

CENTER FOR MIND-BODY MEDICINE
COMPREHENSIVE CANCER CARE 2001

CONCURRENT: Funding for CAM Research: Public and Private Opportunities

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P R O C E E D I N G S

DR. SMITH: I'm Dr. Wendy Smith. I'm from the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine. You may have heard the director of our office earlier this morning, Dr. Jeffrey White. I'm going to give you a few minutes to give you a little bit of background of our office -- what some of the opportunities are. But what we want to do today is spend the bulk of our time introducing you to some of the opportunities that are available at a group of foundations that have come here. We will all stay afterwards and hopefully have a lot of time for questions, discussion. If you have particular proposals that you want to talk about, we would be more than happy to spend some time with you. To give you a little background first. As I mentioned, I am the program director at the NCI office. I'm in charge of research, development, and support. I'll get into a little bit more detail about what that entails, but I wanted to let you know about some new members of our staff. One is Ann Washburn. You can find her downstairs at the NCI booth. She has a lot of material that could be helpful. She is in charge of our information. We also recently hired Colleen Lee, who is an oncology research nurse. Her role is involved in the Best Case Series program. She is also listed here and you can certainly find her as well, if it seems like that that program is a better fit for what you need to do. The National Cancer Institute has a long history of having interest in evaluating complementary and alternative therapies, going back to the 40s through the 60s, where we looked at Hoxey, Gerson, a variety of techniques; the 70s and 80s, where there were sponsored trials and investigations of high doses of Vitamin C, Laetrile; from the 90s to present, the Burzynski work in Texas, some shark cartilage trials. It came out of this history of developing this that the Institute established our office in 1998. Our mission for the NCI: We serve as the liaison to the National Center for Complementary and Alternative Medicine. That is the center at NIH that is directed by Dr. Stephen Straus. It is a different entity from the NCI. We work as a liaison to that group and we coordinate and work together. We coordinate the CAM projects within the entire NCI. Those of you who are familiar with NCI, it is an enormous organization. It was felt that it would be very helpful to have one office that would help coordinate the activities across all the divisions, and branches, and sections of the NCI. We're responsible for developing NCI's CAM agenda. We have a role in interfacing with the public, the CAM community, and the oncology community regarding cancer/CAM research. We are a research organization. Within our office, there are three major programs: The research, development and support program, which is my program; the cancer information program, which is Ann Washburn, and the Best Case Series, which is Colleen Lee. We're going to focus on the research development program. Within that program,

we have several activities, one of which is called the Clinical Trials Program. What we do is we fund large-scale clinical trials and CAM research. The projects that are going on right now, we're funding two trials, Phase III, in oral shark cartilage for cancer. One is with MD Anderson, and the other is with the NCCTG Cooperative Group. These are groups of places that work together, so it's an even larger trial. It's not to one institution. It is to a group of institutions. We are also doing an extensive evaluation of the Kelley/Gonzalez therapy. Some of you may be familiar with that. It's fairly well-known. It's a series of pancreatic enzyme treatments for end-stage pancreatic cancer. We are working with the NCI Conventional Cancer Center at Columbia University in New York to evaluate this therapy. Last summer, we had an announcement for CAM trials through the Clinical Trials Program. So these groups of cooperative groups of hospitals and researchers were invited to come in with proposals which the NCI would fund, to study different kinds of CAM trials. We are funding six large-scale trials that are starting soon out of this program. The other major aspect of the research and development program is the research portfolio. This is a separate way of funding the research. It's a different program. What we're talking about here are things like investor-initiated grants. This is what most people are familiar with when you talk about NIH funding. These are things like RO1's, which are the large-scale applications. Those are the kinds of terms people are most familiar with. We are actively looking to recruit and assist investigators in preparing applications to come to the NCI and other NIH institutes in order to get funding for CAM trials. Here are some of the announcements we have had, which are calls to the community to say, send us things in these topics. The first was a letter RFA, which was to the NCI Cancer Centers, to develop CAM research programs. This is a little bit different because it's not for a particular project. It's for a group of projects. We were investing in developing an infrastructure at the NCI Centers to start developing ongoing research in cancer CAM. We co-sponsored with the National Center an end of life RFA for cancer and AIDS. We funded a series of applications from that. There are several other NCI and Institute announcements. The way you find these things is the NIH Guide. If you're not familiar with the Guide, you can link to that from our Web site. I'll give you the information at the end. But there are lists throughout of the kinds of topics institutes are interested in. The important thing to keep in mind if you have any interest in coming into the NIH for funding, is to call staff members. Each announcement will say, for inquiries -- inquiries are strongly suggested. That's an understatement. They give you the name and the number of the person to call. Call them. Those are people like myself whose job is to help you through the process. Walk you through it. Find the topics that make sense for you, find the initiatives that fits your project. Sometimes we work to help people find collaborators to bring in other expertise that one group may lack. Again, I can't underestimate the importance of calling. When I came on board, one of the first things we did is sort of step back and look at that process. This is enough of a challenge in conventional medicine. It's an extraordinary challenge to put together competitive proposals in CAM. We are offering a technical assistance workshop for people who are interested in applying for funding. We've asked people to submit concept papers; tell us a little bit about your project. We will match those projects with program directors like myself who have expertise in that area. We are inviting people to come to Bethesda. The NCI is paying for the travel to bring people here to sit down, meet with the program directors, and start to work on these applications in increasing their competitiveness. They will also help you figure out which announcement to apply to and when, and again, walk you through it. So we will periodically have announcements like this. This was announced last summer. Concept papers were accepted. I think the end of July, it was closed. But we will do it again. We want to actively, again, encourage people to come in, and do what we

can to help people get through this process. One of the other activities we have coming up is we have established a series of expert panels on research methodology. In CAM, there is no consensus on the appropriate research methodology in design. There is a lot of confusion. So far, what it tends to be is based on personal opinion; this is how I would do the study; this is how Fern would do the study. If we happen to agree, I would get a good score in a review group. If we happen to disagree, I would get a less competitive score. It can't be based on personal opinion. We're striving to come up with a consensus of what the issues, what the goals should be. Now, we don't expect people to follow these expert panels as if they're the gold standard. What we expect is for people to use these as launching pads for the kinds of information that needs to be addressed in applications. Again, the program directors can tie you to this information. There will be papers coming out. The last thing we're focusing on is an invited speaker series. We're bringing in people who have been successful in the grants process, research we're funding, to report their data to the NIH community. It builds a cycle. Other institutes are also interested, not just the NCI. Again, we can help you make those kinds of connections across, and increase the opportunities available to investigators. This is why we wanted to have this panel. Again, we're not the only ones who fund this. There are a variety of places who are looking for good quality scientific research in CAM. We are here, and the National Center for Alternative Medicine is here, to help you develop these kinds of proposals. This is how you find us. This is our Web site. This is the National Center's Web site. We have links across them. There are links to other sites at NIH. I have my card here with E-mail, phone number. Again, find us. Talk to us. It's a complicated system. Yes, it is quite a challenge. I want to step back a bit and hand the forum over to our guests. We're delighted to have these representatives here. First, I'd like to introduce Fern Ingber. She's with the Cancer Treatment Research Foundation. She's going to talk a bit about how they're organized, what their interests are, and how you could approach them, to look for funding opportunities as well.

MS. INGBER: Thank you, Wendy.

DR. SMITH: You're welcome.

MS. INGBER: I'm going to stand because I'd like to be able to see all of you. I'd like to get an idea of how many people here are investigators, or represent investigators, and are looking for funding organizations. Great. Great. Well, I need to tell you that I'm very, very excited about the organization that I work with, the Cancer Treatment Research Foundation. The reason is that we are lean, mean, and entirely focused on funding the best clinical research that is available that really makes a difference in the lives of cancer patients. The excitement for me comes from having worked with many large bureaucratic organizations who do great work, like the American Cancer Society, the National Marrow Donor program and others, but to be able to now work for an organization that has literally no bureaucracy and is interested in one thing, and one thing only; that is really being able to identify the best investigators who are out there doing the most cutting-edge work, ready for clinical trials. It's pretty exciting. One of the things that I think distinguishes us from a lot of other organizations is that we are totally underwritten actually, by Cancer Treatment Centers of America. Because of that generous underwriting, we really are able to apply 99 percent of all the money that we raise directly to cancer research. We have funded people literally from around the world. We've got about 35 active grants going on now. We're easy to find. We're at www.ctrs.org. We do hope that you'll come and check out our Web site.

We really do create partnerships with our investigators and work very, very closely with our investigators. I'm thrilled to tell you that right now, we are funding up to about \$500,000 a year. We look for 2-year grants ideally. There is a packet, actually, I have a little stack of information for you that gives you a little bit of background about the organization itself. It also lists our Board of Scientific Counselors, which really is made up of an incredible group of individuals that really spans the spectrum in terms of expertise. So we have people on our Board of Scientific Counselors, like Dan Nixon, who was with the American Cancer Society and now heads up the American Health Foundation, and has certainly developed an expertise in nutrition; Wayne Jonas, who was one of the founding directors of the Office of Complementary and Alternative Medicine; Jim Gordon, who runs the Center for Mind-Body. The list goes on and on. I think you'll be really impressed to see the individuals who review these grants. The other thing that we are really excited about -- and Wendy and I have really talked in terms of the wonderful private-public partnership opportunities that exist between her office and CTRS and other such organizations. But we are especially interested in looking at those proposals that maybe right now don't fit into the exact criteria of the NCI or that need more rapid attention. We are ready to review proposals immediately. We review at least three times a year. If we see a proposal come through that's really exciting and it can't wait because we really think it's going to make a difference in the lives of patients, we pull a group together and we make sure that it's reviewed immediately. We have turned certain projects around in as little as 2-3 months, and that's usually unheard of. When I say I am excited about the work, it's a great team of people. There are only a few people on our staff. We don't do a lot of fundraising or direct mail or that type of thing. We've been very lucky to identify a few terrific angels who sit on our board of directors, and a few other individuals who are major philanthropists who have joined us and are excited by what we do, the way we do it. I cannot encourage you enough to please, if there is great work that you're involved in, if you know of individuals who are doing terrific work, give us an opportunity to review those proposals. I was thrilled to hear that the NCI, that Wendy's office is running this program which helps investigators in CAM really learn to write an excellent proposal. Because I will tell you that while we are non-bureaucratic and we turn those proposals around on a dime, we don't compromise in terms of the scientific validity and the design, and just how things are structured. So we are looking for the best science that's available. We're looking for those things that really are going to change the lives of cancer patients. We're certainly looking at ways to detoxify conventional therapies. We're looking for true CAM integrative therapies: Everything from psychoneuroimmunology, certainly looking at micro-nutrients, and just really running the gamut. We're interested in things that are dealing with spirituality, as long as they are really put into a good scientific model. So again, I'll be here afterwards. I would be delighted to answer any questions that you have. Ctrs.org. I also have some preliminary proposal applications; if you have some things that are ready to go and you want to take one of these preliminary proposals back to work on the application. But you'll find them on our Web site as well as you will a good explanation of the various grants that we are currently funding; a little bit more about who and what we are and what we represent. We do hope that you'll decide to join us, to be part of what we're doing, of our energy, of our excitement. We know that together, we can accomplish great things. Thank you for your time and thank you for being here today.

Wendy, thank you for inviting me. DR. SMITH: Susan, would you like to go next? MS. BRAUN: I'm Susan Braun, President and CEO of the Susan G. Komen Breast Cancer Foundation. We are a grantmaking organization in the area of breast cancer. We have been around for 20 years, and through that time, have grown to be a fairly good fundraising

organization as well. We've raised over \$400 million since our inception. We granted out, also in a very lean way, which we're pleased with, too. That's important. Volunteers make that happen. Through a couple of different mechanisms now, as we've evolved, we've got a research grantmaking program that is multi-tiered. We have at the Komen Foundation 115 affiliates, which are something like chapters, throughout the United States; each of whom, or each of which raises money in their own community, through events like the Race for the Cure. But many other ways as well. Of their net proceeds, 75 percent stay in the community and are granted by their local committees who make decisions. After having done a community needs profile, they make grants for different kinds of profiles that raise awareness about breast cancer, that look at treatment, that look at detection. Increasingly, our local affiliates are funding programs that we can categorize as alternative or complementary; certainly many spiritually related programs, and so forth. We're very interested in the entire spectrum of survivorship and of wellness. So we see that increasingly in the numbers of grants that are being made by our affiliates. Those are hundreds and hundreds of grants made each year through our affiliate organizations. They are local. I'll give you our Web site a couple of times, too, because you can reach those local affiliates through our Web site. So people who have local programs are encouraged to apply to our affiliate organizations, because they too are grantmakers. The 25 percent that they send to our national headquarters, which is in Dallas, along with other funds, come together into a pool through which we fund what we call our National Grants Program. So far, we've granted out about \$68 million -- \$20 million of that was last year alone -- in research programs for basic clinical translational research, epidemiologic research. We fund fellows. We fund doctoral dissertations. We also fund meeting grants. For example, for this meeting, we have provided some funding as well, and some support. That's also a mechanism at the Komen Foundation for which you can apply for funding. That is an annual cycle. Both are on annual cycles, although with the affiliates, that annual cycle varies by the affiliate. So again, the best thing to do is check the Web site. It's komen.org. It's very easy. www.komen.org. You can also get in through breastcancer.com. or raceforthecure.org. We have found that our portfolio is shifting. When I say we have found that, we raise all of our monies publicly. We are a public foundation. We don't get any monies from any one place. We don't get any government funding. Very little of our funding comes from pharmaceutical companies, or from device manufacturers, and so forth. Basically, our money comes from the public and from corporations that aren't real involved with healthcare. So because of that, we listen to the public and primarily to patients, or to families of patients, and so forth, as to what really needs to be funded. So over the years, we began funding some of the cutting-edge research that we have talked about that has now become far more mainstream. So now we're looking at that entire portfolio and saying, okay, that's become mainstream. We've got an NCI-accredited research grant program. In fact, we're a blinded peer review program, so our reviewers don't even know what institution or what investigator is applying for the grant. So by section, and each one is blinded in the National Grants Program. So when we look at the entire portfolio, as we must do regularly to make sure we're listening to the public, because they are constituents; we say all right, well, if NCI has really begun doing some wonderful work in complementary and alternative, or certainly in beginning there a great history in some of the more typical basic and clinical research and translational research programs, and there are other excellent foundations too that are providing funds. So we'll say, what next needs to be done? What does the public want to see? One thing that we're beginning to hear is the public wants to know more about alternative, complementary, herbal, nutritional, different kinds of therapy. So for us, being kind of older and somewhat

mainstream in who we are, we try to put a leg into both camps, if you will, and say, what is out here that is excellent science and/or that is a new approach to measurement? You know, not necessarily following the standard scientific methodologies, because that may not fit for a lot of what is integrative medicine. And how can we help that to then go on -- these ideas, these concepts, these therapies, to go on and get funding from other organizations. So that's in a nutshell what we do in terms of funding. We will be issuing our RFP for the National Grants Program on November 1st. Again, it's www.komen.org. You can look there for not only that National Grant Program RFP and the categories that are within it, but also for our affiliates, which are located in 45 states. They are in cities throughout the country. They are also grantmaking organizations in and of themselves, to whom and to which you can apply for funding.

PARTICIPANT: Could you all talk about your grant limits while you're -- I mean, that's important.

MS. INGBER: Ours go up to about half a million a year. In fact, we would definitely consider an over \$1 million grant over two years. So it just depends what comes in and how interesting it looks.

MS. BRAUN: Ours are listed on the Web site, but generally, for the larger grant programs, they are up to \$250,000 for two years. There are a few exceptions to that within the program. There are also limitations as to what kind of indirect costs, for example, can be charged in or salaried against the grant. We fund primarily the research itself. In addition to that though, I do want to make it clear, we fund programs as well as research. So with respect to our local affiliates, they are funding programs and not research, and so they individually have limits.

PARTICIPANT: You both mentioned funding -----

MS. INGBER: Well, I can tell you from our perspective, we want to make sure that we are not doing the same old, same old. So it's something that has not been done over and over, and yet, this is a different form. We have people who are discerning enough and have been around the field enough on our Board of Scientific Counselors that they can very quickly see what is new, what is different. Obviously, the other thing that is very important to us and our philosophy is how people live with cancer. So anything within the CAM area which I think provides true quality of life. I'll tell you a for instance; Connie Payton, Walter Payton's widow, launched the Walter Payton Cancer Fund. That has to do with the experience Walter Payton had at the end, when he was finally introduced to complementary and alternative medicine and what a difference it made having been served by some of the best institutions, conventional institutions in the country. It was through -- he happened to be at Cancer Treatment Centers of America. But having been exposed to CAM therapy. He came in a vegetable. I mean, truly, he was uncommunicative, and so forth. He was able to walk out within a couple of weeks and ride around with Matt Suey (?), his buddy in the car, and get back to really a true life. A lot of that had to do with -- not a lot -- all of it had to do with truly applying the best that is out there right now in CAM and integrative therapy. So it was really that combination of the best that exists in psychoneuroimmunology; certainly our naturopathic practitioners and so forth. So we are really looking at what will take us to the next level, so that when another person comes through a door,

you know, how can we make a difference? The other thing is, not all organizations out there are like the CTCA, Cancer Treatment Centers. So until we are able to validate the kind of treatments and CAM therapy, you know, it's really hard to then make sure that they become institutionalized. So we're looking at what are the therapies, the clinical therapies, that are excellent enough, truly different from others, that can be proved scientifically.

PARTICIPANT: So, it sounds like you're looking for something unique.

MS. INGBER: Without a doubt.

PARTICIPANT: Unique. Something that is a crazy idea because it is going to be totally different for your conventional research.

MS. INGBER: I will tell you when you say "crazy idea," I won't rule that out, but I will tell you -

PARTICIPANT: ----- crazy idea and then later on, when people changed their mind and -- this is a very good idea.

MS. INGBER: Mickey with NIC. It's Mickey, right? I will tell you that there is no doubt about it. What we're looking at is maybe something that would be considered a little crazy, but it sure better be in an excellent scientific model, and it has to be publishable at the end of it, so that what we come out with is something that really moves that bar, nationally and internationally.

PARTICIPANT: You're looking for something that somebody could learn from what we have done.

MS. INGBER: Right. We're thrilled to tell you that a lot of the programs that we've funded in the first, second, and third -- you know, in the beginning stage, have then gone on to receive multi-phase funding from the NCI or NIH. So --

DR. SMITH: Why don't we go on? Go right ahead.

MS TROCCHIO: Okay. Thank you. I truly appreciate the opportunity to speak with you today. But first, I would like to thank the Center for Mind-Body Medicine for developing and organizing a very informative and enlightening meeting. I'd like to thank you for taking time to be here today so I can tell you about our new foundation, which is the most exciting organization that I have ever worked at. When you arrived at the meeting, you may have noticed this flyer in your bag, or you may have seen it at the booth in the Exhibition Center. It says, "They have to sell me on the research and I'm not an easy sell." This advertisement briefly highlights the genesis of the Goldman Philanthropic Partnerships and its mission to seek out innovative research and advanced scientific projects through unique funding partnerships, which we call "inspired ventures." I'll tell you a little bit more about that later on, but first, I'd like to tell you about the very special people behind this advertisement. In 1990, Judy and George Goldman were in the middle of planning their youngest daughter's wedding. As they dealt with the many details that accompany planning a wedding, Judy told George that she did not feel quite right. So

she made an appointment to go to the doctor. But what she didn't know was that her life was about to drastically change forever. After visiting her physician and undergoing a battery of tests, Judy was diagnosed with multiple myeloma, an incurable blood cancer that kills 11,000 each year in the United States. Back then, her physicians had few options for her, and most of them revolved around chemotherapy. The diagnosis was even worse than they had thought, because the physicians told the Goldmans that the average multiple myeloma patient has a life expectancy of only 3 years. Faced with this grim news, the Goldmans went to work to find out how to beat this disease. They asked friends, family, business associates, and anyone who could offer hope. Finally, they learned that the Mayo Clinic was doing a trial and some very innovative work in multiple myeloma. So Judy's internist recommended a Chicago-based specialist who was participating in the Mayo clinical trial. The physician asked if she would like to participate. Well, after undergoing 2 years of intensive chemotherapy and completely changing her diet and lifestyle, the doctors told Judy that her disease was in remission. To this day, for 11 years, she remains one of the small minority of persons who are in remission from this horrible disease. But the story doesn't end there. In fact, that is just the beginning. Even though they were ecstatic about the news, they still felt they had a lot of work to do. As a way of giving back, the Goldmans wanted to figure out how to identify cures for catastrophic diseases in ways that might otherwise be overlooked by mainstream medicine. To do that, they felt that they had to form a new kind of foundation that could operate outside of the present philanthropic and medical research funding systems. The result of their hard work is the Goldman Philanthropic Partnerships, a merger of the best in philanthropy and business management, that will inspire new advances in medicine. This year, we launched the Goldman Philanthropic Partnerships with a new mission, to seek out innovative research and treatments leading to cures for cancer and other catastrophic diseases, validate scientific theories on promising research projects, and then advance pioneering research projects through effective business management. With more than 40 years of business experience as entrepreneurs, George and Judy Goldman had a unique vision for their foundation. The partnerships will create a cutting-edge portfolio of projects that will drive research funding. Small funding groups will be formed, which will consist of innovative researchers, dedicated philanthropists, and the foundation. These funding partnerships are called "Inspired Ventures." Like all solid scientific research, benchmarks will be established and hopefully reached. The Goldmans developed the recent mission and vision statement following their work with Dr. Vincent Rajkumar at the Mayo Clinic. Dr. Rajkumar is a researcher in the Division of Hematologic Malignancies. The Goldmans first approached the Mayo Clinic and challenged them to submit their most innovative projects that were difficult to fund. Mayo Clinic responded with nine proposals for consideration. After reviewing this work, through medical advisors, they chose a unique project, entitled "Angiogenesis in Plasma Cell Disorders." That culminated in a \$300,000 grant to Dr. Vincent Rajkumar for his work in cutting off blood supply to myeloma cells in halting cancer growth. This work is currently in its first phase, and following validation by the partnerships, Dr. Rajkumar has subsequently gone on to receive additional funding from the National Institutes of Health and others. That challenge and subsequent funding commitment led to additional decisions, discussions with Mayo Clinic, which culminated in the Judith and George Goldman Symposium on Innovative Research in Multiple Myeloma. That ground-breaking conference brought together, for the first time ever, the leading myeloma researchers from around the world to discuss pioneering research and treatment options for multiple myeloma. In addition to these activities, the partnerships have been very active in other events designed to initiate a dialogue on innovative research. We at the partnerships are very

happy to work with our fellow sponsors, sponsoring organizations here today, in making this year's Comprehensive Cancer Care 2001 Conference a success. We also have been working very closely with Dr. James Gordon on another upcoming event, which will be held in Chicago on December 2nd. It is called "Empowering Cancer Patients." We have organized a partnership involving virtually every major patient advocacy and support group in the Chicago area, to help their members understand the importance of establishing key partnerships involving patients, family, peer groups, and entrepreneurial partnerships. It's one more example of how we hope to increase a public dialogue on research that may lead to ground-breaking cures and treatments. Lately, we have been looking at a number of new perspectives on how to manage and treat cancer and other diseases. Some of these projects include nutraceuticals, herbal, and botanical compounds, leading to prevention and cures for cancer as well as enhancing quality of life; mind-body approaches to treating catastrophic diseases; and customized treatment regimes that target genetics and the environment as causes of disease. We are also looking for new perspectives on old scientific tenets. This covers a range of issues, from advanced microscope work to disrupting microbes through the use of high frequency sound waves and also exploring the theory of biological terrain. Our Web site, www.goldmanpartnerships.org, has more information about our activities. On our site, you'll find a research application form, which I also have with me today -- a one-page form. We have some current research ideas in development, information on upcoming partnership events, and summaries of each Inspired Venture as they are identified and committed, and much, much more as our foundation continues to grow. So please feel free to talk to me, or at the booth, or after today's presentation. Or send me an E-mail. I'd like to take questions from you. I'd like to discuss with you your research topics. There are also other people here right now from the Partnerships who are willing to sit and spend some time with you today and discuss your possible proposals. In closing, I just wanted to say thank you so much for the opportunity to be here with you today, and I hope that you will join us in inspiring new advances in medicine.

DR. SMITH: We have one additional. Evan Ross.

MR. ROSS: Hi. Did anybody not get one of these that would like them? Take one and pass it around. It's a listing of the grants that the National Brain Tumor Foundation provides on an annual basis. My name is Evan Ross. I'm a doctor of Oriental Medicine, and I am the complementary medicine advisor for the National Brain Tumor Foundation. I was going to have you, for a moment, just to sort of make a point -- I'm not going to do this -- but I was going to have you imagine for a moment that you had just been diagnosed with a brain tumor. Then I decided that that would be negative imagery, so I'm not going to do it. My next question was going to be, if that had happened, what do you think the first thing -- after your diagnosis, what do you think the very first thing that you would do would be? I bet you for every single person that I asked, we'd likely get a different answer, especially with respect to complementary medicine. The reason I'm making that point is, what if there was one thing that we knew beyond the shadow of a doubt could improve quality of life for a brain tumor patient, or for their caregiver, or for their family, beyond the shadow of a doubt. I myself am a 6-1/2 year survivor of a Grade IV glioblastoma. So I'm here in many capacities: As a former patient, as a practitioner myself, or clinician, and also as a researcher. Obviously, I said I sit on their Scientific Advisory Board. So in all of those capacities, I want to sort of tell you how things happen from a patient perspective really briefly. I'm not going to talk about all the grants. I'm really going to only talk

about two, because there are only two that are relevant to complementary medicine here. When I was diagnosed, there was no information on complementary medicine. The Internet was running at like 9600. So it was hard to even get information quickly, expediently. I live in Los Angeles. I had to go to UCLA to do the searches that I wanted to do. I truly believe that I would not be sitting here today talking to you were it not for my integration of Eastern and Western Medicine. I obviously feel so strongly about that that I went on to become a doctor of Oriental Medicine and a licensed acupuncturist. So I had to consult with varying practitioners. Then I had to integrate a whole team and make sure that there was proper communication between those individual practitioners. I had to make sure that one therapy wasn't neutralizing the effects of another therapy. For any of you who went to Keith Block's seminar, I was listening to him and saying, wow, I guess I got pretty lucky, because I was doing so many things, it was very conceivable that one thing was cancelling out the other. That's, in my opinion, the magic of the work that he was doing is that it is so scientifically based that he is able to look at things from a biological and a physiological perspective. It's just phenomenal. That aside. Because of me and patients like me who said to the National Brain Tumor Foundation, listen, we need information; we need to know what's that one thing that we can do that is going to improve our quality of life or increase survival time, or what have you. So last year, at this conference, the National Brain Tumor Foundation formed a committee of very renowned people, neuro-oncologists, oncologists, people from UCSF, Johns Hopkins, the NCI, NCCAM, Wayne Jonas, who someone mentioned earlier was there, Mary Ann Richardson. I could go on and on. Ralph Moss, who writes the Moss Reports. An impressive list of people. We sat in a little think tank, in a room about this size. In fact, it might even have been this room. I don't know. We said, okay, what should we do? How should we make this happen? So over the past year, we put together -- I guess it's actually two years ago, because we had our first grant recipient this year. So I'm going to tell you about that in a moment. We figured out how we should go about it. We decided to offer a sum of money, and how we would go about a review process. We formed what the other people who are up here with me formed. Basically what we are looking for is, there are two grants that would pertain to complementary and Oriental -- I'm sorry, I'm so used to saying Oriental Medicine -- complementary and alternative medicine. One is a quality of life research grant, and that pertains to not only brain tumor patients, but their families, caretakers. It's a \$15,000 grant, by the way. Both of them are \$15,000 grants. It could pertain to people who are looking for a way to perhaps use therapeutic touch to -- it could even be for benefitting caregivers of patients. In other words, it does not have to be isolated to the patient per se. Then there is the CAM grant, which is also, as I said, \$15,000. Basically what we are looking for here is a commitment and an openmindedness to unusual therapies -- you know what? It's easier for me to tell you what we're not looking for. What we're not looking for is the magic bullet that is going to cure brain tumors. We could go one by one through every herbal pharmacopoeia and we still wouldn't have information that would actually benefit the patient next year. We're looking for modalities that are going to enhance lifestyle, quality of life, length of life now. So the individuals herbs and their effect and so forth, that's not quite as much what we're looking for. We're more looking for what I would call, to coin a phrase, "big picture research"; research that is going to positively effect brain tumor patients' lives. And as I said, not necessarily looking for the magic bullet cure. What we're looking for is therapies that are going to enhance the efficacy of conventional therapies, much like Dr. Rosenthal was talking about this morning, for any of you who were at his address in the Ballroom; integrative therapies that are going to have an impact as I said -- I keep saying it again, and again, and again -- but quality of life, length of life,

and the lives of the families as well. That's pretty much all -- oh, let me tell about the person who received last year's grant, Lisa Rogers, from the Henry Ford Hospital, just to give you a frame of reference. She received a grant for "Systemic Anti-Oxidant and Oxidative Stress Levels in Associations With Intake in Patients With Untreated Cerebral Glioma." Well, what does that mean? That means if a patient is eating an antioxidant rich diet, does that positively affect their survival time, their quality of life, versus the patient who is not eating an antioxidant rich diet? Very simple. Very basic. Good statistical data, the kind that good -- a properly written protocol, you know; the people on this panel are, you know, the utmost in professional, and they're looking for high quality work. But they're looking at the work -- we, I'm on the panel. We're looking for work that's going to make a difference, make a difference now. So I'm happy to answer any questions you may have. I have my card. The National Brain Tumor Foundation's Web site, if you're interested, is very simple: www.brain.tumor.org. It's simple, but it works. That's kind of where we come from. Simple, but it works. Thank you very much. DR. SMITH: We'd like to go ahead and open the floor.

PARTICIPANT: I'm a natural health practitioner all alone in a pretty hostile environment, Cleveland, Ohio. I have sent you my request. As an individual and not tied into some, you know big research group, but, I'm doing phenomenal work with new technology, where should I go? I mean, I'm not tied into a big, you know, if you get money you can attach yourself to us, but you have to find your own money. So, that Kent State and the Mercy School would help me if I could. But, where would the best place be for an individual, who is doing incredible work, with incredible stuff, go for research money?

MS. INGBER: I will tell you that we are seriously entertaining working with individuals. It depends, you know. We'd really need to look at the grant and see what the area is, and, you know, patient accrual, and the base that you're working with. So whether it's an individual or an institution, I can tell you that as far as CTRF is concerned, I don't think that that's the issue. I think again, we're looking at that scientific model and the way it's established, and the credibility of design, the research design.

SPEAKER: Andrea, we also would like to see your proposal. We have a one-page submission form. You can pick it up. You know we will look at that. We also have a certain validation process that we go through. But we will get back to you within 14 days of receiving the submission form to let you know what you can expect.

PARTICIPANT: I have a question. Because there are such a plethora of opportunities out there in the CAM arena in terms of things that people are looking at, why does the NCCAM fund -- with such limited resources and with such scarce resources -- why do they fund projects that have already been looked at; like, for instance, shark cartilage? There is so much public data on shark cartilage, why did you again fund a project on shark cartilage?

DR. SMITH: The short answer to that is you need to ask someone from NCCAM. I mean, I don't mean to put you off in that way, but the NCI's office, the NCCAM office, are completely different. We come together on some of the initiatives. For example, the Kelley/Gonzalez regimen. The NCI got involved because at the time, the NCCAM was still an office. Because of government regulations, they were not authorized to make that kind of an award. The NCI joined

in a partnership with them to provide the mechanism to support that. Now that they are a Center, they can do that directly. Now, in terms of how those decisions are made. You know, I can talk about the NCI experience. Part of what goes into the funding decisions is what is known, what's already been done, how does this fit into a bigger picture? But another aspect of that is to take a step back and look at the details. There may have been a lot of studies on a particular topic, but if the designs were flawed, if the questions were different, if you piece it apart, you may find that if you still don't know, you still need to look at that. Maybe there is a better way to investigate something further.

SPEAKER: Beth, I can actually speak to that. I met recently with someone from NCCAM, and they told me that actually, that particular study on the shark cartilage was -- because I was curious also -- that there was funding that was given specifically to look at that area. That was really a special request. So it was an exception, I will just tell you.

PARTICIPANT: That piece would bother me, that the NCCAM would take funding and say, okay, I have a product here that someone is paying me to look at. To me, that's not --

DR. SMITH: There's no question, with the appointment of Dr. Straus, since they've brought on Dr. Richardson, that there is a real commitment to looking at scientifically rigorous research in this area. We can't speak to maybe some of the things that have led up in the past. But there's no doubt about their commitment to science, their commitment to cancer CAM, their commitment to moving the field forward in meaningful ways, and making thoughtful decisions about how to spend those limited resources. The NCI has been committed and devoted to working with them, so that we can share our resources, and move things forward.

PARTICIPANT: Thank you. PARTICIPANT: What are the dollar figures that NCI has submitted for doing research? DR. SMITH: I don't know what the -- I don't think that the budget has actually been approved yet, since we're still in the continuing resolution. We haven't heard definitively from our acting director at this point. I know that the director of the office has requested an increase over last year's budget. PARTICIPANT: Which was how much?

DR. SMITH: Last year's budget, I believe, was a little over \$2 million.

PARTICIPANT: Not for the office. How much is NCI going to submit to fund research -- if NCI as a whole has a \$3 billion dollar budget -- to CAM research?

DR. SMITH: To CAM? That's a question for Jeffrey White, for the director. He would know the specifics on that. I can speak to the commitment of the deputy director and I can speak to the commitment of the previous director. Some of you may be aware that the NCI director, Richard Klausner recently left. But there was certainly an internal commitment to CAM. Our office was established from an internal decision. It was not a mandate from Congress. It was not a mandate from someplace else. It was not a mandate from NIH. It was within the NCI. There was an acknowledgment that it was important enough that it was established within the NCI. I think that does speak to the commitment of the Institute and the fact that our office is growing, our staff has doubled. We are increasing. We hope to increase more. Yes?

PARTICIPANT: If I understand, I think in CAM's ----- were saying that they have ----- around over \$100 to \$110 million. Their pool of funding is separate from yours?

DR. SMITH: Yes. That is correct. But again, we joint fund a number of things.

PARTICIPANT: Some of that probably depends on what your definition of CAM is. I mean, I imagine there are lots of projects that you fund that might fall into that category.

DR. SMITH: Yes.

PARTICIPANT: That don't necessarily go through a "CAM" study mechanism.

DR. SMITH: Exactly. Their budget, again, to keep in mind, the NCCAM is devoted to the study of complementary and alternative medicine across several diseases, several different conditions. They include arthritis, asthma. There is a whole variety. Our office is focused just on cancer. They also have a very good cancer program as well. But when you're talking about their overall budget, it includes all of those things, not just a focus on cancer. Question?

PARTICIPANT: The breast cancer foundations fund some of the research but also programs. Do any of the other foundations also fund programs?

MS. INGBER: We are actually beginning to talk to a couple of different organizations. One that is doing basic science research as well as some animal models, whereas we only do clinical. Together, we've been talking about -- you know, should we, let's put it this way. I believe if we were approached with the right kind of program that really was going to make a difference, that we have the connections now, the resources, especially with the people that we have on our Board of Scientific Counselors, who are connected with other organizations who do basic science, that we really could put together a fabulous program and support a program. We'd be very interested.

MS. BRAUN: I'm not sure, though, what kind of program you were talking about, because it sounds to me like the kind of program that you're describing is a little bit different from what I'm talking about in programs. What we fund in the community in programs -- I'm thinking of a couple things like a fly fishing program for breast cancer survivors.

PARTICIPANT: That's not what I'm talking about.

MS. BRAUN: What she's talking about is research programs.

MS. INGBER: Right. An entire community of research.

MS. BRAUN: That's what we're doing is things like that, like spiritual retreats that we have helped fund at the community level, different things like that. The research is all funded out of our central research pool. So, that's programmatic, yes.

MS. INGBER: Right. Whereas we don't do anything but just clinical research. We don't do education or any of the other components.

PARTICIPANT: Thank you.

DR. SMITH: Questions? Comments?

PARTICIPANT: Well, I probably would like to make a comment. Both a comment and a suggestion. I came from background ----- I was a pediatric ----- oncologist practicing for 6 years. We moved to the States in 1988. Then I practiced internal medicine and oncology here. I practiced over 18 years now. But, in both ways of practice -- now I strongly believe, like you said as a patient, that no single ----- works. But, it has to be ----- . It's going to be very complicated and requires lots of creativity to put those pieces together. It's going to be individualized and it has to be that way, because when God created us, each person has unique features. So I think the whole thing is here, we need to have something new. The chemo, radiation has been done a lot, lately too much for too long; the benefit is so long. I've worked and I've trained in Washington, Seattle. Outstanding, you know, ----- you can't go any higher in terms of ----- patients. So that's why I kind of like suggest or I'm asking for your help on behalf of the patients to create something new. Whatever we have now is not working very well.

MS. INGBER: That's why we're all here.

DR. SMITH: Exactly. That's why we're here.

MS. INGBER: I think Wendy is really at the fore -- I think her office is taking a lead nationally in terms of government support, and we're certainly, all of us, very, very committed to making sure we're doing "make a difference" research.

DR. SMITH: This morning, after the first session in a press conference, one of the things that Jim Gordon talked about to the folks is not only the White House Commission that he has chaired, but some other research and recommendations that have been made about looking at different research methodologies, as you were pointing out, that might be more appropriate to the sorts of things that we're trying to measure within CAM. Particularly those individual elements, person by person, that might need to be seen. I know there are a couple of groups working on recommendations of specific methodologies, and Jim can talk more about that. He spoke about it very eloquently today. So I know that there are initiatives ongoing to look at how do you measure more precisely those individual differences and then outcomes of different kinds of interventions at the individual levels, which goes fairly contrary to the randomized control clinical trial.

MS. INGBER: One thing I can tell you that we've done is that we took a look at our Board of Scientific Counselors who range, I said, the gamut from those who come from really conventional, and so forth. So what we have done to facilitate our approval process and making sure that we indeed are open to, as you said, earlier, you know, some off the wall, creative, really terrific thing, is that we have divided that Board of Scientific Counselors, so when a CAM proposal comes in, it really is a group of experts in CAM that really understand the various

nuances. If we see a proposal that really is exciting and terrific but just doesn't quite make it because of design, we'll go back and we'll work with that researcher and they will be a dialogue. So it's not just that, you know; if something comes and it's terrible. You know, we're well aware that the structures that existed for conventional research do not always apply and fit exactly to CAM research. So what we're trying to do, and obviously, this workshop that Wendy's organization is running is really to facilitate and to enable researchers with great ideas to really be approved because they do have a scientific model, but again, it's replicable, publishable, and so forth.

SPEAKER: Catch-22.

PARTICIPANT: That's right. So, when I'm --

DR. SMITH: We are very aware of that issue. We're aware of that concern. There are going to be some announcements coming out for developmental support where you don't have preliminary data, where you can have this funding to help you get that preliminary data, to help you set that up.

PARTICIPANT: You do need something to get there. So what I did is, I applied a very scientific ----- which I can easily get funding. So what did I do? I just used that research ----- to buy time. So, to do something more creative, it would help something new coming.

DR. SMITH: That's exactly why we've created those kinds of announcements. There are going to be a program announcements coming out for developmental projects in cancer CAM. There is hopefully going to be another thing coming out for pre-clinical basic science work coming out. We are trying to address those gaps. The other thing to keep in mind too, is we don't expect the expert practitioners out there to suddenly become expert researchers. Just like we don't expect the expert researchers to become expert practitioners. So another thing we can do is help broker bringing those combinations together.

PARTICIPANT: That's what I was going to ask, if you could give me a Web site.

DR. SMITH: Here. This is who you call at the Cleveland Clinic. Don't be afraid.

PARTICIPANT: I should record that at Case Western, they turned me into the Medical Board when I complained about what they are doing.

DR. SMITH: Don't be afraid. This is a medical oncologist who is one of the researchers in symptoms management. She is very interested now in applying her expertise in that area, to alternative practitioners. She is actively looking for forming partnerships with the expert practitioners. She can't find you either. That's one of the things that we're hoping to be able to help bring together, some of those kinds of things.

PARTICIPANT: Would you have like a Web site where you register and you let them know what you do and --

DR. SMITH: You're psychic, aren't you? We have one in development. That's something that we have under consideration as a format, as sort of a chat room that would be password-protected, so that people can find each other. Again, we are doing everything we can think of creatively to help identify what some of these barriers are and then come up with creative solutions for them. If you have other ideas, if you have other problems, let us know. Again, you know, this is what we're here for. Yes?

PARTICIPANT: -----

MS. INGBER: We receive a large number. I'd say probably, I don't know, 100. We do this, you know, three times a year, that we take a look at. There are so many that don't meet our criteria of grant proposals, because either there's a lot of basic science, there is an animal component, there is -- it's really not clinical. Or they are somewhat same old, same old. So you know, those are cut immediately. I'd say that of those that are really seriously reviewed -- and there are maybe, I don't know, I think this last round there were about 8 that were looked at, there were 5 that received pretty -- you know, that were fundable. So again, there is a whole process though that they go through before they are ever given to our Board of Scientific Counselors. We have same blind review process. It's handled exactly like an NCI review panel, or, you know, the American Cancer Society. It's all done the same way.

MS. BRAUN: Let's see. Our last grant round, we received over 600 proposals and we -- I think about 25 to 30 percent of those received a superior rating. Of those that received a superior rating, about 50 percent thus far have been funded. But we fund out what we earn each year, so that can increase as our funds increase. We get them throughout the year. That is, though, at the national level. Our affiliates have different levels of funding, based again on how much they earn and how many proposals they receive. So it varies from year to year.

MR. ROSS: Given that it is only a \$15,000 grant, one grant is awarded per year. We review it once a year. I think it's due in March and, you know, by May. We received a dozen, 15 applications last year. It was our first year, so when we put out the RFA, we got a small response. But the response we got was incredibly high-quality. It was actually very competitive. It was very difficult to make a decision because they were all phenomenal.

MS. TROCCHIO: As you know, we're new. Our one project that was funded was the one I spoke on with Dr. Rajkumar. That was \$300,000 to the researcher. But we are kind of in a unique position. Each project that comes in to us is looked at on an individual basis. What we turn around then is -- we put together an Inspired Venture for the specific project, where we act as kind of the intermediary between the project, the investigator, the institution, and a group of philanthropists. So when they are donating their money, they are donating their money to your specific project. That has many positives, because they get to know the researcher, they get to know the institution, they get to know exactly where their money is going. So they could work for you. If you're, you know, passionate about your project, if you can explain it, you can tell a good story, you have what you need to take to convince us of the validity of the project, then it gets funded. So we are different. We don't have funding cycles. We accept applications continuously. We review them each individually. At that point, we will make the determination whether they will go to the next level. Or perhaps not at this time, but maybe we will review that

again. If we take it to the next level, that's when we will pursue an Inspired Venture for the project.

MS. INGBER: I should tell you that we do have a handful of philanthropists at this point who do private funding for us. So when there is a project that we know they are especially interested in -- and that half a million project that was just funded was a special -- you know, I went to a funder and said, this looks interesting and so the match was made. So we do have a lot that work that way. So when I said that every once and awhile, something will come in and we'll grab it. That's what happens, and I go to individual funders and they are funded.

DR. SMITH: For us, the success rates are dependent on the particular initiative that's used. For example, in a request for applications, an RFA procedure, there is a certain set aside of money for that. They spend in rank order as far as they can, assuming that they are reasonably competitive. If it's just coming in, it literally competes with the thousands of grants that come into the entire NCI. Overall, it's been my experience working with investigators that the first time you apply for a grant, you typically don't get funded. Some people do. But it is a complicated, difficult, competitive process. So that is not in any way something that should be discouraging. Again, that's what my job is, that's what the program directors are here for, to help you get through this process and help you avoid some of the general pitfalls people tend to make. There are certain mistakes people tend to make. We have Web pages after Web pages to help people write a grant. But it's been my experience, it's much more effective, if you find the program director and you work with them on a one-on-one basis. There are a number of suggestions we can help with. So in general, even in conventional medicine, it is a highly competitive process. In CAM, it's going to be even more so. But we're here to help you do that.

PARTICIPANT: Up to \$2 million, you said in last year's budget, went out to ----- . Is that right?

DR. SMITH: Roughly. That was for all of our activities within our particular office. That's not the entire NCI's amount that's devoted to CAM research. There is CAM research all over the Institute. PARTICIPANT: Yeah. Okay. I guess ----- in your office.

DR. SMITH: Yes. It can tell you, we spent roughly \$750,000 on clinical trials program. We have spent, in collaboration with NCCAM, I believe it was about \$2 million for the letter RFA that's developing the cancer programs within the Cancer Centers. Then we have additional separate grants that have come in. For example, if NCCAM's money has run out to a certain degree, and there are a couple more that are very strong, sometimes we would pitch in and supply money to them. Sometimes they would do the reverse for us. Sometimes we would co-fund something together. But we haven't had, in the 2 years the office has been here, the 3 years the office has been here, an announcement where we can say 100 came in, we funded 10. We will be able to say that. But what we're doing at this point is just coordinating across all the divisions. So it doesn't make much sense to tell you 10 percent gets funded in the Natural Products Division, 5 percent gets funded in, yeah. So it's -- okay. I hope that helps. Additional comments? Okay. Our cards are up here. Our information is up here. Please contact us.

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