

Comprehensive Cancer Care: Integrating Complementary & Alternative Therapies  
Toward a Comprehensive Cancer Treatment  
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Jim, on behalf of Harvard University Health Services I wanted to give you our latest program on the benefits of complementary therapies and our Harvard wellness programs.

It's a pleasure to be here, and on behalf of the American Cancer Society, good morning. There are three areas that I would like to cover in my brief presentation this morning. The three areas are first, the history of alternative and complementary therapies at the American Cancer Society, and I'll mention to you its current roles. Secondly, I'd like to talk to you about what its goals are pertaining to alternative and complementary therapies. I'll also discuss the strategy by which we try to get our messages out and the correct messages about education and the scientific importance and evidence for alternative and complementary therapies.

The American Cancer Society has addressed safety, issues of "quackery" and efficacy issues in cancer treatment as early as 1914. At that time the Society expressed concerns over the claims of some cancer cures and began gathering information. The Society focused on the individual promoting the claim. In the 1950's the Society began publishing information, in response to concerns raised by our American Cancer Society divisions and units all over the country over the exploitation of cancer patients, especially those in the terminal phase of their illness. The information was about specific claims and about criteria for assessing the merit of any cancer treatment or diagnostic test. With the development of the Society's journal, *CA*, a journal for clinicians, a means of disseminating that information to health professionals was established. In 1976, the Society approved the statement on laetrile, one of the few unproven

therapies at that time that went through appropriate clinical testing and was proven to be ineffective and unsafe. In 1981, a listing of unproven therapies was published in *CA*, which became labeled by some as the American Cancer Society's "Blacklist." It's important at this point to emphasize that the American Cancer Society responds to needs expressed by divisions in the units throughout the country who are responding to their patients and to the general public.

In 1990, the American Cancer Society commissioned a study of the prevalence and use of unproven or questionable therapies among more than 5,000 cancer patients and 91 physicians regarding their perception of the use. In our study the prevalence of use was nine percent overall. An increase in use was directly proportional to increased income and education. Important discrepancies were found between patients' and physicians' perceptions of use. For example, patients reported that physicians directed them to the questionable therapies, while physicians reported that they disapproved and were rarely supportive of the method. The Society concluded that more education was needed about questionable cancer therapies for the health professional and the public.

In 1996, the Society adopted the use of alternative and complementary terminology and defined the terms. "Alternative" refers to those therapies unproven or disproven, used instead of standard, conventional, proven therapies, and "complementary" therapies refers to supportive therapies which are used to complement conventional treatment. This definition categorizes a therapy by its use. Any one therapy can be both alternative and complementary. Recently the Society's database of information was expanded to provide information on useful complementary therapies for those with cancer. Because the public does turn to us for accurate and reliable information, the American Cancer Society strives to give the public, the patient and

health professionals the best available current information and guidance concerning alternative and complementary methods of cancer prevention, diagnosis and treatment.

That's the history of alternative and complementary therapies to date in the American Cancer Society. What's going on currently in cancer? It's been most exciting over the past year, particularly over the past several months. There have been discoveries, a great deal of energy, and a great deal of new information and results in cancer research and study.

For the very first time, in 1991 the trend in the increasing mortality of cancer peaked, and ever since that year it has been declining. In 1995 it continued to decline at a half a percent a year. I have just heard as of yesterday or today, that the cancer deaths for 1997 will again be significantly less than 1996 and perhaps the biggest downturn ever. The most significant area of this downturn in mortality is in breast cancer. The decrease in the mortality in breast cancer, from 1996 through 1997 was a six percent decrease in mortality. Something is happening. Something is going right.

Similarly, for the very first time in a press conference in March in Washington, DC, at the National Press Club, the National Cancer Institute, together with the CDC and the American Cancer Society, announced for the first time a downward trend in the incidence of cancer. The peak year was 1992, and ever since that year we have continued to see a decline of almost two and a half to three percent per year. This is striking. Things are going in the right direction.

Obviously we wanted to go much faster. The American Cancer Society has challenged itself with several goals. By 2015 we want to have reduced the mortality from cancer in a collaborative fashion throughout the United States by 50%, and the incidence of cancer by 25%. At the same time, one of the most important goals, especially for those living with cancer, is to improve the quality of life of cancer patients.

Finally, I'd like to talk about information delivery. The American Cancer Society has several strategic directions. One of its areas is obviously research. In research we are surveying cancer survivors as to their use of complementary therapies. I hope that during this conference we will be able to express that and discuss that with you. The other strategy is getting out the information to the public, to the cancer patient, and to the family of a cancer patient. We want to make sure that everybody knows about their disease or about their risk of getting disease.

One of the things that's going on right now is getting that information out in whatever way we can. In 1995, we started to make significant advances in our information systems. We now have thousands and thousands of pages of information, including information on alternative and complementary therapies, on our cancer information database. We have this available in all media. We have a national call center that is never closed. It is open seven days a week, 24 hours a day. You can get information about any aspect of cancer, from the local resources in your neighborhood, to some cancer information about the specific cancer that you're dealing with. That number is 1-800-ACS-2345.

The information that we give is very synergistic with the Cancer Information System of the National Cancer Institute, which is 1-800-4CANCER. We're working quite closely with the NCI on this. In addition, our information is available on the Internet, through our home page, which is [www.cancer.org](http://www.cancer.org). We are answering over a million calls a year, and we have the capacity to now handle even more. 1-800-ACS-2345. Get the answers you want. In addition we now are receiving over five million hits a month, translated into almost a 100,000 people a month that are accessing our information on cancer through the Internet. I expect that will continue to grow.

Finally, let me clearly state the American Cancer Society's position on all cancer therapies. All cancer interventions, whether they be for prevention, detection or treatment, must stand the test of peer reviewed scientific evaluation. We urge cancer patients to remain in the care of physicians who use standard, mainstream, evidence-based treatment for cancer and approved clinical trials of promising new treatments, and we urge cancer patients to share with their health care provider their use of or plans for alternative therapies or complementary therapies being used along with their mainstream treatment. Ladies and gentlemen, I look forward to a very collaborative and constructive conference. Thank you.

Dr. Gordon: Thank you very much, David. Dr. Rosenthal is going to be with us throughout the conference, and he'll be speaking with us again on the concluding panel, "Where Do We Go from Here?" We're very committed at the Center for Mind-Body Medicine to working with the ACS. Several of the advisors to the ACS have worked with us on this conference – Barrie Cassileth and Clem Bezold will be here, and Michael Lerner, who unfortunately can't be here today. We look forward to close collaboration and to providing, with the ACS, the best possible information to patients and their families and to physicians and other health care professionals.

Our next speaker is one of those people whose job is to be a torchbearer for all of us. He is a distinguished medical oncologist who has spent time at the National Cancer Institute on two occasions. He's currently Director of the Division of Cancer Treatment and Diagnosis, as well as Deputy Director for Extramural Science. He is responsible for the oversight, integration, coordination and enhanced communication across all extramural programs of the National Cancer Institute – that's all the programs that are out there in the field. He works very closely

with the Director of the National Cancer Institute, and together I know that they are committed not only to promoting the best possible research, but to making available the best possible information, some of which they're working with the Office of Alternative Medicine on pulling together. I'm extremely happy that Dr. Robert Wittes is with us, to join in this adventure, this scientific adventure and human adventure of bringing together the best of both worlds. Dr. Wittes.

Dr. Wittes: I'd like to first of all add my voice to the chorus of thanks that Dr. Gordon is already garnering for organizing this meeting, and for the presuppositions on which it's based. The idea that it is important to integrate everything we know for the benefit of the patient is an immensely appealing concept. What this requires, of course, is that we regard people not just as bipeds carrying disease, but that we fully realize as healers the complexity of people as human persons. This integration of everything we know is a noble goal. It's actually philosophically impossible to disagree with it in principle. What I'd like to spend a few minutes doing is discussing with you some of the realities that we are going to have to face together as a community, if we're to do this successfully.

Let's search first for some guiding principles on which we should base the effort. The more I've thought about this, there are really only two bedrock principles that we have to pay attention to as we go ahead together. First, we need to have a sense of mutual respect for each other as regards our intentions and our motives. We can agree to disagree sharply about hypotheses, methodologies, analyses, and what results mean – what they mean for patients, what they mean for science, what they mean for phases of the moon, anything under the sun. But, we

should grant each other the presumption of good will and that we are in this for the good of our patients.

The second bedrock principle is a respect not only for each other, but also for evidence. In this way Dr. Rosenthal's talk is actually a perfect segue into my remarks. The evidence is everything. In the end, the quality of the evidence, how persuasive it is, how clean it is, how convincing it is to skeptics, is everything. It's more important in the end than the hypotheses.

Hypotheses can be wrong. They can motivate clinical experiments, or laboratory experiments. You can get interesting results from the laboratory or the clinic, but the hypothesis might still be wrong and the results interesting and important. It's much more important than the weight of tradition. Much more important than the authority of some fancy professor of medicine in a great medical school, more important than what some expert in one of the great traditional medical systems, non-Western traditional medical systems might say, and more important than simply how many people believe. The end of this second principle is that whoever makes a claim of efficacy is really responsible for the quality of the evidence.

There are some corollaries to this, and I speak to you also from the heart. In the course of the next few minutes, you will be able to identify my training and my own biases and the way I look at the medical world. That's part of what I bring to the table as we come together as a community to talk. Because a tradition is 2,000 years old or 4,000 years old, doesn't make specific claims within it correct. Because authority proclaims something does not make it right. This has nothing to do with whether the therapy we're talking about is complementary, alternative, or mainstream. Just think of what's happened to Ptolemaic astronomy or the medicine of Hippocrates and Galen, which were enforced under the weight of authority and tradition for a thousand years before they gave way to Copernicus and the revolution of scientific

medicine in the 19th and 20th century. Great theories destroyed by facts. This is not just an issue for alternative approaches, and I hope you won't think that I'm being presumptuous in saying these things to you. I spend a fair amount of my professional life saying things very similar to this to the mainstream community as well.

The loose and casual treatment of evidence is a constant battleground in mainstream medicine. The medical literature of the last century or half-century is an absolutely fascinating story in the evolution of evidence in the clinic – the change of prevailing notions of what constitutes adequate evidence. Let me just read to you a passage from the *New England Journal of Medicine*. This is a disquisition by Frederick Sperry, a professor of otolaryngology at Yale, on the subject of the common cold. Sperry gave this address to the Vermont Medical Society. He was invited to talk about treatment and prevention of the common cold.

For prevention, Sperry recommended general physical fitness, breathing exercises, cold baths, fresh air, not overdressing in the winter, sheltering a bald head and a sensitive nose from cold air, and the use of vaccines made from foreign proteins, any foreign proteins would do. Diseased tonsils and adenoids should be removed, and swollen mucous membranes in the nasal turbinates should be cauterized to relieve nasal stenosis. For treatment of colds, he recognized the following interventions as having value: cathartics, quinine, Turkish baths, rest, chlorine gas inhalation, belladonna, iodides, sodium bicarbonate and water, nasal irrigations with saline or cleansing of the nasal passages and nasal pharynx by other means, including silver solutions or boric acid, massage of the nose, face and neck to relieve nasal congestion and improve vasomotor control. These statements by a professor in a distinguished medical center reflect the standard of care at the time it was given. This was printed in 1930. It shows that one of the most common human afflictions was being treated with a series of measures, most of which were

entirely without foundation. This example is not exceptional. Any medical journal of the period amply illustrates the extent to which therapy was based on either received wisdom or observational data that was largely uncontrolled or badly flawed by observer bias.

So why is rigorous methodology important in assessing the effect of interventions?

There are at least three reasons. The first is that diseases, even life-threatening ones, show substantial variability in their clinical manifestations and in their rates of progression. You see this consistently with many cancers. The second reason is that many diseases sometimes resolve spontaneously, either partially or completely. This is not so true of cancers. The rate of spontaneous regression with cancers is really pretty low, at least complete regressions, but some cancers can certainly resolve partially for periods of time, without obvious interventions accompanying them. The third is that the behavior of a disease and its impact on people is not static in time. It can be affected, sometimes strikingly, by contemporary developments in diagnosis, staging and ancillary treatment having nothing to do with the primary therapy. And you can think of various examples in oncology where this has been the case.

If we are to be integrative, and we are to talk and work together, we need a common language. We need to have a way of talking to each other, and we need common standards for what we regard as hard evidence. We're not there yet, for a variety of reasons. So let me just give you my own personal sense of what these reasons are and some of the things we're going to have to think about together. Calling what all of you are interested in "complementary and alternative medicine" actually makes many, many approaches, a huge heterogeneity of approaches, sound like one thing. That's surely a great mistake. Defining what you do as the negative of what mainstream medicine does, or as the complement of what mainstream medicine

does, belies a tremendous diversity of approaches. Some of what I am about to say may not apply to various segments of what we are now calling complementary and alternative medicine.

First is the presence to a mainstream mind of what I'll call troubling hypotheses. By that I mean hypotheses that are not understandable in conventional Western scientific terms – for instance, homeopathy. If something is alleged to work, but I can't imagine how it could work, scientifically, and if I have to give up much of what I know about chemistry and physics to explain how it might work, then the evidence that it does work had better be incontrovertible. I mean absolutely no disrespect in the way I've said that. I'm simply saying that if there are certain bedrock assumptions that I have from science, and if what I'm being told is based on hypotheses that are incompatible with that, I'm willing to listen, I'm willing to evaluate, I'm willing to sit down, but the evidence had really better be pretty good.

The second thing is that the two cultures carry on dialogues, in different forums, and publish in different journals. One of the real signal importances of this meeting is that it may represent the beginning of an effort to break that down. Many people in the mainstream community are willing to come and have dialogues with you and to try to figure a lot of this out together. I think attitudes have changed a lot in recent years.

The third point is that many alternative and complementary approaches utilize complex integrated programs of interventions as a package in some therapeutic context. There's not only nothing wrong with that – this may be absolutely the right way to move in specific clinical circumstances. From the point of view of clinical research, the mainstream community is accustomed to attempting to dissect the various components of complicated regimens that it uses, to try to see whether the various components are necessary. We're not very good at that sometimes. I mean we do very complicated things to patients and we don't always

systematically dissect them and know the value of every component. But there's at least a kind of general belief in the community that we really ought to do that, and we're trying to do it more than we did in the past. Either an unwillingness to do that, or a philosophical opposition to doing it, is something that we're going to have to talk about and understand with each other so that we can move forward better. There may be good reasons not to pull things apart, but we have to understand this.

My fourth point is that in some alternative contexts, there is a very strong belief in the need for extreme individualization of therapy. This reflects the belief that every patient is different in detail and no disease process really repeats any other disease process if they occur in two different people; thus, generalizations about how one should approach treatments and approach patients are actually highly, highly patient-specific. This becomes a really hard problem for clinical investigation. It becomes very difficult, for example, to write a protocol describing what one would test, if what one would test depends on the unique insights of a practitioner who has certain standards of belief and certain felt insights about what Joe Smith needs as different from Mary Jones. There are some parallels in the conventional community about this. However, the conventional community doesn't go quite as far as certain elements in the alternative community do, about the need for this kind of individualization. These are some of the things that we're going to have to work out. They're all interesting issues. Some of them are philosophical issues. I'm convinced that interaction will lead to productive pathways for figuring out how to approach this. I look forward to that challenge.

I'd like to mention some things that we're doing now that represent the NCI's effort to move in better ways than we have in the past with alternative and complementary approaches. We have a very good relationship with the Office of Alternative Medicine. We are working with

them to set up a process that Wayne may describe in more detail in his sessions. This will involve the creation of an advisory group of outsiders, representing both conventional and alternative communities (the various kinds of expertise that one needs from both camps) to evaluate claims of efficacy from the alternative medicine community and its practitioners. This may in some cases involve the “best case series” methodology, in which information about anti-cancer claims is evaluated in a systematic way. We will be looking for advice from this advisory group, both OAM and NCI, about what the reasonable next steps would be. The committee could, for example, evaluate a claim and say there’s nothing there, there’s nothing for you to do. It could evaluate a claim and say, well there might be something here, but we can’t tell. The data just don’t speak definitively to whether there’s something there or not. Or they could say, it’s clear that you ought to move with this. There’s something promising here, and you really ought to run with it. You could also say other things, but those are the kinds of signals we’re looking for.

We are beginning an enhanced effort at clinical trial support of various alternative strategies. We’re in the middle of the planning stages on shark cartilage. We’re also beginning to look at green tea as something that we might move forward into clinical trials. There are actually growing amounts of information about green tea and green tea components in the mainstream scientific literature suggesting that there may be rationale for the observed claims of efficacy from alternative and other sources. Claims of efficacy from the alternative medicine community need to be handled basically the same way that we attempt to handle claims of efficacy from the mainstream community. What we’re doing is reconfiguring the PDQ state of the art statement process in such a way that the outside committees that evaluate state of the art claims will have alternative and complementary representatives on them. They will be able to

evaluate these claims with the same dispassion, in the same non-pejorative way that they evaluate claims of efficacy from anywhere. We're beginning this process now.

So a couple of final thoughts. The first is that the dialogue among medicine's many constituencies and communities should continue, should be enhanced. This meeting is a great start. The second observation that I have is in a sense almost a cautionary note. We are dealing with issues involving the presence of two cultures. The NIH and its component institutes are, in the end, institutions of science. To the extent that certain interventional approaches may be nonscientific at their base, but rest upon belief systems that are not, in the end, scientific – they may be great, they may be inspiring, they may be magnificent, but they may just not be science. Thus, they are much more akin in that way to religious belief than to science. One can have great respect for alternative belief systems, but there may be difficulties in the future in trying to meld institutions of science into evaluation systems for things that, in the end, rest on systems of thought that are other than scientifically based. Do not interpret this as an unwillingness to talk. I'm here because I want to talk. I'm here because this interaction is in everybody's interest, and I want to see it fostered and continued. However, I cannot represent myself as speaking for the mainstream community. The mainstream community is as diverse as you are. This is going to take work, and it's going to take a lot of mutual respect and persistence. And so let me thank Dr. Gordon again, and the organizers of the meeting, for including us. I thank you all for now and for in the future.

Dr. Gordon: Thank you very much Dr. Wittes. I appreciate your being here. I also appreciate the considerable thought and intelligence you've obviously given to these issues.