

CENTER FOR MIND-BODY MEDICINE
COMPREHENSIVE CANCER CARE 2000

PLENARY: Crafting the NCCAM Research Agenda

PRESENTER: Stephen Strauss, MD

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P R O C E E D I N G S

DR. GORDON: It gives me great pleasure now to introduce someone who is leading a national effort to do just that; not just in the field of cancer, but in all of medicine and in all of health care.

Dr. Stephen Straus has been at the National Institutes of Health for 23 years doing laboratory research, clinical trials. He's a well known and gifted researcher and he has the charge of heading the National Center for Complementary and Alternative Medicine.

And the wonderful thing, from my point of view so far, about his tenure is that he is actually broadening and fulfilling the mandate of the office. I was Chair of the Advisory Council for the first three years of the Advisory Council and there were many, many areas in which we wanted the then office to go.

In his brief time in the office, Dr. Straus has begun not only to look at those areas, but to make public statements but also to commit resources. For example, for the funding of CAM education programs in medical schools, to looking at novel ways of doing research that match the way CAM therapies really work in the world, to this kind of intimate collaboration with the NCI that helps to produce the cancer advisory panel and conferences like this. So I salute you and thank you and give the podium to Dr. Stephen Straus.

DR. STRAUS: Thank you, Jim. That was very generous.

If we really attended to our personal needs, we'd be sitting in the back yard Saturday morning, before it gets hot, reading the paper, listening to some music. There's a certain logical disconnect with what we'd like for ourselves and our patients and how we're actually spending our time.

Jim actually laid out very well the challenge that we all face in trying to take a movement and a people-centered idea and trying to generate a discipline that is itself sustaining and rewarding as well as compelling. And our job is, in fact, to make a science out of complementary and alternative medicine.

That's what I'm going to talk about; very much the role that we're attempting to play in this process at the NIH.

All of you are here because you appreciate that there's a opportunity, an opportunity that has been to some extent neglected, to some extent misdirected but it's an opportunity that we have at this point in medical development, to advance health care with additional tools.

These practices that are being discussed in the context of integrative cancer care at this meeting but really represent approaches throughout all of medicine, are ones that the American people are gravitating towards and using increasingly. Certainly two-fifths of Americans, by David Eisenberg's estimates -- Mary Ann Richardson, when she was at the University of Texas in Houston estimated that four in five Americans with cancer are relying on complementary and alternative practices.

Our belief is that some of these practices are beneficial, but we have the concern that some are not. Some are safe and some may not be. I think the American people are tired of being caught in a dilemma of a lack of competent guidance, particularly when faced with such challenging moments as a new diagnosis of cancer in themselves or loved ones, as to where to turn.

That's the point in which you need competent information and the National Institutes of Health is at least trying to play a role in providing that.

Now as you know, most of the CAM practice and it's application to cancer is complementary. Individuals want to take on things that are adjunctive to their standard cancer care. Things that may make them feel better, sustain their nutrition, or their mental health and approach during those trying times.

The minority of use of CAM in cancer is as alternatives to conventional medical care and all of us make decisions for ourselves. We have a personal calculus about our own health. We try to make the best decision.

In the case of complementary and alternative medicine, these approaches are utilized with the hope of improving wellness and for the relief of symptoms attributable to chronic degenerative or fatal illnesses, cancer and others.

Now the domains of cancer are vast and I have to disclaim early on that my background as a research internist and infectious disease immunologist leaves me ignorant about many of the thousands of CAM approaches. So what I bring to it is not a knowledge of all these approaches but an understanding of how to look at an area in a cohesive, organized way to obtain rigorous data. And I attempt to do that in concert with people who are the true experts in CAM, which I am not.

Now you know that the American public is already receiving care. We're paying for it out-of-pocket in many cases. And the marketplace is changing rapidly and health

maintenance organizations are beginning to reimburse for certain types of complementary and alternative care.

This is a landmark health care report summary from last year that shows that about two-thirds of HMOs will cover chiropractic care. About a third, acupuncture. About a ninth, massage therapy. And very small percentages, a range of the many other CAM approaches.

On the one hand the marketplace is beginning to provide options. On the other hand, the reason they're doing so is not the reason we would prefer in terms of making public policy decisions.

Most of the HMOs provide these services because their members have asked for them, or their particular states have mandated that they do so. Only 8 percent of them are doing so because these modalities have been established as clinically effective. This is the wrong way to make decisions. We should gravitate towards things that are clinically effective as a high priority.

Now there really is good reason to believe that some of these practices are clinically effective and some have been fairly well studied and we're attempting to put definitive answers in place at this time.

The graph that you're seeing on the two screens represents one very good study, just published in the British Medical Journal last November, in which patients with mild to moderate depression were randomized in a blind trial to receive St. John's wort; a standard tricyclic antidepressant, imipramine; or placebo for a period of six weeks.

The data is looking at the scores in depression improving over the time of the study. You can see that the improvement with St. John's wort and Imipramine, a prescription drug, were comparable and both were superior to placebo but there was, as in many such studies, a substantive placebo effect. But this is some of the best data to suggest that one of these ancient botanical products is biologically active and is clinically useful.

But if one is to have a product that is biologically active, it can do so only because it affects the basic chemistry of the body, and in so doing it might also have unanticipated adverse effects that had not been known about.

But here is data from colleagues of mine at the NIH, a paper by Steve Piscitelli and Judy Falloon and others, published in the British Journal, The Lancet in February; is looking at individuals who are using the important HIV protease-inhibiting drug indinavir, showing that when you're on it for a period of time, you establish a blood level and you sustain that blood level, and the blood level remains well in excess of what one needs to inhibit the growth of the virus. Why the drug works -- you have an adequate amount in the blood that blocks the replication of the virus that causes AIDS.

When the same individual stayed on the drug and had St. John's wort added to the regimen, with the identical dose in the prior study, the blood level dropped 10 fold because the components of St. John's wort accelerated the liver's enzymatic machinery that clears the drugs more rapidly from the blood stream. And there have now been a series of such studies showing that it interferes with levels of birth control pills and important drugs needed to sustain immunosuppression so that organ transplant recipients wouldn't reject their grafts.

So if we're going to take these natural products seriously and invest in studying whether they work, we need to begin to understand what else they do in a cohesive way, rather than assuming that simply because it's natural it has to be good for you and the more the better.

Now the NIH got involved in studies of complementary and alternative medicine a number of years ago but it's only in 1998 that Congress mandated the kinds of funds and authority to really develop a meaningful enterprise. And this is the legislative mandate language for the National Center for Complementary and Alternative Medicine.

We're directed to conduct and support basic and applied research, research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment diagnostic and prevention modalities disciplines and systems -- spanning all of medicine. So we should do this while standing on one leg, but at least we're provided with sources.

Our funding curve which was \$2 million in 1993 and \$70 million this year. It's my expectation and that of the staff I've been recruiting to work with me that it will continue to grow to meet these challenges.

But our challenge, as Jim so eloquently indicated, is to move the state of evidence from anecdotes, the kinds of things that in real life many of us make decisions about, to the kinds of data that are necessary on which to make public health decisions. What one recommends, what one teaches, what one funds, what one reimburses and that requires rigorous science and randomized trials and a very good overview of the state of the field, rather than an aggregate of more anecdotes.

So our job is to take things that look very promising in these early formative stages and move them up the hierarchy of evidence. And things that are already looking promising, like St. John's wort, invest now in definitive trials. And so we have a pipeline of research investment and we're attempting to develop a national and a global enterprise to respond to that.

Our priorities, really in parallel with that hierarchy of evidence, is to invest the most, soonest, in areas which there's the most credible preliminary data; things that we can study now and get answers now. Things that will teach us new science, rather than reiterate old things, respond to the interest of the American public and the things that

they feel are most important will impact upon the most important spectrum of health issues of which cancer is one of the largest.

Ultimately, the results should have the greatest possible public health impact. And these studies, realistically, have to be doable within costs. Clinical trials, as you'll see, can be very expensive and there are some things we'd like to know in life that we actually can't study. There are certain things that would hundreds of millions, or billions, or dollars to get answers about things and so we have to be realists.

Now as an individual who's conducted basic and clinical research for over two decades, I have an understanding of the research methodology, but there are special challenges in bringing this to the area of complementary and alternative medicine because some CAM treatments are complex and multi-modal.

Many treatments are highly individualized by the practitioners, although these are also true of conventional medicine, whether we admit it or not. I mean, no neurosurgeon does that procedure that he or she does exactly the same every time because no patient presents in the same way. But our research has to reflect that.

There are differences in how practitioners approach things and frankly if there is only one person on the planet who could do it and if that person can teach it to somebody else, there is not a generalizable solution in terms of public health however magical that one practitioner.

We have to develop approaches that can be transmitted and taught and diffused. There are problems in complementary and alternative medicine, as in main-stream research; the acceptability of randomization. You can't randomize somebody to placebo between two different antibiotics, say, or placebo for treatment of bacterial meningitis because it's not ethical to withhold antibiotic treatment for bacterial meningitis. And there are certain issues, either in terms of ethics or, more often, in terms of beliefs, that would limit some individuals acceptance of randomization.

We've learned, over the past 15 years, how to do AIDS trials in that context. There's a reality to this.

A big challenge that I will talk about is that the particular test materials in CAM are highly variable and I'm going to come back to that, but that is a huge challenge for us. And there's an issue of how you control studies. What is an appropriate control, or an appropriate placebo? You obviously can't do placebo-controlled studies of massage because, in general, the patient and the therapist has some sense that they're doing something to each other. But you can study massage nonetheless.

Now I'm going to spend some time talking about pieces that we've begun to put in place over the past 14 months in the existence of the Center, to address these challenges in accord with these priorities. One of the things we've done in the past year was begin to

develop a Center's Program because we needed to establish key areas of research infrastructure to respond to particular needs.

And these Centers, as I will show you, are based on particular disease or condition. Each Center a different health area. The Centers are charged with conducting early phase exploratory and developmental trials and small preliminary randomized trials.

The Centers need a portfolio of research that also begins to try to understand not how, but also why. We need to begin to understand why some of these therapies might work.

The existence of these Centers is an opportunity to train people in how one conducts research. To take CAM practitioners into the enterprise and teach them about the research process. To take experienced investigators and teach them something about CAM so that they can work together.

The existence of these programs within main stream institutions provides a new light in those institutions to new ideas. They're not any longer marginalized, or estranged, within those institutions. And the centers themselves have responsibility to reach out into the community to draw patients into the process because ultimately you can't do research studies without human participants; and to draw practitioners, making them understand that we all benefit from this kind of orchestrated approach.

These are the Centers that are currently funded or are under review. This week our review panels reviewed applications to fund our first large cancer Centers and an asthma Center.

We're already funding Centers on arthritis, pediatrics, drug addiction, chiropractic care, cranial facial health, neurological disorders, aging in women's health, cardiovascular disease; another one dealing with issues of minority aging and cardiovascular disease. And as I will show, we also have centers studying botanicals.

Now I told you I'd come back to the issue of selecting our clinical trial material and an example of St. John's wort, or echinacea, or any other botanical is as good as any.

Americans today are buying botanicals the way most of us buy wine. If the label looks nice and it's more expensive, we think it's better. Unfortunately, there have been a lot of studies showing us that there are no guarantees that what's on the label is in the bottle. At least if you have a red wine, there's a good chance there's a red wine in the bottle. Doesn't say it tastes good. But some bottles of echinacea have the wrong plant, the wrong parts of the plant, have other adulterants in it, don't have any of the correct product in it.

For our St. John's wort trial, we actually had to do extensive studies and ended up picking a product marketed in Germany. Not available. As a rule, chemical and biological materials used in complementary and alternative medicine are neither well

standardized nor made under good manufacturing conditions. They lack purity, stability data, bio-availability information, or any other pre-clinical data.

In our studies, studies that we fund, particularly these large studies, have to be conducted under an investigative new drug exemption from the FDA for which at this date is needed. And frankly, I wouldn't want to take things for which this kind of data is lacking.

If you go into the supermarket and buy a bottle of aspirin, there's 325 milligrams of acetylsalicylic acid, plus or minus a few milligrams. You know what's in there. The standard shouldn't be different for other health products. For our research, this is a challenge.

There are public health issues others have to address, but we have to address this in the context of our research. So we have a challenge in prioritizing and conducting our studies to obtain clinical trial material with the requisite qualities.

So we have to turn to the experts. We have funded, in collaboration with the NIH Office of Dietary Supplements, two and will probably fund this year at least one more center of true experts in botanical products whose responsibility it is to identify and characterize the botanicals, assess their bio-availability which means how much is absorbed into the body and the blood stream and how long it lasts there and the activity of the substances; begin to get a sense of perhaps why these products may work; begin to look at pre-clinical and clinical evaluations, train the next generation of experts.

The real experts in this are in their 60s, 70s, and 80s in many cases, because the field stopped being interested in this aspect of pharmacology for a few decades. A few people lingered on and now we need them again. And they help us select the products for our randomized clinical trials.

We're today funding five large expensive multi-center randomized clinical trials using the same kind of design one with demand for any item that we're considering licensing for treatment of any other disease in the United States.

I mentioned St. Johns's wort. I am pleased to announce that we expect an enrollment of 336 patient study to complete this month, centered out of Duke University. We're conducting that study in collaboration with the National Institute of Mental Health.

We're conducting the study of ginkgo biloba through the University of Pittsburgh in collaboration with the Aging Institute of the NIH. This is a study of 3,000 otherwise healthy American adults, age 75 and older, looking to see whether we can prevent the development of dementia.

This is the largest prospective study of the onset of dementia ever conducted. And this kind of study will only turn out two ways. Either it will work and ginkgo will provide the first preventive for dementia, or it won't work, because that's the nature of science, and

we will have learned more in the process about who's at risk and how it appears and what the natural history and progression of dementia.

So this is an extraordinarily important study. This study will cost us \$16 million over the coming 4 years. You don't learn these things on the cheap.

Multi-center study conducted together with my colleagues in the Arthritis Institute, Acupuncture, Osteoarthritis Pain, Brian Berman's group at the University of Maryland is running that multi-center trial. Again, with the Arthritis Institute, a remarkable study of glucosamine and chondroitin sulfate alone and in combination versus a COX-2 inhibitor, a non-steroidal anti-inflammatory drug versus placebo. Five arm study for osteoarthritis.

And this past month in collaboration with the NCI, we're begun, through their cooperative community-based oncology program network, the first large, over 700 patient-study, using shark cartilage for non-small cell lung cancer.

Now this is the spectrum with large aggressive clinical trials based on very good preliminary evidence. But we need, as I said, to develop a pipeline. We need to look at things in the pre-clinical area to begin to look at botanical and drug interactions like the St. John's wort indinavir study.

We need to begin to look for bio-markers, or kinds of activity, not just do you feel better today? Does it hurt less? You know, what does the MRI show? What are the immunological markers because we need to build that objective data into the process.

We need to understand how the body handles some of the natural products. We need to understand something about how they might work and what their active constituents are. Not because it's our responsibility in NCAM to study purified natural constituents, but because if an herb works in treating dementia, wouldn't you want to know what part of the herb is doing it? Whether the whole herb, as is often believed, is better than it's constituents, or the constituents can be used by industry as lead compounds to make even better treatments, or mixtures of constituents. And so we have a scope of responsibility in this area as well.

Almost all of our work, as is true of the NIH in general -- the NIH budget this year is \$18 billion dollars and 89 percent of that funds research around the United States and around the world and \$1 in \$9 is spent conducting research on the NIH campus. We will be building our own intramural research program and we currently have a search committee and an advertisement is open until June 19th, advertised in many journals for a director for our intramural program who'll have a scope of research, resources, and responsibilities like that for our extramural program.

Now not all of our research centers are big trials, or pharmacology, or botanicals. We need the pipeline to take things that people are interested in for this -- some ideas but they're not quite ready yet for those very large trials and we have a portfolio of developmental grants. There's a whole NIH jargon for all of these things. We're like the

Defense Department. It's too early in the morning to give you the names and numbers. But the issue is we have a pipeline that goes from exploratory to definitive in terms of our trials.

Now Jim mentioned, and you'll hear a lot more tomorrow, and I suspect yesterday Rick Klausner mentioned as well, the Cancer Advisory Panel Complementary and Alternative Medicine which really is unique government-private sector partnership to bring us ideas.

Now most CAM treatments are not practiced in the academic research settings. They're practiced by individuals who know very little about research in many cases. And those practices are unknown to experienced researchers and, far too often, are marginalized by mainstream oncologists.

Some of these CAM treatments are proprietary. They're delivered by individuals who market an approach. They have a book, they have an idea, they have a clinic, they have an industry. And those are delivered outside of regulatory scrutiny.

All this assembles together to the reality of the fact that there is mistrust between the community of practitioners and the federal agencies.

So how do you bring an enterprise to take ideas, practice in the community, and ask a federal agency like the NIH to get involved in studying it. So we try to be creative, to do so.

In 1997, there was a workshop in the summer that brought together CAM and conventional practitioners and researchers, members of the then Office of Alternative Medicine, before we were elevated to an independent center, colleagues of the National Cancer Institute and Food and Drug Administration.

The consensus from that meeting was that there needed to be an open non-confrontational forum where CAM practitioners can present their clinical findings. And that's what we now have. We have a 15 member federally-chartered advisory panel with expertise in oncology, CAM, clinical trials, statistics, pathology, radiology, bio-ethics. It's charge is to advise me.

It's to help us identify novel and promising research opportunities, the CAM management of cancer to communicate those research results back to the community.

Now our Center covers all of medicine. As I indicated, our trials are done in close partnerships with the other institutes. So this is an enterprise that we do together with Jeff White and his colleagues in the Office of Complementary and Alternative Medicine Cancer at the NCI and, in fact, we both mutually benefit and look forward to supporting the best ideas that come from CAPCAM. And you will hear more about one of those mechanisms, the best case series, that Jim mentioned earlier. Jeff White's going to talk about that tomorrow.

We have a series of novel mechanisms to try to get studies of CAM approaches in cancer on the streets in real time. Just recently, we've agreed to work with the National Cancer Institute in the unique mechanism they have known as the quick trial mechanism which, in fact, is an expedited submission and review process for clinical trial grants.

The review process of grants is a formidable one because there are over 30,000 a year submitted to the NIH as a whole. And so the quarter or so of those that get funded within the year take about a year for submission, review, and funding. This expedites it.

We've recently asked the NCI director to help us develop CAM approaches in cancer centers. We already have reviewed this week, as I mentioned, our own cancer centers that we're developing with their advice but the NCI has a huge and spectacularly effective network of cancer centers and I'm interested in providing supplements to more of those centers to get more centers interested in bringing these modalities into their research enterprises.

And then there's a process -- I named, last fall, our frontier medicine research program. This is a mechanism we've developed. I think it'll actually be announced electronically and available for applications next week. This is to identify and test modalities for which today there is little formal evidence of benefit, but for which there's substantial public interest.

Institutions will be supported which have records of clinical research excellence, possess adequate research infrastructure, and can incorporate relevant CAM expertise into the selection, design, and overview of studies. And those institutions will be funded to develop and oversee a cluster of exploratory trials within their envelope.

So we could take advantage of pulling bio-statistical and ethical and clinical trial support, which is intensive and expensive, to deal with several exploratory areas at one time.

Let me tell you what we've managed to fund our first year. I mentioned the shark cartilage trial and there are others. We're funding applications to look at the effects of magnetic fields on cancer cell growth.

We have a study at Columbia University, through Karen Antman's center, asking whether Nick Gonzales' nutritional approach to treatment of pancreatic cancer is effective comparing it with standard chemo-therapy for pancreatic cancer.

We're funding a study also at Columbia, traditional Chinese medicine for uterine fibroids and breast cancer.

We're funding a study looking at the effect of support group participation on breast cancer survival to follow-up on David Spiegel's earlier data from Stanford.

We're funding a study of looking at cancer treatment and prevention strategies using herbal nutritional mind-body and bio-pharmacological therapies for a range of cancers in one of the centers. And we have a portfolio that deals with palliative care and that portfolio is going to enlarge. In fact, I'm pleased that the NIH Clinical Center has just announced that it has recruited a new director of palliative and pain care who'll be joining us this August from the Fox Chase Cancer Center.

Other collaborations with the National Cancer Institute. I mention these supplements we would like to provide to the cancer centers, the quick trial mechanism. And we have mapped out because we're already planning our budget for 2002/2003, the next two years of budgets; specific studies targeted at therapies for prostate cancer, specific studies looking at soy extracts for breast cancer and an additional portfolio of exploratory and developmental studies of a range of alternative, rather than complementary, cancer treatments.

Now we have additional responsibilities as part of the NIH not just to conduct research and bring research information into the community. We have to see that that research reaches out and benefits as broad a segment to the American people as possible. And the National Center for Complementary and Alternative Medicine (NCCAM), as well as all the other institutes and centers at the NIH, are now in the process of finalizing our joint strategic plan for addressing what we're calling health disparities.

In NCCAM, our part of this will involve identifying the extent and nature of CAM use by particular racial and ethnic populations who have often traditionally relied on these tools.

We are going to be studying the use of CAM therapies in particular areas to reduce disparities. I'll give some examples. We're going to have an emphasis to increase the participation of under represented populations in our clinical trials. Most clinical trials, many are 94, 96 percent caucasians. That doesn't represent the face of the American people. And our studies have to do a better job.

We have to enhance the ability of minority institutions to support CAM research, to serve their own communities. We've begun to do this. Our Center for Complementary and Alternative Medicine, Minority Aging, and Cardiovascular Disease is working with investigators at the Drew King Medical Center in Los Angeles and at the Morehouse University School of Medicine, in Atlanta, looking at Transcendental Meditation as a tool for reduction of hypertension and looking at an herbal preparation for atherosclerosis. We have a series of future plans that are within the scope of this part of our endeavor as well.

Now there are lots of good researchers in the country today but not many of them working on CAM and so we need to cultivate a generation of investigators who are good and who are interested. And we announced 6 months ago an intent to fund every mechanism that the NIH has for research training to provide individual and institutional awards to fund all phases of the career spectrum from pre-doctoral to mid-career

investigators, for mentored and independent research and for learning both basic through clinical research tools as is related to complementary and alternative medicine.

We have to communicate effectively with the American people. I could give just so many talks like this in front of excited and interested audiences. And we use all the electronic and written media tools at our disposal. Our web site, nccam.nih.gov gets about a half a million hits a month.

You should look at it because our strategic plan is now outlined on that is open for public comment and there's a way to respond right on the web. And I have a staff member assigned just to review and collate these recommendations on the strategic plan. We have an 800 number for our clearinghouse, there's a web site for that.

We have a special CAM citation index which takes 175,000 articles on the National Library of Medicine's Medline database and uses search language that we would be more familiar with in Complementary and Alternative Medicine.

We have a newsletter and we have town meetings. I held the first in conjunction with David Eisenberg's group at Harvard in February, in Boston. And we will have a series of those around the country; not here in Bethesda because I talk in the Washington area too much already.

Now one of our responsibilities is to try to do things that will facilitate the integration of those practices that prove safe and effective. We will do so by providing compelling data through our research portfolio. We're funding an initiative to specifically look how institutions have effectively solved problems, broken down barriers, and what those barriers are -- through our training and curriculum development, our centers program, and our communication.

You know, a little information is a very effective tool because it dispels a lot of prejudice.

And to our students in all the allied health professions, we need to begin to think what should be integrated into their curriculum today. Well, certainly we need to teach them more than we are about pain management and palliative care. We need to teach them more than we are about nutrition and exercise and the role of stress because that occupies very small parts of our formal curricula today.

We need to revisit the pharmacology of natural products which was left out of the curricula for the past four or five decades. We need to have them at least understand what some of these alternative practices are, not that they should become Ayurvedic practitioners, but they should at least spell the word correctly in their referral notes.

And there are other things that we need to broaden our students to. But the integration and education, of course, has to be patient-centered, but it has to be based on rigorous evidence. These young, impressionable minds need to be taught what we know the best, not what the most fanciful ideas are confronting the generation.

Part of my stewardship responsibility is to report to you and to Congress, as I do very often, about how we're spending your \$70 million this year. Funding of large clinical trials and our centers program, investigator-initiated grants 9 percent, funds communications, 4 percent now in training and career development.

We're just beginning our intramural program and other activities. As this process evolves and matures, we will increasingly in terms of proportion, be funding what we call investigator-initiated grants because it's not our responsibility to sit in Bethesda and tell investigators what they should be doing.

We should hear what they think is the best idea. And it's people from the community, not ourselves, who actually review the applications. Scientists from all over the country assembled Monday, Tuesday, and Wednesday this week to review the Centers' applications. My staff doesn't make that decision. So we coalesce ideas from the best and the brightest. And that's what we're about.

That's really a state-of-the-art at the end of our first year really of the National Center. It's an exciting enterprise and I invite all of you to join me and my colleagues in it.

Thank you.

DR. GORDON: Thank you very much, Steve. Steve ended just on time, but he would like and we would like to give a little bit of an opportunity for people to ask some questions of Dr. Straus.

One thing I want to say is one of the other activities of NCCAM has been major sponsorship of this conference, along with NCI and I'm very grateful for that and also one of the things that Steve has done is to begin to take some of the first-rate staff that was in the Office of Alternative Medicine and to bring in some wonderful people. And now, along with Richard Nahin in the area of cancer, Mary Ann Richardson, who's done so much is working with Dr. Straus.

So we have just time for a couple of questions because we have a panel coming up, so please begin.

Right there in the middle aisle. With the lights, I can't see you, so. Will you help her with the mike?

DR. STRAUS: So this is, of course, the hardest question to answer. What is the sound of one hand clapping?

SPEAKER: I actually have a question and a comment and they're related to one another. The study that you mentioned that looked at St. John's wort and the reduction of HIV protease inhibitor; I was wonder if the same sort of study has been done looking at imipramine?

DR. STRAUS: No.

SPEAKER: Well, I guess, my comment then. It relates to something Michael Lerner mentioned yesterday about cultural differences in medical practice. Lynn Payer's wonderful book. I am a researcher and a scientist so I state this in the context of someone who loves science and research. There are still cultural biases and assumptions underlying the questions --

DR. STRAUS: Oh, wait. I'm sorry. You asked whether drug interaction studies have been done with imipramine, or whether St. John's wort interferes with imipramine?

SPEAKER: No, no, no. You first showed a study that said imipramine and St. John's wort are sort of comparably effective --

DR. STRAUS: Yes.

SPEAKER: And then a second study that looked at the effects of St. John's wort on HIV protease inhibitor --

DR. STRAUS: Yes.

SPEAKER: And I wondered if the same sort of research had been done --

DR. STRAUS: I see. With imipramine? Yes.

SPEAKER: Okay. Well --

DR. STRAUS: I'm sorry. I thought you asked if the St. John's wort interferes with imipramine metabolism. Classes of drugs are very well studied in terms of interactions with other large classes today. Those studies have been done.

SPEAKER: Well, I still would like to make the point though.

DR. STRAUS: Please.

SPEAKER: That the questions that we choose to ask, and how we interpret the data, have cultural biases, and assumptions, and --

DR. STRAUS: Yes, of course.

SPEAKER: So, you know, while we try to construct and craft more regular science and research, I don't think we can lose sight of the fact that how we do the studies and how we interpret the data may reflect less than sort of truth with a capital T, as if there's one truth.

DR. STRAUS: I see. But that's true of everything in life.

SPEAKER: Because of political and financial considerations are often profound impacts on research results and research studies, I wanted to ask this question.

Is there any thought currently being given by NCCAM about the results of purity of, for example, herbal products and any desire on the part of NCCAM to upgrade the quality of the supplement industry and keep these products available as over the counter, versus channeling that towards pharmaceutical companies which can certainly provide purity of product in isolated forms? That kind of important, you know, distinction?

DR. STRAUS: It's an important question because you need to understand that the NIH is a research institution. It has no regulatory authority. I have no capacity to affect manufacturer's standards, licensure, credentialing, things like that.

I provide the data and others in the public have to debate whether it's in the American people's best interests to do whatever. I mean, these herbals are available by prescription in Germany, but they're widely available. And they're available through other mechanisms in other countries.

The American people are going to need to decide that if this is what we want in terms of our health, how best to provide it so that we're assured of getting an effective product and a safe product.

SPEAKER: Right. I was just curious to see if an attempt was being made to present that to the public in an open manner, rather than it being presented in research type of settings, but the general public not knowing that this is a question of whether they have the right to choose on this or not.

DR. STRAUS: Well, right now the American public has a right to choose. There are a lot of people who feel that that's the best solution. There are other people who feel differently about it. And that's a debate that others are going to have to decide on.

My job is to do the science and find out what works and then you all decide how to buy it.

SPEAKER: Dr. Straus, I'm very accepting of integrating holistic medicine the body of medicine of what we call Western medicine. But a lot of these practices are based on intuition, and folk medicine, simplicity. Do you have any way of monitoring the civilizing process so that it doesn't become sterile?

DR. STRAUS: Let's see if I understand your question. I believe you're asking if there is a practice that's used by some indigenous culture. Will that culture, in some way, be hurt by the intrusion of others who want to steal from them their ideas and methodologies? Is that what you're asking?

SPEAKER: That's one of the aspects of the many aspects, yes. But it also involves -- a lot of practices that we do are based on intuition, based on energy, and when you have clinicalized most things, it's going to possibly diminish it in a sense.

DR. STRAUS: Okay. So --

SPEAKER: Is there any way to monitor that and put something in place so we don't get too commercialized?

DR. STRAUS: Well, the American marketplace is commercialized and that's the way it's dealing with a lot of this right now. It's very hard for an average person in the public to know where to turn.

Our studies seek to benefit from people who are doing the practices by having them do their practices while we're observing them in the process of the studies.

There are huge cultural issues. The Americans have, in many ways, cannibalized cultural ideas from all over the world and we make it our own. I mean, Chinese food in the United States tastes great. It's a wonderful industry. But it's not what people from China actually recognize as their own food. But it serves our palate and we're not taking away the capacity of people to continue to practice their culinary habits the way they would like.

I don't know how this is going to turn out in terms of the American process. I will say that there are some practices that we have to go abroad to observe and we have an international program in place to do that where we can study practices in their native setting.

SPEAKER: I just suspect that it could be maybe something in the future that would be added as one of the responsibilities.

DR. STRAUS: But we do fund studies relating to cultural anthropology, for example, in terms of traditional practices and that is an interest of those kinds of investigators.

SPEAKER: Okay. Thank you.

SPEAKER: Private pharmaceutical firms finance a lot of clinical trials testing, say, conventional approaches to medicine. Are there comparable investments by those firms in CAM type approaches?

DR. STRAUS: Almost none.

SPEAKER: Almost none. Is there any likelihood that that will come about?

DR. STRAUS: Well, you have to ask yourself why large pharmaceutical companies invest, because they have a profit motive. And part of what I'm doing in meeting with

people from industry is to try to convince them that it is in their best interest to fund research and help develop products.

Some of these are materials that can't be patented, per se. I mean, you know, ginkgo biloba has been here a long time. But companies have learned to get use patents, to get preparation patents, and it's sorts of things.

And the marketplace also will increasingly demand some proof of better quality. There was a question before about standards. However that's decided, and industry is beginning to think itself actively about self-regulating and adopting some of it's own standards for manufacture.

I think they need to do it because, frankly, \$70 million in what's an otherwise large, out-of-pocket industry, isn't enough. Thank you.

DR. GORDON: Thank you very much.

DR. GORDON: Thank you all very much and thank you very much, Steve. It's was great.

(Whereupon, the PROCEEDINGS were adjourned.)

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