klausner can probably answer this much better than me because he has been following those statistics much closer. But certainly life-style changes are a major contributing factor. Individuals are taking better care of themselves. They are more cognizant of the factors that increase their risks for cancer and other diseases such as heart disease. So preventive measures, in my opinion, and also some of the large-scale, newer therapies that are applied across the board I think are the main factors.

Mr. BURTON. Is there an annual report of CAM research activities at NIH?

Dr. JONAS. Yes. There is a biennial report that was required by statute, and that is delivered to the Director and incorporated into the biennial report of the Director of NIH.

Mr. BURTON. Could we get a copy of that? We would like a copy of that.

Dr. JONAS. Yes, sir.

Mr. BURTON. Let me refer to my colleague from California. Do you have any questions, Mr. Horn?

Mr. HORN. With this panel?

Mr. BURTON. Yes.

Mr. HORN. Let me ask a couple of general questions. You might have covered it. Sorry I had to be late.

I am curious to what degree NIH collaborates with foreign institutions similar to NIH? When you come to the National Academy

of Sciences, they have associate memberships, they stress a lot of international memberships of academies of science. Could you tell me a little bit about, No. 1, I know it is difficult to find something similar to NIH. And that is one of our problems in Europe. There is no institutional body that is regarded with credibility when you get into something crazy like Mad Cow disease, which affects trade and everything else. But just tell me a little bit about collaboration with like-minded institutions and name a few.

Dr. KLAUSNER. I think the collaborations are quite extensive. Just yesterday I was at a whole-day meeting with representatives of the Imperial Cancer Research Fund from England, the European Cancer Societies, the Australian Cancer Societies, and the Japanese Cancer Institute to create formal collaborations in one area of research.

The Clinical Trial System for cancer throughout Europe is officially linked to the NCI. In fact, the NCI funds the statistical center in Brussels for that multinational agreement. The clinical trials and oncology societies for doing clinical trials in New Zealand and Australia joined the NCI cooperative group system just this past year. The interactions I think actually are very good and very extensive.

Mr. HORN. Now, I realize scientists—it is an international discipline, obviously, and there are conferences all over the world, and I am sure they meet and collaborate there. But, as you know, we have heard a lot of criticism over the years of the slowness of the Food and Drug Administration to authorize particular medicines or processes, types of operations, so forth, to be used. That criticism comes that, gee, Europe gets things on the market faster than we do.

What is the relationship between the National Cancer Institute and the FDA in this? And what are your observations as a scientist between how Europe clears pharmaceuticals versus how we do, and should we change something there?

Dr. KLAUSNER. Well, of course, representing the NCI and not the FDA as a regulatory agency, what I can say is that over the last several years demonstrably, the approval process has become much more rapid at the FDA. And I can say specifically for cancer it has been, I think, quite extraordinary.

We have a very good relationship with the FDA. Many of the people leading the FDA had been at the NCI and are experts in cancer. And given the rapidity with which new therapies, and I think some remarkable new therapies, are moving through the FDA, I do not see Europe or anyplace else being more responsive than what I see now at the FDA.

Mr. HORN. In terms of the FDA reviewing something, do they call on the National Cancer Institute for advice?

Dr. KLAUSNER. Yes, they do; and so we interact greatly. And, in fact, when we are designing studies we work with them up front so that we do not get into the situation where we are designing a study and the FDA might ask for something that was not built into the study. And the collaborations, again, are getting much more intense as we try to develop better markers for disease so we can get answers more quickly. We are working with the FDA so that they

will agree up front on the markers, such as quality-of-life measures.

So the collaboration is very intense and I think works very well.

On the other hand, we keep a separation because we are not a regulatory agency. We do not determine and should not determine who has access. Our goal is to be separate and to fairly evaluate, to do research, to discover new things and to evaluate what works or does not work.

Mr. HORN. Let me move to alternative therapies and alternative pharmaceuticals, so forth.

How is money allocated within the National Institutes of Health as a whole and all of your many specialized institutes? How do you deal with that if you have in each of those let's say something that would be described as an alternative therapy because it is not traditional? So how is that handled to make sure they get such funding or is that all run through the alternative program?

Dr. JONAS. A number of the institutes fund on their own a number of complementary and alternative types of therapies. And, in fact, Dr. Klausner mentioned that the NCI this last year has put $16 million, for example. The OAM has provided over its entire existence about $3 million into the cancer area for research.

We meet regularly with the Institutes, the Institute Directors and their staff. We have a trans-Federal CAM coordinating committee that Dr. Varmus put together last year and discuss what are the best research opportunities that currently exist for the coming year with each of the Institutes; and, depending upon the other commitments they have, the resources we have, we then develop those.

Mr. HORN. Now does some of your budget come directly earmarked by Congress or do you have to beg, borrow and steal from the NIH Institute in order to have a viable program?

Dr. JONAS. Well, we do both. We usually have an earmarked budget specifically for our office, and we use that with the other Institutes to develop collaborative projects. And when outstanding applications or research projects come in, we work with each of the Institutes and often will co-fund so that there is money coming from both sides into that, and this way we leverage the money.

As I discussed in my testimony, by using the infrastructures that exist, many of the Institutes are already paying for the research infrastructure that we will then use and add onto to conduct research.

Dr. KLAUSNER. Not to disagree with Dr. Jonas, but he's never been known to steal from any institute.

Dr. JONAS. That's true. No institute has ever given us money.

Mr. HORN. I'm talking about bureaucratic stealing.

Mr. BURTON. Mr. Kucinich—before I yield to Mr. Kucinich, real briefly, what percentage of funds do you get compared to what the National Cancer Institute gets?

Dr. JONAS. Well, our budget this year was $20 million.

Mr. BURTON. And what's the National Cancer Institute's budget?

Dr. KLAUSNER. $2.5 billion.

Mr. BURTON. $2.5 billion.

Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman; and I thank you very much for your leadership in this area. Because certainly people all over the country are looking for assistance and a means of dealing with cancer and Chairman Burton's leadership in raising the possibility of looking at alternative therapies as a means of assuring that people have a better chance to live is, I think, a major contribution; and I want to salute you for that, Mr. Chairman.

What we know is that the American people are already moving ahead in search of a cure for cancer, because that's what I think you could attribute to—to what you can attribute the amazing popularity of the use of alternative therapies. The thing that occurs to me is that we hear that there's a lack of scientific studies documenting the efficacy of alternative therapies. Dr. Jonas, could you tell us, is perhaps one reason because of the resistance of traditional medicine to funding alternative research?

Dr. JONAS. Well, traditionally, there has not been an investment by the conventional community which has the bulk of the resources in these areas. That's largely why they're classified as unconventional medicine. And so there has not been a large investment in these areas.

Mr. KUCINICH. There's been a great amount of anecdotal information available. Is there a central data base for that information?

Dr. JONAS. No, there isn't. Anecdotal information or stories can be useful. In fact, it's the foundation for collecting research that then goes into comparative trials, also. But it must be collected in very systematic and complete ways. And most of the information that is collected out in practices is not collected in order to be analyzed in a way to decide whether it works or not works, and so often that information is not very useful for making decisions about the amount of evidence that exists.

Mr. KUCINICH. You know, it may be, in listening to medical practitioners speak on this subject, that the lack of a centralized data base on this is a major obstacle toward being able to evaluate this almost folkloric need which people have for alternative therapies. But it goes beyond folklore. Alternative therapies do work.

What can be done to establish a centralized data base and even a web site? I mean, we're in an era of technological leaps. If we had a web site where people who have experienced the benefits of alternative therapies could literally tell their story and then the professional practitioners could perhaps see if there's some common links. So how would you respond to that?

Dr. JONAS. Well, theoretically, that's possible; practically, it's extremely difficult. And I will give you an example.

We have a process that NCI developed calls the best-case series, which is essentially doing what you're requesting, collecting evidence that certain cases actually were cured by a therapy and actually did have cancer. And frequently, when that evidence is provided, it's found that there were errors in what has been reported. So, for example, the individual did not have cancer or the cancer diagnosis was incorrect or they only reported part of the therapies that they were getting and didn't report all types of therapies which could be effective.

And so the utility of that kind of information, unless it is collected in very rigorous and systematic ways, is often extremely limited and in some cases not useful at all.

Mr. KUCINICH. I would grant you that response to therapies may be idiosyncratic. Given that, we also know that there is a traditional resistance of traditional medicine to alternative therapies, which basically argues against research into alternative medicine.

I might comment to the Chair that such a resistance ironically mirrors the resistance of cancer to a cure by traditional medicine, and that while conventional medicine has done much to improve public health and quality of life, its rigidities may inadvertently be slowing a cure for cancer. Even as conventional medicine could provide us with a cure, the frustration I think of alternative medicine is making it difficult to get one.

And I think it points out the need to what the Chair is aiming at and that is to have a more integrative approach, integrating conventional autopathic medicine with the more complementary and alternative therapies. And I think the—as you gentlemen represent a divergence of views on that, we need some convergence so that the American people can give us feedback as to what they've learned and so you could take advantage of a new type of thinking.

But I would just like to conclude with this: We really need a new type of thinking about this. We're entering into a new millennium. It's time for a quantum leap, where we have a qualitative transformation on the thinking about medicine itself, and this will lead not only, I think, to looking at ways of better managing cancer but also the symmetry which could lead to prevent it as well.

So I appreciate you gentlemen and your participation in this. And I again want to thank the Chair for his outstanding leadership in this area.

Mr. BURTON. Thank you, Mr. Kucinich.

Before I yield to Mr. Miller, let me just say that Mr. Kucinich I think makes a very valid point. Even if you did have a web site and you did get information that was not complete, if you had some staff people that could analyze these cases and check them out, you might very well come up with some conclusive evidence or close to conclusive evidence that could lead to additional therapies that could be used in cancer.

To just say out of hand that the information you're going to get from a computer or from a web site would say it doesn't tell whether they used other things in conjunction with the alternative therapy that they used, I think is to beg the question. The more information you get from cancer patients who have been cured, the better picture you can draw.

And I don't understand why there's a recalcitrance to this kind of an idea. I think a web site and asking people who have had remarkable cures from alternative therapies to put their information in there would be great, and to have a review panel go through that and look at it could be very helpful in coming up with new procedures to save people's lives.

Dr. JONAS. I just want to say we actually have been developing along these lines and working very hard along these lines to develop this kind of practice-based outcomes evaluation. Actually, POMES refers to some of those ideas. Well, for example we're

working with the CDC right now to develop and use some of their field investigation methods to go out and actually collect information that practices this very type of information.

Mr. BURTON. Well, can you solicit data bases from doctors who are practicing CAM?

Dr. JONAS. Well, once there are networks, for example, that collect data within practices, and this is one of the things that we're exploring. We're planning to have a conference next year with the main Federal agency that does this type of research called outcomes research, the Agency for Health Care Policy and Research, specifically looking at the use of this type of research and the collection of this type of data in practices in CAM areas.

Mr. BURTON. Mr. Miller.

Mr. KUCINICH. Excuse me, Mr. Miller. Would the chairman yield for a minute?

Mr. BURTON. If Mr. Miller doesn't mind.

Mr. KUCINICH. Mr. Miller, I want to point out something apropos of what the Chair said. One of the problems I think we have in this is that we have people who are alternative practitioners who, in providing such information, may feel that they would be under some kind of legal attack for practicing medicine. And I know you've raised that issue before about making sure that those who are alternative practitioners are not subject to those kinds of attacks.

Mr. BURTON. Well, I might add, I think we have a doctor before us who is going to appear today who is under scrutiny because he was using alternative therapies to help his patients, and they tried to take his license away from him. Fortunately, that did not happen. But that is really counterproductive. If a doctor is using alternative therapies that work, rather than try to jerk his license, they ought to try and find out why it's working. You know, I don't understand that.

Mr. Miller.

Mr. MILLER. Thank you, Mr. Chairman, and thank you for having the hearing. Someone who sits in the Labor-HHS Appropriations Subcommittee, Dr. Klausner, comes to us often, it seems like, sitting through a lot of meetings as we go through that appropriation process.

NIH—and John Porter likes to talk about this—was really one of the crown jewels of the Federal Government. And we should all be very, very proud about—it is not a partisan issue. We all support it very strongly.

Speaker Gingrich has said often, this is one of the highest priorities for future growth and spending in the Federal Government. We spend about—what—$13 billion a year total, and cancer, I guess, about $2.5 billion. We're talking about round numbers, which is the largest, right?

One of the concerns I've had in going through those hearings is I guess concerns of the bureaucracy. How many Institutes are there, 23?

Dr. KLAUSNER. There are 24.

Mr. MILLER. There are 24 Institutes. And then there are these offices, such as the Office of Alternative Medicine, and how many offices of AIDS research—AIDS is not an institute, by the way?

Dr. KLAUSNER. That's right.

Mr. MILLER. Do you know how many offices there are?

Dr. JONAS. I think actually there are eight program offices.

Mr. MILLER. Eight program offices plus the 23.

Dr. JONAS. I may not be accurate on the total numbers. There are both program and operational offices.

Mr. MILLER. Who do you report to? Who is your boss?

Dr. JONAS. My boss is Dr. Bill Harlon, who is the Associate Director of Disease Prevention.

Mr. MILLER. Are all of the offices under that?

Dr. JONAS. No. There are four offices—the Office of Rare Diseases, the Office of Dietary Supplements, the Office of Alternative Medicine, the Office of Medical Applications of Research—underneath him.

Mr. MILLER. One of those things I learned over the few years I've been on this committee is the interrelationship of all of this. It's like—when we talk about AIDS research, which gets a very large amount of the total budget, not as much as cancer, but the interrelationships of the research, what happens in AIDS research affects cancer, cancer research can help AIDS and all the way across there. So there are a lot of different benefits.

But I get concerned about this bureaucracy; and I don't know how Dr. Varmus can keep track of so many different offices and Institutes. There are so many people reporting to him. Basic management 101 says you have problems there. How does that work? It seems like I read a report you had a meeting with DOD, because they have a large amount of research. I mean there's $200 million, I think, for cancer research at DOD. How much time do you spend in meetings trying to coordinate things each day? Is basically most of your life just meetings constantly?

Dr. KLAUSNER. I spend a lot of time in meetings. And although I think many of them are quite productive, I think in those discussions and that coordination is how we recognize that—we do need structures. I'm a scientist. I spend my life discovering things. Bureaucracy is not something I like. But we need structures to make things work, but actually science doesn't neatly fall into these structures. And so what really we need is a matrix of collaboration.

Actually, I think, by and large, that happens very well. We feel as colleagues at the NIH, we come to it because we came with a desire to work on disease, physicians and scientists. I'm trained as a physician and a scientist.

AIDS is a good example. A lots of AIDS research goes on through the NCI. And, in fact, with the AIDS virus, we were able to make so much progress because it was a cancer-type virus. That was in the range of cancer-type viruses that we knew a lot about. The structure of the proteases, where we finally get effective therapies, was not the answer, was solved at the NCI.

And it works through this matrix of people talking to each other, collaborating, interacting. The scientists often don't really pay much attention to what institute they're in or funded by. They seek out their community that works. And we, in fact, try to make those barriers as transparent as possible so that the science gets done independent of the internal structures to make the wheels turn.

Mr. MILLER. The Alternative Medicine Office, it's relatively small, obviously, in the total budget of NIH. Is the purpose or expectation or the goal to not necessarily be a large, independent, grant-issuing institute or do you do a intramural research or is it basically extramural?

Dr. JONAS. We have a small intramural research training award program in which some of the intramural labs from any of the Institutes can make applications for doing projects intramural. But we are a coordinating office and a crosscutting office across all 24 Institutes. So we work with all of them. And I and my staff spend a lot of time working with each of the Institutes on developing specific projects with them, yes.

Mr. MILLER. One of the concerns we have on the committee, and I don't know how Representative Porter feels about this, we have—physicians don't make the decisions, that we need to rely on science as much as we can. But I know over the past few years we've given encouragement for the alternative medicine program in the appropriation bill. Over the past few years, what have we pushed you toward and helped you along, good or bad?

Dr. JONAS. Well, as I mentioned in the testimony, we have several projects now going on with over half of the Institutes, including funding 11 research centers around the country and funding several large clinical trials. We are looking at St. John's Wort on depression with the National Institute of Mental Health. I mentioned acupuncture and osteoarthritis with the Arthritis Institute; nutritional therapies of heart disease with the Health, Lung, and Blood Institute, and the funding that the office has gotten has gone into those type of projects.

Mr. MILLER. One more question before my time is up. The Library of Medicine, how does that work as far as providing information? They're talking about the web site versus information in the Library of Medicine. Is that separate or is that——

Dr. KLAUSNER. It has that status, yes, as a separate Institute.

Mr. MILLER. They come separately in their appropriations?

Dr. KLAUSNER. Yes.

Mr. MILLER. But that's a wealth of information. What information is available through the Library of Medicine on this area of alternative medicine?

Dr. JONAS. Yes, we worked very closely with the National Library of Medicine. They're in the process of, for example, looking at ways to enhance and increase the numbers of journals that they enter into the National Library of Medicine's electronic data base, which is the main source for medical information throughout the world.

We have also extracted complementary and alternative medicine citations from their data base to make it easier to access, and those are now available on our web site. And we've been working closely with them in developing other data bases and enhancing the data base in these areas.

Mr. MILLER. Would this be the No. 1 source of alternative medicine literature in the world, is the Library of Medicine, or is there some other that's even more?

Dr. JONAS. The National Library of Medicine is the No. 1 source of information for all medical information, including complementary and alternative medicine.

Mr. MILLER. Thank you. Thank you for the job you're doing. I'm proud of you.

Mr. HORN. Could I ask one question?

Mr. BURTON. Yes, Mr. Horn.

What we're going to—after you ask your question, we're going to bring another panel up. Dr. Jonas and Dr. Klausner have kindly agreed to wait until after the next panel, because we may have some additional questions for them after we hear from some other doctors. So, with that, go ahead and ask your question.

Mr. HORN. Mr. Miller reminded me that there has been a very excellent program in the Department of Defense that was founded by Jack Murtha, who is on Defense Appropriations. And one of the reasons it was founded, and that's before our time in coming here, was that a very distinguished researcher on cancer was turned down by the National Cancer Institute, because he never had a grant from the National Cancer Institute. And he was funded under—and was at a very distinguished university. He was funded by the military money, and there's some great results that have resulted from that.

Now, on that business of, gee, you've never had a grant from the NCI, so we can't fund you. I mean, this is a catch–22 if I ever heard it.

Dr. KLAUSNER. That does not happen. In fact, just the opposite. We set aside money to bring new people in to give their first grants. It's actually a special set-aside to make sure that we can attract those people in. And, actually, the NCI doesn't make that sort of decision. The grants come in, his proposal came in and peers come together and they review it and they rate it and then determine its rating.

And it's often viewed that then NCI decides not to fund it. That's not true. We make an up-front decision that we will stand by the recommendation of independent peer review and then fund what reaches a certain level.

Mr. HORN. Do you try to get anybody from the alternative medicine side on some of those peer review committees?

Dr. KLAUSNER. Well, yes. When the NCI is doing its own review and it's relevant to complementary alternative medicine, we then will seek out expertise for those particular reviews. And one of the places we turn to is turn to the Office of Alternative Medicine. I think that works very well.

One thing to remember is that most review that goes on of grants that come in, while the Institute funds that, they don't review them. There's a separate Center for Scientific Review. So it's actually separated from us to give the peer review system an independence. We simply get the results of those and then provide the funding.

Mr. HORN. I learned long ago that sometimes it's helpful to have a gadfly on review committees of any kind who are asking the tough questions, and nobody wants to be laughed at or something, but maybe they ought to be asked. Do you have that kind of person on one of these panels?

Dr. KLAUSNER. One of the things that the NCI did, and it was pointed out in the IOM report, is that we set up a special advisory committee to me of consumers, many of whom are particularly interested in alternative and complementary medicine. There are now 15 people; 400 people applied. We chose 15.

And one of the goals is to make sure that on all of our review committees are consumer advocates to ask those questions, to see how we make decisions, how we argue about science and that evidence and for them to participate, not just to observe but for them to participate.

We're creating training programs for them, that they're helping—they're actually helping us create by telling us what they need. And my certain—my hope is that they are exactly that sort of gadfly that says, why do you think that's important? Why do you think that's not important? Why are you criticizing this?

Mr. HORN. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Horn.

We will excuse you now and have our next panel, and I appreciate you staying around to hear what they have to say.

We have Dr. James Gordon, director of the Center for Mind-Body Medicine; Dr. William Fair, Urologic Oncology at Memorial Sloan-Kettering Hospital; Dr. Vince Speckhart, who is an oncologist and private practitioner; and Dr. Larry Key, urgent care physician, Michigan State University.

Stand and let me swear you in, please.

[Witnesses sworn.]

Mr. BURTON. We would like to, if it's possible, have you limit your statements to 5 minutes so we can get to the questions. We'll try to be liberal if you really need a little extra time, and then any additional comments you might want to have submitted for the record, we would submit it for the record.

Who would like to go first? Dr. Key?

## STATEMENT OF LARRY STEPHEN KEY, D.O., URGENT CARE PHYSICIAN, MICHIGAN STATE UNIVERSITY

Dr. KEY. I would like to thank you for inviting me here today. It's a real privilege to speak.

Chemotherapy by any other name is still chemotherapy. My chemotherapy is no longer ABVD or MOPP but pancreatic enzymes and a healthy diet. The ideal chemotherapeutic agent will produce a minimum of toxic side effects. It would kill only cancer cells, not hair cells, sex cells or gastrointestinal cells from the mouth to anus. It would be relatively inexpensive and openly available to the public. It would not make you sicker or be, ultimately, responsible for your death.

My treatment protocol utilizes pancreatic enzymes to attack cancer cells. These enzymes are naturally occurring substances and, therefore, cannot be copyrighted or owned by any one company. Certainly, no pharmaceutical manufacturer would willingly investigate a product they cannot own. No company or business should be forced to take a loss in order to test a product it can never market. On the other hand, cancer is such a far-reaching, devastating disease that any reasonable treatment program should be considered.

It is that word reasonable which becomes a stumbling block. Who decides what is reasonable? Taking a chance on sounding crass, I must remind you that, to some, cancer patients are a crop, a renewable resource.

In 1935, the treatment of my disease, Hodgkin's lymphoma, was arsenic and radium/radiation treatments. Have we come much further? In some ways, yes. But at what cost? I, myself, have deprived a State medical facility of nearly $1 million by refusing a bone marrow transplant. That same facility is recognizing the additional loss of over $89,000 for chemotherapeutic treatments I refused to take. This does not include the loss from standard testing which is always required with orthodox treatment protocols.

It would seem illogical to have many of our main cancer research programs driven and funded in large part by those corporations which stand to gain the most financially from the continued use of their products.

If I'm a researcher whose research program is financially dependent on the support of a major pharmaceutical manufacturer, how likely am I to be absolutely honest with my findings, if those findings financially threaten my ongoing research and my livelihood? I'm not proclaiming some great conspiracy is at hand, only that human nature is just that, human.

The converse is also true. There are charlatans and quacks taking money from cancer patients as I speak. Those patients are buying what is offered. They are dying and do not care about the claims of either orthodox practitioners or alternative therapies. What is reasonable? They are dying. Anything is reasonable. The key is in what is offered. If the orthodox practitioners and researchers proclaim alternative approaches are bunk, without giving them an honest, open-minded evaluation, they could be missing an answer. The answer.

I am reminded that a moldy orange is the basis of the entire antibiotics industry. By the same token, any person who claims only those products which are natural should be used in the treatment of disease is as much in error as those who say only man-made products can be trusted. Most of us throw out moldy oranges without a second thought. We cannot afford to do this with possible cancer cures.

The rub is man-made products generate billions of dollars yearly, have vast research facilities and are attractive to the brightest minds. Alternative treatment programs, unless hawked as infomercials, have no hope of ever being fairly evaluated and ascribed as valid treatments. It would be hard to imagine an infomercial pushing the benefits of bone marrow transplants or expounding on the nifty effects a hit of vinblastin produces.

There is no need to do this because these products are wrapped in the cloak of respectability given to doctors, researchers and pharmaceutical companies. They hold a monopoly on the treatment of protocols which are very lucrative. Pancreatic enzymes are a great deal less expensive than orthodox chemotherapy and, in my opinion, a great deal more effective. This is bad news to the makers of classic chemotherapy and bone marrow transplant centers.

Cancer patients do not care about credentials, chemistry or credibility. They care about staying alive. Whether or not their doctor

is allopathic, osteopathic, homeopathic or naturopathic makes little difference to patients who are struggling to make sense out of a senseless disease. What is reasonable? Anything that works. And you will never know what works unless you drop preconceived notions about alternative treatments and support those programs which show promise.

I have cancer. I sit before you today because I had the courage to take on a treatment program that made sense to me as a trained professional. You, as representatives of the people, need to take the same kind of calculated risk I took. Personally, I would never fault you for financially supporting individuals who are actively evaluating unorthodox methods as much as being disgusted with you for not having the courage to risk for being thought foolish or gullible. Saving face will never save lives when it comes to this disease.

On behalf of cancer patients in this country and the world over, I ask your support both financially and in spirit for alternative cancer treatments. Thank you.

[The prepared statement of Dr. Key follows:]

I HAVE CANCER. I HAVE CANCER. I HAVE CANCER. I HAVE CANCER. IT IS THREE O'CLOCK IN THE MORNING AND I AM AWAKE. I HAVE CANCER. I WAS SLEEPING BUT NOW I AM AWAKE. I AM STARING INTO THE BLANKET OF DARKNESS SURROUNDING ME. I HAVE CANCER. I WANT TO SLEEP. I WANT TO BE LEFT ALONE. I HAVE CANCER. IT USED TO BE JUST ME INSIDE MY BODY. MY WHOLE LIFE WAS SPENT HAVING A RUNNING CONVERSATION WITH MYSELF...WITH ME. I HAVE CANCER. IT WAS PRIVATE, INVIOLATE, SOLITARY. I AM STUNNED. THERE IS ANOTHER THING IN HERE WITH ME. IT SINGS A MANTRA. OVER AND OVER. IT BECOMES THE BACKGROUND SOUND TO EVERY MOMENT OF MY EXISTENCE. I HAVE CANCER. I HAVE CANCER. IT HAS A SMELL, A TASTE. IT DRIPS LIKE A FAUCET IN AN EMPTY SINK. I HAVE NO APPETITE. I WEAR FATIGUE LIKE A SECOND SKIN. NO ENERGY. NO ENERGY. I HAVE CANCER. I HAVE CANCER. I HAVE CANCER. I HAVE CANCER.

**WHO GETS CANCER?**

THE ANSWER TO THIS QUESTION DEPENDS ON YOUR VANTAGE POINT. CANCER IS AT TIMES PERSONAL AND IMPERSONAL. IT IS PERSONAL WHEN SOMEONE YOU LOVE OR CARE FOR IS STRICKEN. IT IS IMPERSONAL IF IT HAPPENS TO *"OTHER"* PEOPLE...PEOPLE WITH "FAULTY" GENES, "UNHEALTHY" HABITS, OR JUST PLAIN BAD LUCK. CANCER GETS *BEYOND* PERSONAL WHEN YOU HAVE IT YOURSELF. DO NOT READ ANOTHER WORD UNTIL YOU REREAD THE OPENING PARAGRAPH OF THIS TESTIMONY. UNLESS YOU CAN PLACE YOURSELF IN THE ROLE OF A CANCER PATIENT, FOCUS YOUR THOUGHTS ON MY PRINTED WORDS, AND IMMERSE YOUR BEING INTO MY WORLD--THIS TESTIMONY WILL NOT SERVE TO INFORM THE ONE PERSON WHO SHOULD BE THE MOST AWARE OF CANCER'S ENTRAPPING EFFECTS. THAT PERSON IS *YOU*. WHO GETS CANCER? YOU GET CANCER.

**WHAT CHANGES WHEN YOU GET CANCER?**

YOU MAY OR MAY NOT KNOW THAT HAVING A VIEW OF YOUR FUTURE "SELF", IS A DRIVING FORCE IN YOUR LIFE. IT IS WHAT KEEPS YOU GOING...WHAT KEEPS YOU ALIVE. *"FUTURE VISION"* MUSTERS A BROAD SCOPE. YOU SEE YOUR FAMILY, YOUR FRIENDS AND COLLEAGUES...YOU SEE THE WORLD WITH FUTURE VISION. IT SETS THE STAGE FOR HOPE. CANCER DRASTICALLY LIMITS YOUR VIEW OF THE FUTURE...TUNNEL VISION WITH A CATARACT, LOSS OF THE FAMILIAR. NOTHING IS THE SAME...NOTHING.

IRONICALLY, ONE OF THE ONLY TIMES IN YOUR LIFE THAT YOU CAN CLEARLY IDENTIFY WHAT YOU PRIZE MOST IS WRAPPED IN THE FACT THAT YOU HAVE A TERRIBLE DISEASE. WITH A SORT OF "ZEN OF BEING", A GESTALT OF IMPORTANCE, A PROLONGED FLASH OF INSIGHT YOU RECOGNIZE THE OVERWHELMING SIGNIFICANCE OF SO MANY SMALL THINGS...SO MANY *NEW* TREASURES. THE PEOPLE YOU LOVE, THE NATURAL WORLD SURROUNDING YOU, YOUR FIVE SENSES, THE EMOTIONAL SATISFACTION OF WORK...IT IS LIKE BEING REBORN AND POSSESSING THAT ELUSIVE "SIXTH" SENSE.

*THE WORST THING ABOUT HAVING CANCER IS NEVER BEING ABLE TO TAKE **ANYTHING** FOR GRANTED.*

WE CAN GLIDE THROUGH OUR DAYS BECAUSE WE CAN IGNORE MOST OF THE INPUT OUR MIND IS FED. WE DO NOT HAVE TO "ACKNOWLEDGE" WHAT WE TAKE IN BECAUSE OUR PERCEPTION IS THAT IT JUST DOES NOT MATTER...WE CANNOT BE BOTHERED BY IT. YOU MAY NOT REALIZE WHAT A LUXURY THIS CLOUDED VISION IS; UNTIL IT IS TAKEN FROM YOU. ITS LOSS LEAVES YOU STUNNED... INTROSPECTIVE...NUMB.

**THE MEDICAL COMMUNITY**

*I HAVE WHAT?*

AFTER THE INITIAL SHOCK, THERE IS A WHIMSICAL FREEDOM THAT COMES WITH BEING TOLD YOU HAVE CANCER...WHAT ELSE CAN LIFE DO TO YOU?...YOU HAVE "THE BIG **C**"! HIT ME WITH YOUR BEST SHOT! I CAN RELAX NOW--I'M OUT OF THE GAME...DOWN THE CRAPPER...DONE FOR. GOD!...THE REALITY FRIGHTENS YOU!

*A CANCER BY ANY OTHER NAME...*

STAGE IV-B MIXED CELLULARITY HODGKIN'S LYMPHOMA, FIBRO-SARCOMA, EWING'S TUMOR, LYMPHOCYTIC LEUKEMIA, BASAL CELL CARCINOMA, RENAL CELL CARCINOMA, WILM'S TUMOR, SMALL CELL CARCINOMA OF THE LUNG, KAPOSI'S SARCOMA, CUTANEOUS MALIGNANT MELANOMA...THE LITANY GOES ON AND ON AND ON... A LISTING OF EFFICIENT PREDATORS SILENTLY STALKING.

*IF YOU HAVE TO HAVE ONE...THIS IS THE ONE TO HAVE.*

NOT ALL CANCERS KILL YOU RIGHT AWAY. SOME TAKE WEEKS, SOME MONTHS, AND, IF YOU ARE LUCKY...SOME TAKE YEARS. THERE IS NO SUCH THING AS A GOOD CANCER. THEY ARE *ALL* BAD.

*THE LANGUAGE OF CANCER:*

> *"A NEOPLASM IS AN ABNORMAL MASS OF TISSUE, THE GROWTH OF WHICH EXCEEDS AND IS UNCOORDINATED WITH THAT OF THE NORMAL TISSUES AND PERSISTS IN THE SAME EXCESSIVE MANNER AFTER CESSATION OF THE STIMULI WHICH EVOKE THE CHANGE. THIS ABNORMAL MASS IS PURPOSELESS, PREYS ON THE HOST, AND IS VIRTUALLY AUTONOMOUS."*
>
> -MY MEDICAL SCHOOL
> PATHOLOGY TEXTBOOK

LET ME TRANSLATE. CANCER IS MEAN AND SENSELESS. IT IS CRUEL AND DOES NOT CARE. IT PLODS ON WITH IMPUNITY. IT WILL ROB YOU OF YOUR POSSESSIONS AND TAKE YOUR LIFE.

*TESTING...TESTING...TESTING...STEP RIGHT UP AND SEE THE HUMAN PIN CUSHION!*

YOU SOON REALIZE THAT HAVING CANCER GIVES OTHER PEOPLE THE RIGHT TO INVADE EVERY ORIFICE AND AREA OF YOUR BODY. THIS IS USUALLY DONE WITH A SHARP-POINTED, METAL IMPLEMENT. YOU ARE NOT EXACTLY SURE WHY *THEY* ARE DOING THIS. YOU KNOW *THEY* TOLD YOU WHY...YOU EVEN SIGNED A PAPER THAT SAID *THEY* COULD, BUT FEAR HAS NEATLY ERASED YOUR MEMORY. YOUR MOUTH IS DRY, YOUR PALMS WET, YOUR GUTS ROIL...YOU KNOW A SANE PERSON WOULD GET UP AND RUN. BUT...YOU LET *THEM* DO WHAT *THEY* WANT TO DO. YOU HAVE CANCER...SANE BEHAVIOR IS NO LONGER AN OBVIOUS CHOICE.

*HOT LIGHTS, COLD STEEL, AND YOU...*

OCCASIONALLY HAVING CANCER MEANS *THEY* WILL REQUEST THAT YOU ALLOW *THEM* TO SURGICALLY EXCISE, IN PART OR WHOLE, VARIOUS PIECES OF YOUR BODY. THESE EXPERIENCES HELP BRING INTO FOCUS THE INVASIVE NATURE OF CANCER. IT SCARS YOUR BODY, IT IMPRINTS YOUR MIND. IT CHANGES YOU FOREVER.

*LIVING A "DAY-GLO" LIFE*

YOU LEARN ALL ABOUT X-RAYS, "CAT" SCANS, MRI's, BONE SCANS AND RADIATION THERAPY. YOU KNOW WHICH ONES ARE INVASIVE AND WHICH ARE "NONINVASIVE".

**THE WHITE-COAT BRIGADE**

*THOSE LITTLE THINGS THEY DON'T ALWAYS TELL YOU:*

* MOST CHEMOTHERAPY MAKES YOU STERILE.

* ONCE YOU HAVE CHEMOTHERAPY OR RADIATION YOUR CELLS (AND THEREFORE YOUR BODY) ARE AFFECTED FOREVER.

* A SIDE-EFFECT OF CHEMOTHERAPY IS CANCER.

*THOSE LITTLE THINGS THEY TELL YOU:*

* "YOU MAY EXPERIENCE A *LITTLE* NAUSEA".

* "YOUR HAIR WILL COME BACK".

* "MY AUNT NEVER GOT *SICK* ON HER CHEMOTHERAPY".

*"EGOS...NOTHING MORE THAN EGOS": AN ONCOLOGIST'S FAVORITE PHRASES.*

* "I THINK THE TREATMENT IS WORTH THE RISK."

* "IT'S NOT PERFECT...BUT IT'S ALL WE HAVE."

* "DR. XXXXX WAS CHIEF OF MY TRAINING PROGRAM AT *"THE "* UNIVERSITY. I DISCUSSED YOUR CASE WITH HIM AND HE AGREES WITH MY RECOMMENDATIONS. WE NEED TO MOVE ON THIS RIGHT AWAY.

**"YOU'RE DYING": THE DOOR TO ALTERNATIVE CANCER TREATMENT**

IT IS NOT UNTIL "ORTHODOX" MEDICAL TREATMENT OF YOUR CANCER FAILS THAT TACIT APPROVAL OF *ALTERNATIVE* TREATMENT IS GIVEN. **ONCE AGAIN, GO BACK AND READ THE OPENING PARAGRAPH OF THIS TESTIMONY BUT...READ IT KNOWING *ORTHODOX* TREATMENT HAS FAILED.** MANY SEEK ALTERNATIVE TREATMENTS; WHAT FOLLOWS ARE THE REASONS THEY SHOULD BE SUPPORTED IN THEIR EFFORTS.

**WHY I CHOSE AN ALTERNATIVE THERAPY**

*" A MAN'S GOT TO KNOW HIS LIMITATIONS."*

- A CLINT EASTWOOD CHARACTER

MY INITIAL DIAGNOSIS OF LYMPHOMA IN 1986 WAS FOLLOWED BY A YEAR OF CHEMOTHERAPY. **MOPP**, AS IT IS CALLED, CONSISTED OF **M**USTARD NITROGEN (USED DURING W.W.I BY THE GERMANS TO GAS ALLIED TROOPS), **O**NCOVIN (CAUSES YOUR HANDS AND FEET TO GO NUMB), **P**REDNISONE (GIVES YOU A BIZARRE MENTATION AND CAUSES YOUR FACE TO BLOAT), AND **P**ROCARBAZINE (MAY CAUSE LEUKEMIA -- MAKES YOU STERILE). MUSTARD NITROGEN AND ONCOVIN WERE ADMINISTERED VIA I.V.. THESE DRUGS, LIKE MOST CHEMOTHERAPEUTIC AGENTS, DAMAGE YOUR VEINS MAKING SUBSEQUENT I.V. STARTS MORE AND MORE DIFFICULT. CHEMO NURSES START TO HAWK FOR *ANY GOOD VEIN*. THE BACKS OF YOUR HANDS, YOUR FOREARMS...ANY PLACE AN I.V. NEEDLE CAN BE INSERTED IS OPEN FOR SPECULATION AND PENETRATION.

**PENNY LOAFERS AND CHEMO BAGS MAKE ME PUKE...**

IT IS A WELL KNOWN FACT THAT MOPP HAS A REMARKABLE PROPENSITY TOWARD MAKING YOU PUKE YOUR GUTS OUT. IT DOES NOT MAKE YOU VOMIT...IT MAKES YOU PUKE. HOSPITAL AT EIGHT O'CLOCK...CHEMO AT NINE O'CLOCK...HOME AT TEN O'CLOCK... PUKING STARTS AT ELEVEN FORTY-FIVE. ONCE EVERY TWENTY MINUTE FOR SEVENTEEN HOURS YOU HUG THE COMMODE AND "DRY HEAVE". IT IS EXHAUSTING! THE ANTI-EMETIC DRUGS YOU HAVE TAKEN ARE OVERPOWERED BY THE BODY'S URGE TO PURGE ITSELF FROM THIS POISON. THE MIND MAKES ASSOCIATIONS WHICH ARE NOT EASILY CONTROLLED. HEARING THE SOUND OF PENNY LOAFERS (MY ONCOLOGIST'S FAVORITE SHOE) COMING DOWN THE HALL--EVOKES WAVES OF NAUSEA. JUST SEEING THE BROWN BAGS (COLORED TO PREVENT LIGHT FROM ALTERING THE CHEMO DRUGS) REQUIRES A WASTE BASKET BE AT THE READY. THE WINDING STEM OF YOUR WRISTWATCH FEELS LIKE AN I.V. START--YOU STOP WEARING THE WATCH. EVERY TWO WEEKS YOU HAVE YOUR BLOOD DRAWN TO FOLLOW YOUR WHITE BLOOD CELL COUNT. IF THE CHEMO HAS NOT DESTROYED TOO MANY OF YOUR WHITE BLOOD CELLS...IF YOUR "COUNT" IS NOT BELOW 1.0 (NORMAL 4.6 - 10.8), YOU CAN TAKE ANOTHER HIT OF CHEMO. YOU LIVE AND DIE BY *THE COUNT*. YOU PRAY FOR A COUNT LESS THAN 1.0 SO YOU WILL NOT HAVE TO TAKE ANOTHER "HIT". WITH A COUNT LESS THAN 1.0 YOU COULD DIE FROM INFECTION...WHO CARES...DAMN CHEMO!

**THE CHEESE IS ALWAYS FREE IN A MOUSETRAP**

AFTER SIX CHEMO SESSIONS ON MOPP I AM REEVALUATED. THIS MEANS A BONE MARROW SAMPLE WILL BE OBTAINED. THIS CONSISTS OF "DRILLING" INTO THE SACRUM (THE BONE AT THE END OF YOUR SPINE) IN ORDER TO COLLECT THE CELLS NEEDED TO MONITOR MY CANCER. THIS PROCEDURE CAUSES BEADS OF SWEAT TO POP OUT ON MY FOREHEAD. THIS IS BECAUSE IT REALLY HURTS. I AM A TOUGH GUY...BUT IT REALLY HURTS. THE RESULTS ARE IN. THEY FIND ONE CANCER CELL ON THE FORTIETH SLIDE OF FORTY SAMPLES. I AM THIRTY-FIVE YEARS OLD, I WEIGH ONE HUNDRED AND TWENTY-SEVEN POUNDS (DOWN FROM ONE HUNDRED AND EIGHTY-FIVE POUNDS NINE MONTHS PRIOR) AND, I AM *STILL* DYING OF CANCER. I FINISH THE LAST SIX MONTHS OF MEDICAL SCHOOL WHILE ON CHEMOTHERAPY. I WILL NOT GIVE UP.

**A LITTLE KNOWLEDGE IS A GOOD THING**

I TRAVEL TO THE CLEVELAND CLINIC TO BE EVALUATED. THEY TREAT ME WELL. I AM A DOCTOR. A NEW DOCTOR BUT, A DOCTOR NONE THE LESS. THE NEWS IS THE SAME...STAGE IV-B HODGKIN'S LYMPHOMA LOCATED IN MY BONES...A SOMEWHAT RARE PRESENTATION...NOT A GOOD CELL TYPE...BUT, *IF YOU HAVE TO HAVE A CANCER, THIS IS THE ONE TO HAVE.* I AM TAKEN TO SURGERY AND HAVE AN *INFUS-A-PORT* PLACED UNDER THE SKIN OF MY LEFT UPPER CHEST. THE PORT IS CONNECTED TO A TUBE THAT GOES DIRECTLY INTO MY VENOUS SYSTEM. IT ALLOWS CHEMO TO BE ADMINISTERED I.V. WITHOUT HAVING TO *FIND A VEIN.* WHEN I AWAKEN FROM SURGERY THE CHEMO THERAPY IS ALREADY BEING ADMINISTERED THROUGH MY NEW INFUS-A-PORT. I START THROWING UP IN THE CAR ON MY WAY HOME FROM THE HOSPITAL. THIS HAS BEEN A SAME-DAY-SURGERY OUTPATIENT PROCEDURE. MY NEW THERAPY IS **ABVD** (**A**DRIAMYCIN - CARDIOTOXIC, **B**LEOMYCIN - DAMAGES YOUR LUNGS, **V**INBLASTINE - SIDE EFFECT: CANCER, AND **D**OXORUBICIN - MAKES YOUR URINE RED). I START MY MEDICAL INTERNSHIP. THE WORK IS GRUELING--TWELVE DAYS ON...TWO DAYS OFF...TWELVE HOURS A DAY OR UNTIL YOUR DUTIES ARE DONE. I ONLY MISS ON THE DAYS I HAVE CHEMO...I PUKE FOR SEVENTEEN HOURS AND GET UP AND GO BACK TO WORK. I PRAY FOR WHITE COUNTS LESS THAN ONE. TAKING CHEMO HITS EVERY TWO WEEKS IS MAKING A TOUGH YEAR OF INTERNSHIP EVEN HARDER. AFTER MY FIFTH HIT OF CHEMO(I AM SUPPOSED TO HAVE A TOTAL OF SIX)...I QUIT TAKING IT. IF I AM GOING TO DIE... SO BE IT. I CANNOT TAKE ANY MORE CHEMO. NEVER AGAIN...NEVER AGAIN...NO MORE "RAT POISON"...NEVER AGAIN.

**MY LEGS REMAIN AS SMOOTH AS A BABY'S BUTT**

I CONTINUE ON WITH MY LIFE. I GRADUATE FROM MY EMERGENCY MEDICINE RESIDENCY. I AM TEACHING AND TRAINING RESIDENTS. I BECOME A DIRECTOR OF MEDICAL EDUCATION. I TRY NOT TO THINK OF CANCER TOO MUCH. I TELL PEOPLE I *USED* TO HAVE IT BUT, I BEAT IT. I AM A *CANCER SURVIVOR*! MY DAUGHTERS ARE ENVIOUS OF MY SMOOTH, HAIRLESS LEGS. SEEMS CHEMOTHERAPY WORKS BETTER THAN ELECTROLYSIS. NO LEG HAIR EVER COMES BACK...UNFORTUNATELY THE CANCER DOES.

**LET'S SAY WE DO, THEN DON'T**

IT IS ONE A.M. AND I AM AWAKENED BECAUSE IT FEELS LIKE SOMEONE HAS THROWN A BUCKET OF WATER ON ME. I AM SOAKED. NOT JUST SUMMER-TIME, DAMP PAJAMAS BUT, SOAKED. MY WIFE TURNS TOWARD ME AND STARTS TO CRY. IT'S BACK ISN'T IT... SHE ASKS..ALREADY KNOWING THE ANSWER. I CHANGE, THROW SOME TOWELS ON THE BED AND TRY TO GET BACK TO SLEEP. I NOW KNOW WHY I HAVE BEEN SO TIRED. IT WAS MORE THAN THOSE SIXTY-HOUR WORK WEEKS I HAD BEEN PUTTING IN. MY OLD FRIEND HAD COME TO VISIT ME AGAIN. IT HAD BEEN EIGHT YEARS BUT HE WAS BACK...I CAN HEAR THE MANTRA BEGIN.

**SAME TUNE....DIFFERENT MELODY**

AFTER A "WORK-UP" CONSISTING OF MULTIPLE TESTS, X-RAYS, NUCLEAR AND CT SCANS, AND MAJOR ABDOMINAL SURGERY, THE CONCLUSION WAS PRESENTED. MY HIGHLY TRAINED ONCOLOGIST SUSPECTED I WOULD HAVE A NEW TYPE CANCER BROUGHT ABOUT BY MY PAST CHEMOTHERAPY (NOT UNUSUAL). HOWEVER, THE MAYO CLINIC INFORMED HIM IT WAS STAGE IV, MIXED CELLULARITY, HODGKIN'S LYMPHOMA....QUIETLY RETURNED...RELAPSED...THE MANTRA GOT LOUDER.

**TELL YA WHAT I'M GONNA DO...**

MY ONCOLOGIST GAVE ME THE TREATMENT CHOICES: *SALVAGE CHEMOTHERAPY* OR A *BONE MARROW TRANSPLANT*. NEITHER SOUNDED TOO EXCITING. HE WAS PUSHING THE BMT (BONE MARROW TRANSPLANT) AND SCHEDULED ME TO BE SEEN AT *THE* UNIVERSITY OF MICHIGAN TRANSPLANT CENTER. MEANWHILE, I DID A COMPUTER SEARCH FOR THE RESULTS OF TREATMENT FOR RELAPSED LYMPHOMA. I HAD A 24% CHANCE AT 5-YEAR SURVIVAL. I WAS GOING TO DIE. I KNEW IT AND SO DID THE ONCOLOGIST.

**THAT PRAYING IS DRIVING ME NUTS!**

BEFORE EACH TEST OR SCAN, BEFORE ANY PROCEDURE WAS PERFORMED ON ME, I ALWAYS PRAYED FOR GUIDANCE AS TO WHAT TO DO. IT DROVE MY ONCOLOGIST NUTS! HE WOULD SAY WE NEED TO THAT MEDIASTINOSCOPY RIGHT AWAY AND I WOULD SAY...LET ME PRAY ABOUT THIS. I ALWAYS DID WHAT HE WANTED ME TO DO. I WAS VERY THOROUGHLY EVALUATED; I CAN SAY THAT. AFTER MUCH PRAYER, FAMILY DISCUSSION, AND CONSIDERATION, I DECIDED THAT I WOULD HAVE NO TREATMENT AT ALL. WHEN I TOLD MY ONCOLOGIST MY DECISION, HE WAS FLUSTERED. HE COULD NOT COMPREHEND HOW AN INTELLIGENT MAN LIKE MYSELF, A DOCTOR, COULD MAKE SUCH A DECISION. I SAID IT WAS FOR THOSE VERY REASONS I COULD MAKE A DECISION. I WAS INTELLIGENT *AND* A DOCTOR. I ASKED HIM HOW I WOULD DIE. HE SAID WHAT DO YOU MEAN? HOW WILL I DIE I REPEATED. HE SAID FROM METASTATIC SPREAD OF MY CANCER, FROM INFECTION. BUT, HE CONTINUED *...PEOPLE DON'T DIE FROM YOUR DISEASE, THEY DIE FROM THE TREATMENTS*. MY POINT EXACTLY. I WENT TO MY PRIEST FOR LAST RITES AND TO MY ATTORNEY FOR A WILL. I WAS GOING TO DIE WITH DIGNITY.

**DEATH: YOU CAN RUN BUT YOU CAN'T HIDE**

I HAD LOST MY JOB, I WAS LOSING MY LIFE. I WAS TIRED AND MISERABLE. WITH TOO MUCH TIME ON MY HANDS I STARTED CLEANING OUT OLD PAPERS AND MEDICAL JOURNALS. I FOUND AN AUDIO TAPE SOMEONE HAD GIVEN ME WHEN I WAS FIRST DIAGNOSED WITH CANCER IN 1986. *"THE METABOLIC / NUTRITIONAL APPROACH TO CANCER TREATMENT" NICHOLAS J. GONZALEZ, M.D....*I REMEMBER THINKING WHEN THE TAPE WAS FIRST HANDED TO ME...JUST WHAT I NEED! A "HIPPY-DIPPY" TREATMENT FOR CANCER. I HAD TOSSED THE TAPE INTO THE BOTTOM OF A BOX AND HAD NOT SEEN IT FOR EIGHT YEARS. MY WIFE AND I WERE GOING TO WATCH OUR GIRLS RUN IN A TRACK MEET AND I BROUGHT IT ALONG FOR A LAUGH...SOMETHING FOR MY WIFE AND I TO CHUCKLE AT AND MAKE FUN OF.

**IF IT'S BROWN AND HAIRY AND BARKS...CHANCES ARE IT'S A DOG: COMMON SENSE AND CANCER TREATMENT**

MAYBE I WAS CRAZY BUT AS I LISTENED TO WHAT THIS GUY GONZALEZ SAID, HE MADE SENSE. CARROT JUICE...DIETS... ENZYMES...IN THEORY IT HAD POSSIBILITIES. I WAS NOT LAUGHING ANY MORE. I TALKED IT OVER WITH MY WIFE AND DECIDED TO TRY AND FIND THIS GUY. THERE WERE FOUR DR. GOZALEZ'S LISTED IN NEW YORK CITY...I TOLD THE OPERATOR TO PICK ONE...SHE DID, AND GUESSED RIGHT.

**HOLD THE PHONE...I'LL BE RIGHT OVER**

I ASSUMED SINCE THIS WAS AN UNORTHODOX TREATMENT PROGRAM I COULD JUST "SIGN UP" AND THEY WOULD WELCOME ME (AND MY MONEY) WITH OPEN ARMS. I WAS WRONG. I WAS INFORMED I NEEDED TO MAKE AN APPOINTMENT FOR A TWENTY MINUTE PHONE INTERVIEW AND SEND MY MEDICAL RECORDS. I HAD TO HAVE PROOF THAT I HAD CANCER--VERIFIED BY AN RECOGNIZED AUTHORITY (MAYO, ARMED FORCES INSTITUTE)--NO "PSYCHIC" DIAGNOSIS ACCEPTED. AFTER THE INTERVIEW--IF I WAS ACCEPTED--I WOULD HAVE TO COME TO NEW YORK CITY FOR TWO DAYS. THE INITIAL ASSESSMENT WOULD BE $1500.00. DON'T CALL US...WE'LL CALL YOU. IF THIS GUY WAS A QUACK, HE SURE WAS PICKY. I SET THE INTERVIEW DATE, GATHERED VOLUMES I & II OF MY MEDICAL RECORDS AND WAITED FOR OVER TWO WEEKS. FINALLY DR. GONZALEZ'S OFFICE PHONED. HE WAS CONCERNED BY THE MASSIVE DOSES OF CHEMOTHERAPY I HAD ALREADY HAD BUT WAS WILLING TO GIVE ME A TRY. I MADE AN APPOINTMENT AND BOUGHT PLANE TICKETS.

**WE HAVE MET THE ENEMA...AND HE IS US**

THE THOUGHT OF PUTTING JUAN VALDEZ'S FINE COLOMBIAN COFFEE UP MY KEYSTER KEPT REPLAYING ITSELF IN MY MIND. IT DID BEAT THE OLD "I HAVE CANCER" MANTRA. I DECIDED TO KEEP AN OPEN MIND. I WOULD LISTEN TO EVERYTHING THIS GUY HAD TO SAY AND IF I COULD NOT CONVINCE MYSELF THAT IT HAD A SOUND BASIS IN ANATOMICAL AND PHYSIOLOGICAL FACT...I WOULD SIMPLY WALK AWAY FROM THE PROGRAM; $1500.00 POORER BUT WISER. WHEN I WAS ACCEPTED INTO THE PROGRAM I WAS ASKED WHETHER OR NOT I HAD ANY SPIRITUAL BELIEFS. I SAID I DID.
I WAS TOLD I WOULD NEED THEM...NOW THAT WAS A SWITCH!

**ORTHODOX DOC'S: MY WAY OR THE HIGHWAY**

NOT WANTING TO WASTE AN OPPORTUNITY TO ASSIST MY HIGHLY TRAINED ONCOLOGIST--I ASKED HIM IF HE WOULD LIKE TO "FOLLOW ME" (MEDICALLY SPEAKING) DURING MY LITTLE FORAY INTO THE WORLD OF ALTERNATIVE CANCER TREATMENT. ALL HE WOULD HAVE TO DO IS PROVIDE AN EVALUATION AT REGULAR INTERVALS -- BLOOD WORK, AN OCCASIONAL X-RAY, AND SO ON. I EXPLAINED IT WOULD BE A GOOD WAY TO DISCOURAGE OTHER RENEGADE PATIENTS FROM VEERING OFF THE ORTHODOX COURSE.
I MEAN, I WAS A DOCTOR AND AN INTELLIGENT MAN, IF IT DID NOT WORK HE COULD EXPLAIN TO THE OTHERS MY FOLLY. IF IT DID WORK, HE COULD TRY THE TREATMENT PROTOCOL FOR HIS OTHER PATIENTS (I WAS NAIVE). HIS "THANK YOU BUT, NO THANK YOU" WAS PERCEPTUALLY COOL...I DO NOT THINK HE LIKED THE IDEA... SOMETHING TO DO WITH A POOR WASTE OF GOOD COFFEE.

**HAIR SAMPLES -- MAYBE THE FBI IS ON TO SOMETHING!**

PRIOR TO MY ARRIVING IN NEW YORK FOR MY INITIAL EVALUATION, DR. GONZALEZ HAD REQUESTED I SEND HIM A HAIR SAMPLE TO ASSIST HIM IN ANALYZING MY METABOLIC STATE. BEING IN THE OWNER OF ONE OF THE SHINIEST PATES ON TWO CONTINENTS, I PUZZLED OVER WHERE TO OBTAIN THIS DESIRED SAMPLE. I WAS NOT ABOUT TO HACK AWAY AT MY NEATLY TRIMMED BEARD SO I OPTED FOR AN AREA A LITTLE LOWER DOWN. I THOUGHT..."HAIR WAS HAIR" AND WITH A SMILE, SENT HIM *THE SAMPLE*. WHEN I DISCUSSED THIS WITH MY MEDICAL COLLEAGUES I WAS MET WITH JIBES AND DISBELIEF. I MADE A MENTAL NOTE TO NEVER AGAIN SPEAK ABOUT COFFEE ENEMAS AND PUBIC HAIR IN PUBLIC.

**I'LL TAKE MANHATTAN**

NEW YORK CITY WAS EVERYTHING I EXPECTED AND MORE. NOISE, CONCRETE, MORE NOISE, TAXI HORNS HONKING THEIR OWN LANGUAGE, "STREET" PEOPLE, SAILORS, *THE* EMPIRE STATE BUILDING. WHEN I FINALLY ARRIVED AT DR. GONZALEZ'S OFFICE I WAS PERPLEXED AT FINDING THE SHRUBBERY CHAINED TO THE BUILDING...WHOA...THESE PEOPLE STEAL TREES? CLUTCHING MY WALLET I TRIED TO ENTER THE BUILDING. THE DOOR DID NOT GIVE. I HAD TO PUSH AN INTERCOM BUTTON, IDENTIFY MYSELF AND, BE "BUZZED" IN. *SHADES OF SEINFELD...THIS WAS NEW YORK!* IF GONZALEZ LOOKED LIKE KRAMER...I WAS GOING HOME.

SQUAD C-10 - DISTRICT OF COLUMBIA JOINT FUGITIVE TASK FORCE (DCJFTF)

SQUAD C-10, CONSISTING OF 13 FBI AGENTS, 15 MPD OFFICERS, 8 DEPUTY U.S. MARSHALS AND 12 ADDITIONAL FEDERAL AND LOCAL LAW ENFORCEMENT OFFICERS, FOCUSES EXCLUSIVELY ON THE APPREHENSION OF VIOLENT FUGITIVES. SINCE ITS INCEPTION IN AUGUST, 1989, THE DCJFTF HAS BEEN RESPONSIBLE FOR THE ARREST OF OVER 6,000 VIOLENT FUGITIVES. THE CONCEPT OF SQUAD C-10 HAS BEEN SO SUCCESSFUL THAT IT HAS BEEN EXPANDED INTO NORTHERN VIRGINIA THROUGH A PARTNERSHIP WITH THE FAIRFAX COUNTY POLICE DEPARTMENT AND THE FAIRFAX COUNTY SHERIFF'S DEPARTMENT.

SQUAD C-21 - FBI/MPD MAJOR CASE TEAM

SQUAD C-21 INCLUDES 11 FBI AGENTS AND 10 MPD OFFICERS. THE MISSION OF SQUAD C-21 IS TO INVESTIGATE HOMICIDES WHICH ARE GANG OR NARCOTICS RELATED OR INCLUDE SUBSTANTIAL INSTANCES OF OBSTRUCTION OF JUSTICE. SQUAD C-21'S MISSION ALSO INCLUDES THE INVESTIGATION OF SERIAL KILLERS, HIGH PROFILE CASES, SUCH AS THE BALLOU HIGH SCHOOL FEMALE STUDENT HOMICIDES AND THE STARBUCKS MURDERS, AND CERTAIN ASSAULT WITH INTENT TO KILL (AWIK) OR HOMICIDE CASES WHERE POLICE OFFICERS ARE THE VICTIMS. IT IS A SPECIFIC GOAL OF SQUAD C-21 TO CAUSE A MEASURABLE REDUCTION IN THE NUMBER OF VIOLENT CRIMES IN WASHINGTON, D.C. AND REDUCING THE EXISTING HOMICIDE RATE. SINCE ITS INCEPTION IN JUNE, 1992, SQUAD C-21 HAS SOLVED A TOTAL OF 212 HOMICIDES. CURRENTLY, SQUAD C-21

**ALL WORK AND NO PLAY MAKES JACK A *DEAD* BOY...IF HE HAS CANCER**

I WORKED TOO HARD. SIXTY TO SEVENTY HOUR A WEEK WAS TOO MUCH FOR MY BODY BUT, I LOVED IT. I WAS AN ADRENALINE JUNKY ...A "CODE BLUE RANGER"...AN EMERGENCY MEDICINE MAVEN. IT WAS KILLING ME. DR. GONZALEZ WAS THE FIRST PHYSICIAN TO TELL ME WHAT WE ALL KNOW...ALL FEEL...TOO MUCH MENTAL AND PHYSICAL STRESS IMPAIRS THE IMMUNE SYSTEM. I MADE A MENTAL NOTE TO RELAX...AFTER YEARS DRIVING THE LEAD CAR IN THE RACE "PIT STOPS" WERE NOT IN MY CREED.

**SAUNAS, SWEDES, AND SWITCHES: SKIN DETOX**

INITIALLY, WHEN I HAD A LARGER TUMOR LOAD, I BECAME MORE TOXIC AFTER TAKING THE ENZYMES. MY MENTAL MEASURE WAS TO LOOK FOR GOUT. CHEMOTHERAPY KILLS ALL SORTS OF CELLS. WHEN THE CELLS DIE, THEIR CONTENTS (INCLUDING URIC ACID) ARE DUMPED INTO THE BLOOD STREAM. THE INCREASE IN URIC ACID MEANS GOUT. GOUT IS A NIFTY LITTLE DISEASE WHICH MAKES YOUR BIG TOE FEEL LIKE SOMEONE RAMMED A PHILLIPS HEAD SCREWDRIVER THROUGH IT. IT HURTS. TWO WEEKS AFTER I STARTED TAKING THE ENZYMES I HAD GOUT. LABORATORY TESTS SUPPORTED THE FACT THAT I HAD AN INCREASE IN URIC ACID. THE GOUT PASSED. I CONTINUED MY ENEMAS AND ENZYMES. THE ORGANIC FOOD DIET, THE CARROT JUICE...ALL BECAME PART OF A DAILY ROUTINE. SLOWLY, I WAS GETTING BETTER. WHENEVER I FELT SILLY PERFORMING ANY PROTOCOL I WOULD SEARCH FOR THE ANATOMIC AND PHYSIOLOGIC REASONS WHY IT WORKED. FOR INSTANCE, COFFEE (CAFFEINE-A XANTHINE) WHILE A STIMULANT WHEN TAKEN ORALLY, WORKS IN A DIFFERENT FASHION WHEN ABSORBED THROUGH THE G.I. MUCOSA. APPARENTLY IT IS MEDIATED VIA THE PARASYMPATHETIC NERVOUS SYSTEM ALLOWING SMOOTH MUSCLE RELAXATION AND, THEREFORE, RELAXATION OF THE DUCT SYSTEM OF THE LIVER. THIS LETS THE LIVER DUMP TOXINS MORE RAPIDLY THAN IT NORMALLY WOULD. IT WORKS. THAT IS ALL I CAN SAY...IT WORKS. SKIN BRUSHING WAS A LITTLE TOUGHER. USING A BRUSH TO BRUSH MY SKIN (ALWAYS DISTAL TO PROXIMAL -- TOWARD THE CENTER OF THE BODY) SEEMED A LITTLE HOKEY. THAT WAS UNTIL I LOOKED A LITTLE CLOSER. THE SKIN IS THE BODY'S SECOND LARGEST DETOXIFYING ORGAN. A MICROSCOPIC VIEW REVEALS ARTERIOLES CONNECTED TO VENULES WITH A LYMPH CAPILLARY BETWEEN. INCREASE BLOOD FLOW (BRUSHING) INCREASE LYMPHATIC DRAINAGE, INCREASE DETOXIFICATION. NO MAGIC...JUST STRUCTURE AND FUNCTION.

**EVERYTHING NEW ISN'T NECESSARILY GOOD, AND EVERYTHING OLD ISN'T NECESSARILY BAD**

I HAVE BEEN ON THIS METABOLIC / NUTRITIONAL TREATMENT PROGRAM FOR OVER THREE YEARS. I HAVE HAD TRADITIONAL LABORATORY TEST AND A VARIETY OF SCANS PERFORMED. FOR THE MOST PART MY RESULTS RANGE FORM NORMAL TO SLIGHTLY IRREGULAR. MY TUMOR LOAD HAS SHRUNK DOWN. RESIDUAL REACTIVE LYMPH NODES REMAIN IN MY LUNGS (NOT UNUSUAL FOR THIS TYPE OF CANCER) BUT DO NOT HINDER MY RESPIRATORY EFFORT. MOST HAVE SHRUNK, THE OTHERS ARE NOT ENLARGING. THE ONCE, GOLF-BALL SIZED LYMPH NODE LOCATED AT THE BASE OF MY NECK -- (AN INDICATION OF MY ABDOMINAL PERIAORTIC ADENOPATHY) IS NOW BARELY PALPABLE. A FORMER BODY BUILDER, I WEIGH TWO HUNDRED AND TWENTY-FIVE POUNDS. I TRY TO EXERCISE AT LEAST THREE TIMES A WEEK. AFTER NOT WORKING FOR TWO YEARS, I NOW WORK THIRTY-SIX HOURS A WEEK AS AN URGENT CARE PHYSICIAN AT MICHIGAN STATE UNIVERSITY'S STUDENT HEALTH CENTER. SOMETIMES I GET FATIGUED -- A LITTLE REMINDER TO KEEP IT SLOW. I AM A PRODUCTIVE MEMBER OF SOCIETY. I AM A GOOD FATHER, A GOOD HUSBAND, A GOOD DOCTOR....BUT MOST OF ALL...I AM HERE! I WORK WITH A PHYSICIAN WHO LOST HER HUSBAND TO HODGKIN'S LYMPHOMA. A CHEMIST, HE WAS EXPOSED TO THE SAME BENZENE PRODUCTS THAT GAVE ME MY CANCER (I WAS EXPOSED AT AGE FOURTEEN WHILE WORKING IN A DRY CLEANERS). SHE IS AMAZED AT MY HEALTH. ANOTHER CO-WORKER'S HUSBAND HAS *MY* DISEASE. HE OPTED FOR THE MORE ORTHODOX ROUTE OF SALVAGE CHEMOTHERAPY AND BONE MARROW TRANSPLANT. HE IS MISERABLE. HE WEIGHS NINETY POUNDS "WET WITH A ROCK IN HIS POCKET". HIS SKIN IS THE COLOR OF AGED PARCHMENT. HE LIVES IN A PRIVATE HELL. ALIENATION FROM HIS WIFE, CHILDREN, AND SOCIETY ARE A WAY OF LIFE. HE IS ANGRY. AN ENGINEER, AN INTELLIGENT MAN, HE IS WAITING TO DIE. FOR HIM, CANCER'S MANTRA IS A DRONE...DEATH WILL BE INEVITABLE AND WELCOMED.

**TELL A LIE LONG ENOUGH AND IT BECOMES THE TRUTH**

MY FINAL THOUGHTS FOR YOU INCLUDE A DISCLAIMER. I WILL TELL YOU THAT I DO NOT HATE OR DISAVOW THE WORK OF ORTHODOX ONCOLOGY. BY A QUIRK OF FATE, CHEMOTHERAPY KEPT ME ALIVE LONG ENOUGH TO TAKE PART IN MY PRESENT PROGRAM. HOWEVER, IF I CAN PREVENT ONE OTHER HUMAN BEING FROM SUFFERING THROUGH, NOT JUST THE CANCER BUT THE TREATMENTS OF THIS DISEASE--I WILL DO SO. I WILL DEVOTE MY LIFE TO IT.

Mr. BURTON. Mr. Speckhart—or Dr. Speckhart, excuse me.

**STATEMENT OF VINCE SPECKHART, M.D., ONCOLOGIST/ PRIVATE PRACTITIONER**

Dr. SPECKHART. Congressman Burton, distinguished members of the committee, I thank you for inviting me to give testimony here today.

As background, I graduated from New York Medical College 40 years ago, and have had a broad practice experience. Along the way, I've been an Air Force flight surgeon, a medical missionary in Malawi, Central Africa, a general internist, a medical oncologist and, for the past 15 years, a practitioner of alternative medicine.

I very much am in the marketplace as a physician, but I have a desire for good research. I was the founding president of the Virginia Oncology Group, with the intent to find new statistical designs. And I've also been a member of rather conventional chemotherapy groups such as Eastern Cooperative Group and the Mid-Atlantic Oncology Program and had been for years.

After 13 years of using FDA-approved chemotherapy protocols, I concluded that such therapies were extremely toxic, poorly tolerated and not effective in prolonging survival of most solid tumors of adults. Over a 10-year period, I signed 170 death certificates a year by using chemotherapy. It was obvious to me that I was not treating the essential issues in the management of patients with cancer.

In 1983, my patients began to request therapies other than chemotherapy. I agreed and, without even knowing it, I became an alternative medicine practitioner and was red flagged by the opponents of this form of therapy.

Being a classical oncologist at the time and a clinical investigator, I was pleasantly surprised by the clinical responses that I saw using complementary and alternative medicine. I gave Urea to a patient who had recurrent cancer after 1 year of very aggressive chemotherapy by me. When I said that I think you need some more chemotherapy, she looked me right in the eye and said, I'm not going to take any more of that crap. This kind of surprised me. But it was an honest response by a patient who obviously found the therapies that I was giving being offensive.

By giving her Urea, she had a complete response of tumor in her lung and liver by x ray and by other parameters. She had no bone marrow toxicity, no hair loss, no heart damage. Her quality of life was excellent. She was seen traveling on her husband's Harley-Davidson motorcycle 10 years later.

I could cite other responses using other forms of therapy.

For example, I reported to the Office of Technology Assessment of the U.S. Congress a 75 percent response rate using Autogenous Vaccine. They recommended that further trials be conducted. My medical board, disregarding the fact that Autogenous Vaccine was grandfathered into the 1938 Food, Drug and Cosmetics Act as the ordinary practice of medicine, refused to let me use it. So here we have a board of medicine monitoring research with no experts to give them advice, other than for the people that were allopathic.

The first rule of therapeutics is "do no harm". I could not adhere to this rule by using chemotherapy. Therefore, I was eager to use

less toxic methods of therapy, nutrients, vitamins, minerals, enzymes, chelation therapy. They all had a part to play in my case management. Homeopathy seemed to be useful. Herbal therapies all had their place. Comfort measures such as massage therapy, deep muscle relaxation techniques, lymph massage could help remarkably in relieving the need for narcotics. Various detoxification programs, including the use of saunas, acupuncture, hypothermia, all seemed to have their place, in my clinical judgment.

I have just completed establishing a data base of 670 cases use electroacupuncture. I can now demonstrate a relationship between the bacterial, viral, fungal, chemical and pesticide signals for each acupuncture point that's clinically relevant. Even dental heavy metals, such as mercury, gold and titanium, can be recognized in various clinical conditions. In my experience, this technology has great potential for clinical application and should be studied.

I'm in the process now of publishing that data. My fear is that, if I get involved with government, that my data will be lost in the recesses of the National Cancer Institute, and I will lose control of my data, and that's a very, very significant practical reality.

The basic scientists have been telling us all along that the human body, like other biological systems, is integrated, nonlinear, that it's dissipative, nonequilibrial and dynamic. And I know these are big words, but it basically says you have to feed it, you have to follow it, and it's not like ball bearings and spark plugs.

Alternative medicine addresses many of the issues of the nonlinearity and focuses on the body, the host in which the tumor is growing; and the intent is to maximize the normal curative effect with the host, with the body.

A cancerous tumor, therefore, is an effect. It's an effect of the body's inability to maintain a healed state. Yet the current system's focus is almost entirely on the "lump and the bump," that is, on the tumor or its components with the object to destroy it by means of a manufactured product.

This system is linear and reductionist. Suppressive therapy with chemotherapy has led to enormous toxicity and to the development of multiple drug resistance, a current major medical problem. You can go into any intensive care unit of a hospital and see that there are antibiotics—and chemical therapy resistance is not a problem of the future. It is a problem now. Research into nondrug therapies is urgently needed in order to overcome this problem.

Specifically, biophysics should be explored in such areas as quantum and potential fields, magnetic field evaluation using the S.Q.U.I.D. technology, that is the superconducting quantum interference devices. Subtle energy states and biological information systems are all just on the horizon. We're entering into a new paradigm, and we have to go from molecular biology to biological physics. It's very important for us to get that through our conscious thinking.

Many practitioners in alternative medicine have their unique method of addressing the health care of their patients. One practitioner may emphasize dental metals, another use of enzymes, yet another immune stimulation. But they all use multiple modalities of treatment. In order to evaluate the efficacy of each practitioner, his method must remain intact.

This will require a change in policy by the FDA. Requiring study of each individual component of the system would not be productive in defining the outcome of the method itself, since these are integrated and nonlinear. There are many, many factors involved. Studies incorporating both standard and/or alternative methods should be conducted.

One of my great concerns is the lack of physicians to conduct clinical trials. In my experience, the regulation of alternative medicine has taken on the characteristics of a police state. There has been a deliberate attempt by its opponents of alternative medicine to characterize it as being fraudulent and unscientific.

Opponents encourage the reporting of all alternative care practitioners to State and Federal regulators. This has discouraged many physicians from entering this field and has placed a heavy financial burden on those in practice. I, myself, have spent $300,000 in my legal defense to maintain my license. Only last week did I get an unrestricted license after a 5-year struggle. The Virginia board now basically has said I violated no laws and I am vindicated.

I'm sure 110 of my satisfied patients at the hearing had something to do with the outcome, but I am so busy, I don't know what to do. I only schedule 3 months in advance, because I feel it's unfair to the patients coming to me to schedule any longer than that. I'm sure I could schedule patients a year or 2 years in advance; but when you have cancer, you may not do that. So, to be realistic, I schedule only 3 months in advance.

It has been a routine perception of mine that I can fill up my book within 2 hours of the first day that I open my book. And now I'm booked up until January. I can't fit any more in. This is very labor intensive on the part of the physician.

Physicians must be free to prescribe safe and effective therapies from whatever school of thought they are trained. Remember, medicine, like law, engages in "practice". There is no guarantee of outcome. Using alternative therapies should not be a cause for license revocation or probation.

I encourage the committee to fund both basic research, which is very important, and clinical trials in alternative medicine through the National Institutes of Health and the Office of Alternative Medicine.

Thank you.

Mr. BURTON. Thank you, Dr. Speckhart.

[The prepared statement of Dr. Speckhart follows:]

Congressman Burton, distinguished members of the Committee, I thank you for inviting me to give testimony here today.

I graduated from New York Medical College 40 years ago and have had a broad practice experience. I was an Air Force Flight Surgeon, a Medical Missionary in Malawi, Central Africa, a General Internist, a Medical Oncologist, and for the past 15 years, a practitioner of alternative medicine. I was the founding president of the Virginia Oncology Group and the member of the Eastern Cooperative Oncology Group and the Mid Atlantic Oncology Program.

After 13 years of using FDA approved Chemotherapy protocols, I concluded that such therapies were extremely toxic, poorly tolerated, and not effective in prolonging survival in most solid tumors of adults. Over a 10 year period, I signed 170 death certificates per year by using chemotherapy. It was obvious to me that I was not treating the essential issues in the management of patients with cancer.

In 1983, my patients began to request therapies other than chemotherapy. I agreed, and without even knowing it, I became an "alternative medicine practitioner" and was "red flagged" by opponents to this form of therapy.

Being a classical oncologist and a clinical investigator, I was pleasantly surprised by the clinical responses that I saw. I gave Urea to one patient with breast cancer. She had a complete response of tumor in her lung and liver and had no bone marrow toxicity, no hair loss, and no heart damage. Her quality of life was excellent. She was seen traveling on her husband's Harley-Davidson motorcycle 10 years later.

I reported to the office of Technology Assessment a 75% response rate using Autogenous Vaccine. They recommended that further trials be conducted. My Medical Board, disregarding the fact that Autogenous Vaccine was grand fathered in the 1938 Food Drug and Cosmetics Act as the ordinary practice of medicine, refused to let me use it.

The first rule of therapeutic is "do no harm". I could not adhere to this rule by using chemotherapy. Therefore, I was eager to use less toxic methods of treatment.

Nutrients such as vitamins, minerals, and enzymes all have an added benefit in treatment of cancer. Chelation Therapy, although not curative, has been helpful in eliminating toxic heavy metals. Homeopathy and herbals are useful. Comfort measures including massage therapy, deep muscle relaxation techniques, and lymph massage frequently eliminate the need for narcotics. Various detoxification programs, including the use of saunas, are also helpful. Acupuncture has therapeutic benefit in many ways.

I have just completed establishing a database in 670 cases using Electro-Acupuncture. I can now demonstrate which bacteria, viral, fungal, chemical, and pesticide signals are seen on each acupuncture point. Even dental heavy metals, such as mercury, gold, and titanium can be recognized in various clinical conditions. In my experience, this technology has great potential for clinical application and should be studied.

The basic scientists have been telling us all along that the human body, like other biological systems, is an integrated, non-linear system that is dissipative, non-equalibrial, and dynamic. Alternative medicine addresses many of these issues and focuses on the body, trying to assist it in maintaining disease free state.

A cancerous tumor is an effect of the body's inability to maintain a healed state. Yet, the current system's focus is almost entirely on the "lump and bump", that is, on the tumor or its

components with the object to destroy it by means of a manufactured product. This system is linear and reductionist. Suppressive therapy with chemotherapy has led to enormous toxicity and to the development of multi-drug resistance, a current major health problem. Research into non drug therapies is urgently needed in order to overcome this problem. Biophysics should be explored in such areas as quantum and potential fields, magnetic field evaluation using S.Q.U.I.D. (super conducting quantum interference devices), subtle energy states, and biological information systems.

Many practitioners in alternative medicine have their unique method of addressing the health of their patients. One practitioner may emphasize removing dental metal, another use of enzymes, yet, another immune stimulation. But they all use multiple modalities of treatment. In order to evaluate the efficacy of each practitioner, his method must remain intact. This will require a change in policy by the FDA. Requiring study of each individual component of the system would not be productive in defining the outcome of the method itself, since these are integrated, non linear systems. Studies incorporating both standard and/or alternative methods should be conducted.

One of my great concerns is the lack of physicians to conduct clinical trials. In my experience, the regulation of alternative medicine has taken on the characteristics of a police state. There has been a deliberate attempt by its opponents to of alternative medicine describe it as fraudulent and unscientific. Opponents encourage the reporting of all alternative care practitioners to state and federal regulators. This has discouraged many physicians from entering this field and has placed a heavy financial burden on those already in practice. I, myself, have spent $300,000 in my legal defense. Only last week did I get back an unrestricted license after a five year struggle. I am sure 110 of my satisfied patients at the hearing had something to do with

the outcome

Physicians must be free to prescribe safe and effective therapies from whatever school of thought in which they are trained. Remember both medicine and law engage in "practice". There is no guarantee of outcome. Simply using alternative therapies should not be a cause for license revocation or probation.

I encourage you to provide funding for both basic research and for clinical trials in alternative medicine through the National Institute of Health and the Office of Alternative Medicine.

Vincent J Speckhart, M.D., MD(H)

Mr. BURTON. Dr. Fair.

## STATEMENT OF WILLIAM FAIR, M.D., UROLOGIC ONCOLOGY, MEMORIAL SLOAN-KETTERING HOSPITAL

Dr. FAIR. Mr. Chairman, members of the committee, I'm Dr. William Fair, attending surgeon at Memorial Sloan-Kettering Cancer Center and professor of urology at Cornell University Medical College. I also serve as chairman of the Complementary and Alternative Medicine Committee of the American Urologic Association.

In addition to my professional qualifications, I also appear as someone who has had a personal experience with cancer, in my case, colon cancer, treated with four surgical procedures and a year of intensive chemotherapy. My presence here today with an excellent life quality 18 months after exhausting all curative therapy known to allopathic medicine is in itself a testimony to the effect of complementary medicine and cancer management.

In analyzing the available scientific data on complementary medicine, I was amazed and pleased to find out just how much good clinical and experimental data exists showing a benefit of CAM techniques in the management of cancer and how much opportunity there is to test essentially minimally nontoxic approaches that promise to significantly improve or maintain the quality of life in cancer patients.

On the other hand, I was dismayed to learn how little validated scientific testing was done on some approaches despite widespread use of these techniques among the lay population and how little research funding is available to properly evaluate a number of complementary medical approaches that anecdotally appear useful and represent eminently testable hypotheses.

It is quite possible that some measures now considered alternative may eventually become standard therapy. For example, in the 17th century the use of foxglove, the digitalis plant, was ridiculed by physicians when it was used as a substitute for blood-letting or leaches in the treatment of congestive heart failure.

Unfortunately, the term CAM embraces a large spectrum of practitioners, from those with valid scientific approaches to the charlatans and the quacks who prey on the fears and anxiety of the cancer patient for purely financial gain. Thus, the unscrupulous promoter who advocates wearing crystals on your hand or ear candling as a cancer cure should not be confused with those who use nutritional support, exercise, stress reduction, acupuncture, herbs, and spirituality to provide demonstrable benefit to cancer patients. In fact, these modalities should be considered as part of standard therapy.

Chairman Burton has correctly pointed out that the very word cancer is so terrifying and the impact on the individual is so profound that, faced with a diagnosis, an individual seeks help and treatment from whatever source he or she can find. The facts that the alternative medicine business has grown from 13 billion in 1990 to an estimated 50 billion in 1997 and that more people visit alternative medicine practitioners than primary care practitioners in the United States speak to the attractiveness of these approaches to consumers.

Last, the critics of CAM bemoan the lack of scientific studies documenting efficacy. This criticism is valid, but the lack of evidence-based medicine is not unique to CAM and exists in traditional medicine as well. We need to continue the search for a cure for cancer. But cures should not be the only goal. To increase funding which will allow adequate research trials of complementary techniques aimed at slowing disease progression, such as has been demonstrated in AIDS therapy, and improving life quality should be viewed as part of our overall strategy in the war against cancer.

Despite the staggering amount spent out-of-pocket by Americans, the NIH expenditures for research in this area is minuscule and should be greatly augmented. As an academic physician involved in cancer research, teaching and clinical care and as an individual afflicted with the scourge of cancer, I believe we and American medicine are falling far short of what is needed to maximize cancer care for our citizens.

My recommendation to the committee to stimulate more research in this most important area is as follows: The recent establishment of a Cancer Advisory Panel to the Office of Alternative Medicine is a step in the right direction but not nearly enough. The panel may make recommendations to the OAM, but the real fate of any grant proposal will be decided by the study section to which the grant is assigned.

Initially, there will not be enough CAM grant proposals to warrant the establishment of a separate study section, but I am dubious that any of the existing study sections will look with a great deal of favor on the complementary medicine grants competing with the other grants submitted to the NCI. I believe the only way to ensure adequate oversight of these grants is to have someone sympathetic to the CAM community appointed to the National Cancer Advisory Board. An individual with a true interest and commitment to CAM sitting on this committee could exert a powerful influence in assuring that complementary medicine grants are given an adequate review and, equally important, that information be disseminated from the National Cancer Advisory Board to the CAM community concerning strategies to increase the likelihood of success of grant applications.

A representative on the NCAB, chosen because of research experience and knowledge of the role of complementary and alternative medicine and cancer management, would assure the CAM community and the American voter that our government is aware of the growing demand for CAM services and is determined to evaluate these modalities in an impartial, scientific and carefully scrutinized manner.

Thank you very much for the opportunity to address this committee.

Mr. BURTON. Thank you, Dr. Fair.

[The prepared statement of Dr. Fair follows:]

Mr. Chairman, Members of the Committee of Government Oversight & Reform: I am grateful to Congressman Burton and the committee members for allowing me to address the Committee and express my personal opinions on the need for more research funding in the area of complementary and alternative medicine.

I am Dr. William R. Fair, Attending Surgeon and former Chief of the Urology Service at Memorial Sloan-Kettering Cancer Center, and Professor of Urology at Cornell University Medical College. I also serve as Chairman of the Complementary and Alternative Medicine Committee of the American Urological Association. In addition to my professional qualifications, I also appear as someone who has had a personal experience with cancer—in my case colon cancer and over the past 3 ½ years have had 4 surgical procedures and a year of intensive chemotherapy. My presence here today with an excellent life quality, 18 months after I exhausted all curative therapy known to allopathic medicine, is in itself a testimony to the effect of complementary medicine in cancer management.

As a result of a longstanding research interest in the role of nutrition on cancer—particularly prostate and breast cancer—plus the stimulus of my own condition, I have extensively analyzed the available scientific data on complementary medicine. I was amazed and pleased to find out just how much good clinical and experimental data exist showing a benefit of complementary or alternative medicine (CAM) techniques in the management of cancer and other chronic diseases, and how much opportunity there is to

test essentially minimal or non-toxic approaches that promise to significantly improve or maintain the quality of life in patients with cancer.

On the other hand, I was dismayed to learn how little validated scientific testing was done on some approaches despite widespread use of these techniques among the lay population, and how little research funding is available to properly evaluate a number of complementary medical approaches that anecdotally appear useful and represent eminently testable hypotheses.

It is important for the committee to appreciate the distinction between complementary and alternative medicine as used in my testimony. I believe the best term is complementary medicine which embraces techniques not generally taught as part of a medical school curriculum, that may be used to complement or augment standard therapy rather than an alternative to replace orthodox treatment. Although some mesures now considered alternative may eventually become standard therapy and replace commonly accepted procedures. For example, in the 17th century the use of Foxglove, the digitalis plant, was ridiculed by physicians when it was used as a substitute for blood-letting or leeches in the treatment of congestive heart failure.

Unfortunately, the term CAM enhances a wide spectrum of practitioners, from those with valid scientific approaches, to the charlatans and quacks who prey on the fears and anxiety of the cancer patient for purely financial gain. Thus, the unscrupulous promoter who advocates wearing crystals on your head or ear candling as a cancer cure should not

be confused with those who use nutritional support, exercise, stress reduction, group support acupuncture, herbs and spirituality to provide demonstrable benefit to cancer patients.

Chairman Burton has correctly pointed out the very word "cancer" is so terrifying and the impact on the individual so uncertain, that faced with the diagnosis an individual seeks help and treatment from whatever source he or she can find. The facts that the alternative medicine "business" has grown from 13 billion in 1990 to an estimated 50 billion in 1997 and that more people visit alternative medicine practitioners than primary care physicians in the United States speak to the attractiveness as these approaches to consumers.

Lastly, the critics of complementary and alternative medicine (CAM) bemoan the lack of scientific studies documenting efficacy. This criticism is valid but the lack of evidence based medicine is not unique to CAM but exists in traditional medicine as well. Consider the use of autologous bone marrow transplant for women with metastatic breast cancer. In the 5-year period between 1989-1994 there was a 6-fold increase in the use of bone marrow transplantation despite the lack of demonstrable survival advantage using their expensive, morbid and occasionally fatal intervention. In contrast, a landmark study by Spiegel and colleagues at Stanford University demonstrated a doubling of survival in breast cancer patients receiving a single 1 ½ hour session of group support for 1 year. As expected the median survival in the control group was 18 months versus 36 months in those receiving group support. Ladies and gentlemen, I submit that if these figures were the result of a new drug or expensive interventional procedure that would allow an

industrial profit it would make the front page of every newspaper and be covered by every TV news channel in the country.

I strongly believe that we are entering a new era in our approach to cancer therapy in which not cure, but control, of the malignant growth may be the goal of treatment. As I reflect on the approach to chronic disease taught in medical schools, I am struck by the fact that only with cancer do we consider the absolute cure of the problem is the only acceptable goal. Yet in dealing with other chronic potentially fatal diseases it is accepted that control of disease progression is adequate even if cure is not possible.

Thus, while we recognize, for example, that the total cure of cardiovascular disease, diabetics, asthma and arthritis is not currently possible, NIH funded research has enabled advances that provide ways of controlling disease progression and maintaining or improving quality of life even if cure is not possible.

We can potentially apply the same strategy to some cancer. In prostate cancer, for example, it is recognized that the time from when the first cell undergoes a malignant change until the disease can be a threat to life may well be 20-30 years! Imagine, if we could simply show the growth rate of the prostate tumor in 65 year old men using complementary techniques such as nutrition, exercise, stress reduction, etc., by 50%—in most men this would be tantamount to a cure without resorting to the potential morbidity of radiation, surgery or chemotherapy.

I believe that we need to continue the search for a cure for cancer but despite the prodigious advances in molecular biology, immunology, genetics and other areas, the cure will not come easily. To increase funding which will allow adequate research trials of complementary techniques aimed at slowing disease progression and improving life quality should be viewed as part of our overall strategy in the war against cancer.

We have heard the impressive statistics conveying just how important complementary and alternative medicine is to the average American. Despite the staggering amount spent out of pocket by Americans, the NIH expenditures for research in this area is miniscule and should be greatly augmented.

In conclusion, as an academic physician involved in cancer research, teaching and clinical care, and as an individual afflicted with the scourge of cancer, I believe we, in American medicine, are falling far short of what is needed to maximize cancer care for our citizens. My recommendations to the committee to stimulate more research is this most important area are as follows:

1.) The recent establishment of a Cancer Advisory Panel to the office of alternative medicare (OAM) is a step in the right direction but not nearly enough. The panel may make recommendations to the OAM, but the real fate of any grant proposal will be decided by the study section to which the grant is assigned by the NCI. Initially, there will not be enough CAM grant proposals to warrant the establishment of a separate study section; I am dubious that any of the existing study sections will look with a great deal of

favor on the Complementary Medicine Grants competing with other grants submitted to the NCI. I believe the only way to ensure adequate oversight of these grants is for the Chairman to push to have someone sympathetic to the CAM community appointed to the National Cancer Advisory Board. An individual with a true interest and commitment to CAM sitting on this committee could exert a powerful influence in assuring the Complementary Medicine grants are given an adequate review, and equally important, that information be disseminated from the National Cancer Advisory Board to the CAM community concerning strategies to increase the likelihood of success of grant applications.

A representative on the NCAB chosen because of research experience and knowledgeable concerning the role of complementary and alternative medicine in cancer management would assure the CAM community and the American voter that our government is aware of the growing demand for CAM services and determined to evaluate these modalities in an impartial, scientific and carefully scrutinized method to enforce effectiveness and safety.

2.) At some future time a study section devoted to a reviewing CAM grants would be a worthwhile goal but I believe such a demand would be impractical and unwarranted at this time.

I thank you for giving me this opportunity to address the committee.

Mr. BURTON. Dr. Gordon.

**STATEMENT OF JAMES S. GORDON, M.D., DIRECTOR, CENTER FOR MIND-BODY MEDICINE**

Dr. GORDON. Thank you, Chairman Burton. It's very good to be here.

I want to begin just by thanking you explicitly for your efforts in representing Americans to move these issues ahead, not only with regard to cancer treatment and cancer research but toward expanding our whole perspective on what constitutes good medicine. And I want to say that, because this movement to change medicine is very much to transform medicine and enlarge it, it is very much a popular movement; and I think that you and others in Congress have had a major role in this movement. So I want to acknowledge that.

I also want to say that I'm very pleased to be testifying with my colleagues on this panel whose testimony really has moved me because of their personal experience and also with Dr. Klausner and Dr. Jonas. I think that there's definitely a new day dawning in this work, and I feel very good about it.

I want to say a little bit about what my role has been and then make some specific suggestions for this committee.

First of all, I spent 10 years as a research psychiatrist in the National Institute of Mental Health; and, in recent years, I've been a professor at Georgetown Medical School and founder and director of the Center for Mind-Body Medicine and a clinician in private practice. I was also the first chair of the Program Advisory Committee to the Office of Alternative Medicine.

So I have—on the one hand, I have the very immediate perspective of a practitioner and in some ways similar to Dr. Speckhart. On the other hand, I have a kind of a national perspective. And one of the roles that I've had consistently since 1971 is somebody who is interested in the frontiers of medicine and of healing both initially within the psychiatry but then much more broadly; and my efforts have been to help bring people who are doing the most interesting work together with those who are in a position to examine, evaluate and, if appropriate, forward that work.

And we're at that stage now. I see myself kind of as a convener, if you will. We're at the stage in cancer research where I think this is an important function, not just for me but collectively for, I think one that this committee is helping us to fulfill, and one that I think all of us here need to be more responsible for.

Dr. Jonas mentioned the conference we had called Comprehensive Cancer Care: Integrating Complementary and Alternative Therapies this June. It was sponsored by the Center for Mind-Body Medicine. We had cosponsorship from the Office of Alternative Medicine, and it was an extraordinary event. Partly for, if I should say, with a little bit immodesty, but I was very impressed by the willingness of people on all parts of the cancer care spectrum to come to the conference, for people who are doing with the kind of research that Dr. Speckhart is doing to—and Dr. Gonzalez to share what they're doing, for people from the NCI, including the Deputy Director of the NCI, to come, to listen carefully, to respond thoughtfully. And I think that this dialog is immensely important.

We had over 1,000 people come to the conference, 115 presenters from all over the world and representatives of many of the major private cancer Institutes. Dr. Fair was there from Memorial Sloan-Kettering and many of the other institutions.

And there's some information about that conference, so I won't—in the packet, that everyone has—so I won't go into that in detail except to say that I was so impressed by Dr. Wittis; by Dr. Robert Temple, who is representing the FDA; Dr. David Rosenthal, who is president of the American Cancer Society; to come and to listen sometimes to people airing grievances and, more often, to people presenting data and to really take it seriously and to offer immensely constructive suggestions. We're going to be continuing with that conference each year; and we, of course, invite you to participate in that as well.

Now one of the things that's very interesting in listening to and reading Dr. Klausner's testimony, is how many of the things that I'm suggesting—that I have suggested in my written testimony, they are all under way at the NCI and between the NCI and the OAM, and I'm extremely gratified. And some others we had an opportunity to speak before this meeting, he agreed to several other initiatives as well.

So what I want to do is go very quickly through the things that I feel are important and then to respond to some of the questions that you and some of the other Members have asked and some of the issues that have been raised.

First of all, I think the Cancer Advisory Panel moving ahead quickly is extremely important; and I just want to express my appreciation for that. I agree with Dr. Fair that there needs to be a member of the community that has a vital interest in complementary and alternative medicine on the National Cancer Advisory Board. That seems to be extremely important, and I see that that needs to go forward. That represents a real commitment to having that voice represented.

Third, I spoke with Dr. Klausner about that I was going to suggest, I ask that NCI cosponsor as well as help us plan next year's comprehensive cancer care conference, and Dr. Klausner expressed his enthusiasm for doing that. So I'm very pleased to say that.

Dr. Klausner mentioned a lecture at NCI on complementary and alternative medicine. I would suggest that they there needs to be more than one lecture, that there needs to be some kind of series to advance the dialog.

One of the things that I noticed when I've lectured at NIH is the number of scientists, particularly some of the younger scientists, who are exquisitely interested in these areas of complementary and alternative medicine research. I remember one talk I gave, there were nine, I happened to count them, nine young scientists who came up afterwards and said, how can we do work in this area? I'm a molecular biologist or I'm interested in heart disease and whatever it was, how do we develop intramural research projects?

So I think we need to address that as well, and one of the ways to do it is by beginning to have kind of a lecture series where people can ask the hard questions and there can be this ongoing exchange.

The NCI Journal column I think is a wonderful idea. It's another one that we share.

I think there are a few other areas that are a bit harder. I think—one is I think we really need to take a look, and this follows the Institute of Medicine report, to really take a look at some of the funding priorities at NCI, but not only at NCI, we're talking about here, but all over NIH. How much money are we really devoting to prevention? How much money are we devoting—Dr. Waxman mentioned issues of tobacco, but there are other issues as well. How much money are we devoting to complementary and alternative therapies and what kind of research are we going to undertake?

One of the things I think—although it's important to look at specific agents, whether it's a chemotherapy or shark cartilage or green tea or any of the others, I think it's really important to really think through from the ground up what kind of research do we want to do? How much do we want to devote, for example, for looking at comprehensive therapies, rather than looking at specific modalities? And that was mentioned with regard to Dr. Gonzalez's work as well as Dr. Speckhart's work, and there are many other people. And that's not often the way research is funded.

So I think we really need to kind of have a fundamental discussion about research priorities. We also need to—and Dr. Klausner and I were talking about this earlier. There needs to be a very clear look not only at complementary therapies but at the process of integration and of creating therapeutic settings at cancer centers which address all of a patients needs—their needs for information about complementary and alternative therapies, the integration of specific therapies, and also just their human needs.

One of the sad things that happens in cancer centers across the country is, the worst thing is not the complementary and alternative medicine isn't included, although I think it's important, the worst thing is how people are treated humanly. And I think we really need to devote a very high level of attention to that.

Very quickly, I agree with Mr. Kucinich in terms of putting out more information. We need to do that. One of the things that we're doing—and this might be an example or something we could expand on—is we're putting out the presentations at—that were made at comprehensive cancer care along with the evaluations and the critiques. And we're putting that out on our web site so that people can read the data that's presented and read, for example, at NCI, scientist critique of that data. And I think this might be a way to deal with some of the issues of putting out information that has some kind of evaluation along with it.

International work is very important. I was in China last year. There's some very interesting complementary and alternative therapies for cancer in China that we are not even beginning to think about here. And I think that we need to—I agree there is a foundation for doing that work. We need to do a lot more of it.

I think we need to look—and I know this is a particular concern of yours. We need to look at FDA regulations. One of the advisors to the American Cancer Society, when he was commenting on Dr. Temple's presentation at our conference, he said, the problem is not you. The problem is not your scientific acumen or the way you're

enforcing the rules. The problem is some of the rules. They're getting in the way.

And so I think that the work you're doing in this area really needs to be moved ahead so that we can develop more flexible ways of studying some of these exciting new therapies and we can engage the FDA as an ally in this process. The Office of Alternative Medicine, the NCI cannot do all of the work that needs to be done in this area.

The Office of Alternative Medicine needs to become a center. It needs to have a larger budget. It needs to have its own authority, its own review committees, and that will be of considerable help in moving and working together as a more equal partner with the NCI.

And, finally, there needs to be a great deal more, and a couple of people have mentioned this already, a great deal more in the realm of education. In the realm of education at the medical school level, it's proceeding, but slowly in terms of complementary and alternative therapies. And also—and Dr. Klausner and I were talking about this earlier as well—we need to educate more and more people, professionals who can provide the kind of function that perhaps Dr. Fair and I provide in talking with people who have cancer about what their options are and helping them put together the best integrated program.

So I think that we need—and this is something that we're very eager to take part in—that we need an effort to train the people to do that, people who are going to be responsible and thoughtful about helping patients make the best possible choices.

Thank you very much, and thank you for the extra time. I appreciate it.

Mr. BURTON. Thank you.

[The prepared statement of Dr. Gordon follows:]

# Testimony to the Committee on Government Reform and Oversight

**James S. Gordon, MD**
**Director, Center for Mind-Body Medicine**

Six weeks ago, the Center for Mind-Body Medicine, with the collaboration of the NIH's Office of Alternative Medicine and the University of Texas Health Sciences Center, held the first annual conference on *Comprehensive Cancer Care: Integrating Complementary and Alternative Therapies*. (See attached articles from *USA Today* and the *Journal of the National Cancer Institute*.)

This conference brought together for the first time those who are doing the most interesting research and clinical work with complementary and alternative therapies with leaders of the American cancer establishment, including David Rosenthal, MD, President of the American Society, Robert Wittes, MD, Deputy Director of the National Cancer Institute, and Robert Temple, MD, Deputy Director of the Food and Drug Administration. Some 115 clinicians, researchers, and patient advocates from around the world presented their work, and more than 1000 people attended.

The conference grew out of obvious and pressing needs that many of us have recognized and that I have experienced in several of my professional roles – as Director of the Center for Mind-Body Medicine, an organization that provides support groups and referrals for hundreds of people with cancer each month; as the first Chair of the Program Advisory Council for NIH's Office of Alternative Medicine; and as a clinician in private practice, who receives calls every day from people with cancer and their families.

While we have made some advances in the treatment of some cancers, it is painfully clear that conventional therapy does not have all of the answers. It has also been clear that conventional oncologists and cancer centers are, at present, ill-equipped to help patients make wise choices among complementary and alternative therapies (more than 50% are already using these therapies), or to guide them in the integration of these with conventional cancer care. This conference was designed to answer some of these patient needs, as well as to provide guidance for future directions in research, clinical practice, and the dissemination of information. It was a vehicle for providing and critically evaluating information about complementary and alternative therapies that seem promising and how they can be integrated into a truly comprehensive program.

The mood of the conference was remarkably harmonious. There was a sense that people from all parts of the cancer care spectrum – NCI and FDA administrators and scientists, as well as complementary and alternative researchers and clinicians – were reaching out to one another, making the effort to move beyond past grievances and misunderstandings to work together to help shape an agenda which would enable us to better prevent and treat cancer.

The last session of the conference was a panel discussion on "Where do we go from here?" The members of that panel enthusiastically agreed to help plan next year's meeting. These included Dr. Rosenthal; Wayne Jonas, MD, Director of the Office of Alternative Medicine; William Fair, MD, Professor Urologic Oncology at Memorial Sloan-Kettering; Ernst Wynder, MD, who has been active for 40 years in exploring causes and treatments of cancer; Mary Ann Richardson, DrPH, who heads the Center for Alternative Cancer Research at the University of Texas; Clem Bezold, PhD, a futurist and advisor to the ACS; and Ralph Moss, PhD, a leading figure in providing accurate information about alternative therapies to the medical community and the

public. Dr. Wittes, who was unable to be part of the panel, has also indicated his interest in working with us on planning next year's conference.

We look forward to creating a yearly event that will continue to provide state-of-the-art information on integrative cancer care and research on complementary and alternative therapies to all those who are providing care to cancer patients, doing or fostering cancer research and offering information to the public.

My experience with this conference and over the years has led me to suggest the following steps that would help establish a common base of knowledge, facilitate information sharing and dialogue about difference, and foster creative collaboration.

1. **The timely creation of a Cancer Advisory Panel, an advisory board to the Office of Alternative Medicine and the National Cancer Institute which will include leaders in conventional oncology, as well as in complementary and alternative treatments.** This panel, which has been discussed and agreed upon in principle by the OAM and the NCI, will address all issues related to alternative cancer treatment – therapies to be tested, the way trials should be done, how information will be disseminated, etc. It will also serve as an ombudsman to mediate any differences that may arise in the conduct of trials, dissemination of information, or any other area.

2. **Inclusion at every level of government involvement of men and women who are committed to the thoughtful integration of complementary and alternative therapies into cancer treatment.** This would include the appointment of one or more such people to be members of the National Cancer Advisory Board.

3. **Participation of the NCI in co-sponsoring as well as planning and next year's *Comprehensive Cancer Care* conference.**

4. **Establishment of a lecture series at the NCI, at which leaders among those who are studying and using complementary and alternative therapies would present their perspectives and their work to, and receive feedback from, NCI scientists.** The Center for Mind-Body Medicine would be happy to work with the NCI to develop such a series.

5. **Creation of a regular column in the *Journal of the National Cancer Institute* on news related to complementary and alternative therapies.** The column would present fair and objective evaluations of the work being done and help make discussion about this work more a part of the ongoing NCI dialogue.

6. **Establishment of an ongoing discussion of NCI funding priorities.** Only a small portion of the NCI's budget goes to prevention and to clinical trials. Research on complementary and alternative therapies, most of which cannot be patented, may well not be undertaken by pharmaceutical houses because it cannot be expected to yield large profits. Therefore, there needs to be specific attention paid, and adequate public funding set aside, for clinical research on complementary and alternative therapies for cancer.

7. **Development of mechanisms and resources by which NCI and OAM can assist researchers and clinicians to organize their data, present their findings, and do research on complementary, alternative and integrative approaches to cancer.** This is the kind of work the Center at the University of Texas is already doing and there needs to be a far greater commitment to it.

8. **Transformation of the Office of Alternative Medicine into a National Center for Integrative Medicine with a significant increase in its budget.** Even with the best will and re-evaluation of its priorities, it cannot be expected that the National Cancer Institute will be able to meet all the needs for clinical and basic research in complementary and alternative therapies for cancer. A National Center for Integrative Medicine would have the authority and the flexibility to do field investigations of new therapies, establish granting mechanisms and review committees with the appropriate degree of expertise, and to gather, evaluate and disseminate information about the utility of complementary and alternative therapies.

It is my hope that this committee will consider and further these initiatives, and that those of us outside and inside the National Cancer Institute can continue to work together to devise the most comprehensive, effective, and respectful strategies for the prevention and treatment of cancer.

Mr. BURTON. Let me ask a few questions.

I would just like to say that the recommendations that all of you have made we have, and we will go through all of those. And Dr. Klausner and others, we would like to write you a letter enumerating all of those, I'm sure you have all of those in your mind, and make some suggestions that may be good or may not be good and get your response to them. Because I think some of the things that these gentlemen have said make a lot of sense and might help enhance your ability to get to the bottom of these problems.

Dr. Key, what advice would you give to others who have Hodgkin's disease? You talked about you didn't take—you decided not to take chemotherapy and you decided not to take some of the other conventional treatment because you thought it was going to do more harm than good. You've taken these alternative treatments and it's—how long have you survived now with that?

Dr. KEY. Well, 3½ years.

Mr. BURTON. OK 3½ years.

Dr. KEY. This is a relapse for me, also. I did have over a year of chemotherapeutic treatment. So I have a very direct comparison. In all honesty, what I would recommend without a doubt is, if I were given the choice again, knowing what I know now, I would have never taken chemotherapy for this disease. I say that knowing Hodgkin's lymphoma and the treatment of it by orthodox methods has come a long way. I'm thankful that I did stay alive, but the side effects and the—just the whole overall treatment were devastating to me and my way of thinking.

I feel as though I'm a relatively well-trained individual and an intelligent man, and I always ask myself—and I was thinking today how many anecdotes make a fact. I'm sitting before you not toxic, I'm able to work, I'm able to continue on my life because of the work that's been done with the metabolic nutritional approach to cancer. I would recommend strongly to use that approach rather than using the orthodox chemotherapeutic methods.

Mr. BURTON. And your doctor was——

Dr. KEY. Dr. Nicholas Gonzalez.

Mr. BURTON. Dr. Gonzalez. I understand Mr. Horn has to leave, so I'll yield to him for a question.

Mr. HORN. I thank you, Mr. Chairman. I'm sorry I have to leave this hearing for the campaign finance discussion that will be on the floor.

I have one question. All of your testimony was very interesting and I enjoyed having it; but, Dr. Speckhart, I just want to know one thing. You said of the 110 satisfied patients at the hearing, you were sure they had something to do with the outcome. Those 110 which are satisfied patients, what percent of your particular clients would they represent? Did you have 400 patients or 1,000 patients?

Dr. SPECKHART. About 1,000.

Mr. HORN. You've had about 1,000?

Dr. SPECKHART. Yes.

Mr. HORN. So this is about essentially 10 percent of the 1,000?

Dr. SPECKHART. That's right. They're living close enough to that geographic area where they can come in for a hearing.

Mr. HORN. What happened to the other 900 patients?

Dr. SPECKHART. Most of them are doing pretty good.

Mr. HORN. Did half of them die or what?

Dr. SPECKHART. No, it's far below that. Whereas before I was signing 170 death certificates a year, now 2 or 3 a year, maybe. But that doesn't mean that just two or three a year die. There are those that are under the care of some other physicians, and some have come in too late and all that. But in my clinical judgment, the use of electroacupuncture and following that paradigm seems to me quite useful in case outcomes, enough to drive me to continue doing it.

And, you know, your work is judged by its fruits. And, as I say, I have such a large number of people calling me. I can't handle all the problems, quite frankly. I have to teach this, and I have to provide peer-reviewed literature so I can get them to come. But also I have to have the approval of the State. Because when you're damaged goods, you can't appeal to anybody. If you're looked upon—if you have a probationary license, that doesn't exactly get a president of a university saying, well, I want to do business with you. So you really have to have some degree of credibility, and that was the first thing that they went after, was my credibility.

Mr. HORN. Sure. Well, thank you very much for putting that in broader context.

Dr. SPECKHART. You're welcome.

Mr. HORN. Thank you, Mr. Chairman.

Mr. BURTON. Yes, sir. Thank you, Mr. Horn.

Dr. Fair, you work at Sloan-Kettering?

Dr. FAIR. Yes, sir.

Mr. BURTON. And you have been a specialist in prostate cancer; is that right?

Dr. FAIR. That's correct.

Mr. BURTON. And before you had your bout with cancer, did you have a different perspective on how to treat it?

Dr. FAIR. Absolutely. Although we had been working for a few years on the role of diet and slowing the progress of prostate cancer, and it's another story, but I firmly believe that the end result of prostate cancer will not be necessarily curing it but just slowing the progression so that the man lives a normal life span.

But as a result of my own illness, I began looking around; and even in my own institution, there was no place I could go that could give me the information on these alternative therapies. So a lot of it was on—I mean, all of it was basically my own effort, which made me realize how difficult it would be, if not impossible, for someone who doesn't have the same training to find out this information.

So that what I've adopted is diet, nutritional supplementation, exercise, stress reduction, such as yoga and meditation, herbal therapy; and all of these were based on clinical or experimental data showing it had some benefit in my disease. And I might add, as soon as I find anything else that fits that criteria, I will use that also.

Mr. BURTON. And it worked?

Dr. SPECKHART. It seems to have.

Mr. BURTON. Mrs. Morella, do you have any questions?

Mrs. MORELLA. I appreciate your having this hearing, Mr. Chairman, and I am trying to get filled in on what you said. I have your

testimonies before me, and I know that you have the experience and the expertise, and we are hoping to look at the safety and efficacy of other issues.

Also I wanted to comment, Mr. Chairman, that I am pleased also that you have from NIH Dr. Richard Klausner, from the National Cancer Institute, who has testified and also Dr. Wayne Jonas who testified. You chose to have some good experts here.

Dr. Speckhart, from what I understand, you have been practicing, by many doctors' views, sort of unconventional medicine. Does this put you in peril as a practitioner in any way?

Dr. SPECKHART. No. When all these issues came up in 1992, my practice went up by leaps and bounds. It was like wearing a purple heart. I never advertise; I have no radio broadcast, and I have no newsletter. I just wanted to do what I thought was best for my patients.

Mrs. MORELLA. I also heard that you had cancer yourself?

Dr. SPECKHART. Yes, cancer of my nose.

Mrs. MORELLA. Did having cancer effect the way that you looked at the disease?

Dr. SPECKHART. Absolutely. There was nobody to give me advice as to what I should do, and I looked into my own self, and I found that dental problems were the biggest issue, metals and infections underneath crowns and things like that. So I set about to have all of the metal removed and all of the diseased teeth taken out. I see this routinely, that dental metals are a big issue. And patients waiting to come to my office, based on the data that I have from the data base, I recommend, while you are waiting around, to have the metal taken out of your mouth. It is a big barrier. If the metal is taken out, I find that the cases go to completion a lot more rapidly.

Now, this is a big area and I know it is a politically hot issue to say heavy dental metals ought to be looked at. I don't know of any trial which has been done to address this issue, and we ought to do it in a dispassionate way, based on the data that I have, but that is the type of thing that we can integrate with the National Cancer Institute.

It would be easy, for example, if I can say with reasonable certainty from my data that there is a relationship between, let's say, mercury amalgam and breast cancer. It would be easy to do standard therapy in one protocol and in the other arm take the metal out and look at the outcome. It would be fairly straightforward.

Now, I think there would have to be a lot more comfort on the part of those designing such a trial to say that at least that is the case, and the responsibility I have with this early data is to show outcomes. And I think that can be done, but the limitation that I have is that I am working out in the marketplace. I have to make a living. I have a staff to keep up. And all the work that I have done in research has been out of my own private pocket, and I haven't had any outside help, and I am constrained by time. At the end of the day, I am pretty tired.

I am 68, and I can't sit down and do innovative work on research. I will do that on weekends. Now that the board action is over, I have a little more vigor coming back. I think I have enough energy to do that, and I want to disseminate. I have given lectures

and things like that. But I need help. I need somebody with expertise that can say, I can take your data and this is valid and this is not and put it into a package and have it go up to another level. I am not covetous of it; I just want to get it out there.

Mrs. MORELLA. Do you think that the treatments that you do could be clinically tested?

Dr. SPECKHART. Everything that I do works off a voltmeter. It is three-dimensional space time. It is very analytical. And it should be fairly straightforward. After all, I think we have to do research into biophysics. That is a large area that has to be developed.

Look what happened with geology after the invention of the seismograph. We really began to understand what was going on underneath the surface. With electroacupuncture, you can get signals from the skin and see what is going on with various organ systems. It is nontoxic and noninvasive, and you can work your case.

I can iterate. I can go over a patient one time and see what I have as energy blocks and do the same thing again. You keep working the case until you don't get any more iterations and then observe as a trained physician to see the clinical response. It really works nice for somebody that is analytical in nature.

Mrs. MORELLA. Dr. Key, let me ask you a question about conventional oncologists. Do you think that they are doing the best for their patients; and, if not, what would you suggest?

Dr. KEY. I don't believe that I have ever met a clinical oncologist or physician personally that would do anything but the best for their patients. I think the problem is in how you look at what you do.

When I was first given the tape of Dr. Gonzalez's program, I honestly looked at it and said, here is what I need, is a hippy-dippy approach to cancer. I tossed it in a box, took the traditional therapy. Eight years later I relapsed and was given the opportunity to have a bone marrow transparent or salvage chemotherapy. I knew I had about a 24 percent chance of living, which is a 76 percent chance of dying. I found that tape when I was cleaning out a box and put it in on the way to a track meet to watch my girls run. I was doing it just as something to do.

What this gentleman was saying made a great deal of anatomic and physiologic sense. What happened, as a physician and cancer patient, my view changed. If any one of you sitting here has cancer, you know taking an alternative approach is not outside the bounds of normalcy. In fact, it may be the best way for you to go.

No, I don't think that oncologists are trying to do their patients in. I think when my lymphoma specialist looked at me and said, do this bone marrow transplant, knowing that I had a 24 percent chance of living through it and I would have a miserable existence, he told me to do it because that is what he is trained to do. He is not allowed to look at alternative treatment by others in his profession. So that is the answer. I don't think that they are out after us. I think they need to change the way that they look at what they do.

Mrs. MORELLA. Dr. Klausner testified earlier, he talked about collaborative efforts that are being made to develop the CAM information and the research opportunities expansion. Would you like

to just briefly say yes or no if you think NCI is moving in the right direction in that regard?

Dr. SPECKHART. Yes, I think they are. However, having gone through 5 years of Government supervision, I am very cautious about what happens after you give permission for Government to enter into your work; and it could very easily dissolve into nothing, as previous experience demonstrates. So there has to be some way where Government assists us, rather than we assist in Government.

What is happening in the country is, rather than get Government involved, there is a lot of private research going on; and corporate structures want to get involved without having the imprimatur of government. And it seems to me that, as a licensed practitioner, the only thing that having an M.D. did was it gave the Government the right to supervise what I was doing. And there are a lot of people that would like to stay away from the aftereffects of government intervention, which is control, and I would like to see that change, if we can construct a way to evaluate this data so that the innovator of this could maintain some control over the way data is managed, rather than by just carte blanche turning it over to a Government agency and waiting for something to happen. They don't have the same urgency that I have, I will tell you that.

Dr. GORDON. I think it is important to be involved. Most of the therapies are non-patentable. Large corporations are not going to invest large amounts of money to develop these therapies. And I think the role of the Government actually needs to be enlarged, particularly in this area, in terms of supporting the research.

The second thing, and I think Dr. Speckhart pointed this up very well, one of the roles that the Office of Alternative Medicine Center at the University of Texas is doing is helping people like Dr. Speckhart pull the research together. Because individual practitioners, some who are doing the most interesting work, some of them don't have the research temperament, they don't have the facilities and money to undertake these studies. So I think in every step of the way, the NCI and OAM can help people develop their research projects.

The other thing that is important and I am re-emphasizing this, it is crucial that there be more people trained to do this work. First of all, encouraged to be open-minded. Medical school encourages people to learn a lot but not always to be open-minded. We have to encourage physicians to be more open-minded, and we have to encourage people to be trained in these areas.

I have talked to many clinicians. We need more people who can do our work. The demand is enormous. The demand, whether it is for Dr. Gonzalez's therapy or Dr. Speckhart's work, any of the work that we are doing is immense, and we need many more oncologists who are interested in this work, and we ought to do whatever we can to promote it.

Just as kind of a footnote, one of the interesting therapies that I saw in China was electroacupuncture, and they are getting some amazing results with very large tumors being shrunk to virtually nothing in a very brief period of time.

Mrs. MORELLA. Do you want to comment, Dr. Fair?

Dr. FAIR. No.

Mrs. MORELLA. Thank you, Mr. Chairman, very much.

Mr. BURTON. Thank you, Mrs. Morella.

You mentioned that you were signing 170 death certificates a year and now you are signing 2 or 3 and you attribute that to your change in approach?

Dr. SPECKHART. Initially, when I first got into oncology, most doctors are very happy to let you be in control of those patients because they knew that there is nothing that they can do. And basically many of them, being very savvy, saw that they were going to die and they would just as soon not get involved in it. That is when things were pretty loose in medicine. Now money is tighter, and primary care physicians want to have control over their patients.

But at that time, yeah, when I got a case, then everything related to that case regarding cancer was in my court. So I was directly responsible for it.

But I found, I was a missionary for a while, and I saw cancer in foreign countries, and they didn't have the same problems.

I didn't have chemotherapy over there, and I was also in practice before chemotherapy became popular. It was my impression when I started to give chemotherapy patients went downhill very rapidly. I couldn't look my patients straight in the eye and say, I think I can help you. I knew that it was generally a downhill course for them.

And when I started to use complementary care, they didn't have the side effects of drugs. I think we are looking more at the natural effect of the cancer itself, rather than the compounding effect of toxic therapies. To me, there was an increase in quality survival just by being conservative with chemotherapy.

Now, it is hard to say when you use multiple modalities whether—which one is effective. It was my impression that chemotherapy was very toxic, and it did not improve survival, not by me signing 170 death certificates. In a 15-year period, I could see complete responders in less than 20 cases in the thousands that I saw. It said to me that I was missing the point somewhere.

And we were always encouraged, a cure is right around the corner, we have another drug or combination when, in fact, that wasn't the problem. The problem was the host, and there had been precious little work ever done in that area. When I was in medical school, that was the highest form of therapy; but yet when I started practicing, that was the lowest form of therapy.

So prevention never really was part of therapy until I got involved in alternative therapies, and then you could see that you could identify the preconditions that led to cancer or lead to cancer. The electroacupuncture therapy is a wonderful technique that needs to be explored and documented.

Patients basically suffered a lot from chemotherapy in my experience, and it became a matter of conscience and I just couldn't do it. And gradually over time, I don't think that my practice dipped a bit. It was a gradual progression into alternative therapy.

Mr. BURTON. Dr. Key, someone told you that no one dies of the disease you have, they die from the treatment? Who told you that?

Dr. KEY. My specialist in lymphoma.

Mr. BURTON. Before you went to Dr. Gonzalez?

Dr. KEY. Yes.

Mr. BURTON. I want to introduce a bill that would mandate that there be one person on there from the alternative and complementary medicine area and see if we can't get that passed in the next year, and maybe we can just make sure that there is somebody on that board.

The other thing that I would like to suggest is that there are a lot of suggestions here today from some eminent doctors, and what I would like to do is send you, as I said before, a letter enumerating all of these and if you can evaluate and give us a response, I would appreciate it.

Dr. KLAUSNER. Sure.

Mr. BURTON. We also have committee proposals for extramural research grants in the area of alternative therapies in health and cancer practices. We will send that to you as well.

Also, we talked about the funding for the alternative medicine and complementary medicine. Dr. Jonas says he gets $20 million and you get $2 billion at NIH—or at NCI?

Dr. KLAUSNER. That is correct.

Mr. BURTON. Maybe we should look into giving Dr. Jonas' agency more money and make the case on the floor about that. We will be working on that as well, and if you folks agree with us, we would sure appreciate your support. I am not suggesting that we take it from you, Dr. Klausner, but maybe we can find some additional money.

Do you have anything that you would like to say about the comments of the gentlemen that just preceded you?

Dr. KLAUSNER. Yes. I really appreciate the sense that we all have that our therapies are not as good and they are often more toxic than we would like. I would not like to leave the impression that we have information that in any way would suggest that the majority of patients treated with chemotherapy are killed by their chemotherapy. In fact, the only place we have that information is in the context of clinical trials where we watch and measure the fraction of patients who die from complications of treatment versus the disease, and it is overwhelming the patients that die from the disease and not the chemotherapy. I appreciate and understand especially the therapy that Dr. Key, the original therapy, MOPP, had a lot of acute toxicity, and we don't use it any more, and 11 years ago when he took that, there were not the treatments for the side effects of therapy.

This is a process where we are struggling with a very difficult set of diseases to try to get therapy that both is effective and less toxic. Things are changing and moving.

I will point out that 40 years ago—you point out people said things were impossible—a child with cancer, a child with leukemia was given a month or two to live, and they all died.

Now with this chemotherapy, as imperfect as it is, through clinical trials now for leukemia 70 to 80 percent don't just live 5 years but are cured; 1 out of 900 young Americans that are becoming adults are now the cured survivors of childhood cancer. We have a long way to go, but to not mention the many extraordinary people who have spent their career and lives trying to save people's lives against a very difficult disease where the problem is not just—the

problem is the disease. It is not just attitude. I think it is very important to maintain that perspective.

We need to make more progress. That is what we are about. The NCI wouldn't be there if that disease wasn't there, but I think it is very important not to send the message that there are some therapies that predictably and reproducibly cure people.

I think Dr. Gonzalez would not recommend people not receive chemotherapy for Hodgkin's disease, but I want to be careful that we not leave a message that sends a message to the American people misinformation about cancer and chemotherapy.

Mr. BURTON. Thank you. I hope with the great strides that have been made that the information that we are getting from other sources, from other doctors in other fields, that we are able to incorporate that and maybe add to and give every doctor in this country more tools with which to fight this disease.

Did you have any final comments, Dr. Jonas?

Dr. JONAS. Yes, sir. I appreciate your having this hearing and talking to us about the progress. Of the presentations that were made, we are integrally involved in a number of them that were actually discussed. The Gonzalez therapy, the NCI and we are involved in supporting a clinical trial this year.

We have made practice visits to almost all of the therapies mentioned here today. I have personally made visits to Dr. Gonzalez's practice, Dr. Speckhart's practice, to the vaccine practice that your wife currently undergoes and other diet therapy practices currently around the world, including some mentioned in China.

We provided a grant to study this electrical therapy in rats in China which showed some remarkable results in rat sarcoma, and we have requested this researcher out at the University of California apply for a larger grant.

I think you have heard today the exact issues we are trying to address, promoting dialog in these areas so there is an increased exchange between CAM practitioners and the researchers that can take it forward, and also the need to have another view, a view which recognizes health supporting activities as having a major impact on cancer and going forward with research in those areas. Thank you.

Mr. BURTON. Mrs. Morella, do you have any other comments?

Mrs. MORELLA. NIH is, of course, one of my favorites, not only because it happens to be in the district that I represent but the fact that it is a premier international front of research. And it was 22 years ago when my sister died of cancer, and she was on chemotherapy. I have found out that if she were alive today her cancer would be cured, because we have made those kinds of strides. This is why we in Congress have funded handsomely the National Institutes of Health, because we know of the quality of life and the tremendous savings that we have made.

I am pleased that you do have the OAM, that you are involved in alternative therapies. People are looking for hope and they are looking for other ways, and they know that maybe something can come about. So I compliment you on that, and I think that we are in no way demeaning the research that is being done, which we encourage and want to encourage you to fund.

Mr. BURTON. He said, no one dies from the disease, they die from the treatment?

Dr. KEY. Basically, yes. In fact, that is almost a verbatim quote.

What happened was, after a literature search and computer searches and cutting through the jargon of all of the journals and cancer-free period, survival time, I came up with the fact that I have about a 24 percent chance of living. After analyzing that, I was evaluated by everyone he asked me to be evaluated by. When I came back and sat down with him, I said, thank you very much for all of your efforts. I appreciate your efforts, but I am not going to do anything.

I said, how do I die? And he looked at me and he said, what do you mean? I said, how do I die? He said, metastatic disease. But he said that they don't die from your disease, they die from its treatment. I said, my point exactly. He was being honest and not flip.

And I invited him, after I chose to see Dr. Gonzalez, please follow me, do a scan, do a blood test; and he didn't want to have any part of it. Yet I work with this man, both my oncologist and his partner, who is my good friend, and they always look at me and shake their heads.

One other anecdote, his partner oncologist was walking into the office to report to a parent of a 21-year-old man that he was going to die from Hodgkin's lymphoma. He had had the bone marrow transplants and so on. The physician walking in met a nurse who happened to know me also, and they were chatting about how well I was doing, and the parent heard this. And so when Dr. Gulick walked in, who was trained at Cleveland Clinic, said there is nothing else we can do, we can continue to feed you the chemotherapies, he said, I don't mean to be rude, what about this other guy?

Yes, why don't you give him a call?

This young man applied to get into Dr. Gonzalez's program and wasn't taken in. I called Dr. Gonzalez more as a friend and a plea. This young man was my son's age; you can't let him die. Dr. Gonzalez looked at me. He said, Larry, I get over 125 calls a day. I can take three people. I have to take the three people that I am going to be most helpful with. This young man has massive chemotherapy, and previous bone marrow transplants just about preclude him from having a good outcome.

Now, I didn't read that as he is only taking people he can cure. He took me. He almost didn't want to take me because I had so much chemotherapy. I looked at it, how can Dr. Gonzalez live turning people away? How do you do this?

So, yes, my oncologist did look at me and say you don't die of the cancer, you die of the treatment. On the other hand, he did it without blinking.

Mr. BURTON. You know, I don't know how you change the mind-set. When Dr. Marshall cured me with just some antibiotics and bismuth of a disease that everybody else thought was caused by nerves, stomach ulcers—I was at a party, and I told him about my experience with Dr. Marshall, and he became visibly angry. His mind-set was that stuff doesn't work.

And I was sitting there in front of him. I know it works. I had this stomach problem for 2 years after I came back from Africa, and it was gone. He walked away and wouldn't talk to me.

And that is one of the things that I was talking to you about, Dr. Klausner, a while ago. I don't know if it is a mind-set that has always been there and will always be there, but it needs to be changed so that people like Dr. Marshall and the others that I mentioned are at least looked at as far as their alternative therapies are concerned.

I don't think that I have any more questions other than just one. Dr. Fair, you said that you tried to introduce the use of yoga for presurgical patients at Sloan-Kettering. What happened?

Dr. FAIR. I had 50 yoga teachers that were pro bono coming in and were going to instruct the patients a week before surgery with breathing and meditation and relaxation techniques and give them a tape and at the time they came in for surgery would meet them in the presurgical area at 6 a.m. The nurses were ecstatic, and the surgeons were excited, and the anesthologists viewed it as a great move because they would be able to look at pulmonary saturation and so forth, but it sort of just died. The administration felt that this was probably not the kind of thing that we ought to be doing at Memorial or we should be more in a general program.

Mr. BURTON. Scientific?

Dr. FAIR. Yes. I have not given up on it yet, but it is still hanging there in the balance.

Mr. BURTON. I want to thank you. You might want to stick around while we talk with Dr. Klausner and Dr. Jonas one more time.

We really appreciate your testimony and, even more than that, I appreciate your humanity and your concern and willingness to take those chances to increase the knowledge of medicine. Thank you very much.

If we can have you come back up, Dr. Klausner and Dr. Jonas.

How are you going to integrate the things that you have heard here today into your research? Do you have any ideas about that?

Dr. KLAUSNER. I think, to reiterate some of the things, I think the steps that we are taking are the steps that we need to both communicate information about complementary and alternative medicine, make it available and accessible to people. From all of the things that we have heard from everyone is that we need validation. We need to be able to tell patients what is likely to work and what is not likely to work, and I think that is what we are setting up to do. That is what I heard, and I agree with that.

Mr. BURTON. Would it be possible to put an alternative medicine or complementary medicine person on the cancer advisory board, National Cancer Advisory Board?

Dr. KLAUSNER. It is possible. The President appoints those members, not me or even the Secretary. There are people on the board who are interested in certainly aspects of complementary medicine, but that is a Presidential advisory board.

Mr. BURTON. But there is not an advocate for complementary alternative medicine on the board?

Dr. KLAUSNER. No.

You have to be careful with alternative therapies because they mean hope, but we have to balance to make sure that they are viable, safe and effective, and I know that you are doing that. So I appreciate your having this hearing. I know Dr. Jonas would love to know that you are going to try to get him more money.

Mr. BURTON. Thank you all for being here, and we will be in touch. The hearing stands adjourned.

[Whereupon, at 12:30 p.m., the committee was adjourned.]

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