

CENTER FOR MIND-BODY MEDICINE

COMPREHENSIVE CANCER CARE 2001: INTEGRATING COMPLEMENTARY &  
ALTERNATIVE THERAPIES

CONCURRENT: New Research on CAM Approaches

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P R O C E E D I N G S

DR. RICHARDSON: Let me introduce our session. Well, I'm going to present. I'm Mary Ann Richardson from the National Center for Complimentary and Alternative Medicine at NIH, and we have three presenters and we'll each talk around 20 minutes, and then we'll have questions after each presentation, time for a few questions, and then we'll have a comment. Let me introduce the group. We have, to my left, Dr. Ian Coulter. He was born in New Zealand. He holds degrees in sociology from the University of Canterbury and the London School of Economics in political science. He's also been trained in educational management at Harvard University. And Ian is the PI on the Evidence-Based Practice Center at RAND Corporation, the Evidence-Based Practice Center that's focused on evaluating CAM therapies. That's funded through the Agency for Health Care Research and Quality. He is also a panel member of our CAPCAM, our cancer advisory panel, that evaluates innovative approaches, and they review best cases. So Ian's on that as well. He has been working in the area of chiropractic for over 20 years, and just published a book on that last year called "Chiropractic Philosophy for Alternative Health Care." He's done a lot of work in terms of compiling systematic reviews. But what he's going to talk about today is the best case series.

DR. COULTER: Well, I'm delighted to see that you all didn't listen to Jeff White and go to his session, because if you had, it would have emptied this room.

DR. COULTER: This is an unusual presentation, since I'm not going to talk about the results of this study; we're going to talk about the way we're doing it, and mainly because this is kind of a new tactic we're taking to try and create this best case series. As you heard from Jeff, there's a tremendous desire now to do best case series, and NCI is trying to encourage providers to come forward and maybe come in front of our committee, but the technique of doing them and the ability to do them is a bit problematic. You heard Mary Ann say that this has been done by the Southern California Evidence-Based Practice Center. Our evidence-based practice for CAM is within the Center. The Center itself is made up of several institutions; RAND is the lead, but it includes UCLA, it includes USC, it includes San Diego, so there are many institutions attached to the Southern California Evidence-Based Practice Center. For those who don't know what these are, they were established in 1997 by the ANC for Health Care Policy and Research, which is the agency that we actually report to. There are 12 centers funded throughout the United States, and

there's one in Canada at McMaster University. The purpose of them is to develop evidence-based reports on topics selected by the agency or by the government, usually in discussion with us, but usually they set the tasks. So in our case, NCCAM usually determines the topic that we get. We also have performed evidence-based work for third parties as well. These are the Centers, for those who are interested. As I said, they're spread throughout the United States, and there's one in Canada. The Southern California one was contracted to provide technical support to the National Center for Complementary Alternative Medicine, and within that the sort of work we have been doing is, we've done a systematic review of mind-body therapies with GI problems. And for those who are interested, this has just been published by the ANC for Health Care Research Qualities, available now. A second one, which is just about to come out -- we've done a systematic review of our ayurvedic medicine for diabetes. We've done one for sammy (phonetic), which has been done submitted, but it's still being reviewed by outside experts and eventually will be published sometime in the following year. And we have another more recent one on ephedra (phonetic), which is another one we're doing, which again will come out sometime next year. So this is the kind of work we normally do at Evidence-Based Practice Center, and it's the kind of work that we're contracted to do for CAM. The background for this best case series, though, is quite different, and it's quite different from the other work we do in the Center. In fact, we have never done a project like this within the Evidence-Based Practice Center before, although we have done research that's sort of similar. You heard from Jeff White and you heard Mary Ann say that there is a committee called CAPCAM for those -- these acronyms get a bit confusing, but it's a Cancer Advisory Panel for Complementary Alternative Medicine. It's a joint committee between NCI and NCCAM. And within there, Jeff White has a unit within NCI that's called OCCAM, and this is the group that actually tries to develop best-case series. So, now, we'll have a test on all that at the end of this, right? So I hope you're paying attention here. I suppose the logic of doing this was to provide a forum where particular providers who believe they have a promising treatment for cancer could come forward and present what they thought the best case is, and then CAPCAM would either try and stimulate research or help them develop a research project or maybe refer it somewhere else. And you heard this morning that shark cartilage was one of the ones that came through this route. The problem that's occurred, and again, why Jeff wanted to talk to every one of you that he can in the next 2 days is that we haven't been overwhelmed with candidates. I think the only time I've been on the panel, I think it's three have come forward, and so there have been insufficient candidates, is the problem. On this committee, there are CAM providers as well, and as we have talked to them and as we have talked to the ones who have appeared, we've come to develop a good notion of the barriers to developing best case series, and there are lots of them. One of them, of course, has been the fact that most of the people who are providers are not trained to do best case series, and though they can go to Jeff White and then go online and he will help them develop one and he'll actually walk them through it -- he'll show them the guidelines; he'll provide support and so on -- that's still a fair chunk of involvement or commitment that a provider has to make. And most people providing care are flat-out providing care. So they don't usually have the expertise. And then in terms of the resources and the time, many of them point out that this is pretty overwhelming. It's actually quite costly as well to develop a best case series. So this does involve quite a lot of work. In fact, as we're finding out, it involves a tremendous amount of work. So the recommendation was, therefore, to come to the Evidence-Based Practice Center and to have us develop a best-case series to become more proactive. And the reason that that was chosen is because RAND has developed a method for studying appropriateness, which is practice-based.

We do it for the last 20 or 30 years -- sometime in the '70s, anyway -- we produced a whole series of reports on the appropriateness of hysterectomies, of CABG bypass surgery, and we have used this method, in fact, for studying CAM. And the one we had one was a chiropractic study, which some of you may know we published in the Annals of Internal Medicine, looking at the appropriateness of manipulation for low back pain. So we had adapted this method already to a CAM-based project, and we used it quite successfully, and we demonstrated that you can actually go into the practice and you can do it. In this case, we chose five sites throughout the United States and Canada. We chose 25 practices, and we did a random selection of files, and then we had a set of standards by which we could judge the appropriateness of whether the manipulation should have been given or not given, or we've also judged where it should have been given and wasn't given. So we had done this before, and I had made the proposal to CAPCAM that this may be a method that could be adapted to this case series. And the reason I suggested that is because it does involve the same kind of technical challenges where you're going into a practice -- now, in this case, we were randomly choosing the practitioners and we were randomly choosing the files, and so they weren't recommending the best cases; we were actually choosing them randomly. But it seemed to us that we could adapt this. The challenges, of course, are identifying providers that you may want to do this with. Recruitment quite clearly is a challenge. The office format, we've learned from the chiropractic one, varies considerably in CAM, from quite palatial, sort of run very much like a medical practice, to very, very modest and simple kinds of practices in the way in which files are organized are quite different and complicated. We actually came up with a very interesting way of getting -- we actually used a measuring tape to actually get random files. We actually considered the files as a book on a bookcase, and then we used a random generator to take the number of inches, and then to check for file bias, we'd take the one to the right. It sounds kind of complicated, but it works, actually, quite well, because the files are all over the place, and you don't know where they're going to be located. And then the files themselves are a bit challenging, because often they're not written up in the way that a standard medical file would be. And although we've had lots of experience with doing medical files -- for 20 or 30 years -- we had no experience at that time of doing CAM files. And then, of course, ----- the results can be a challenge as well. And last but not least, there's a large amount of politics involved in this, as there is in all CAM research. You have to build trust. The people that you're working with have to feel that you're not doing it for political reasons to hurt them in any way. And since there's a history in chiropractic of them being attacked in this way, it took us a while to get them to agree. And since we were going to publish the amount of inappropriate care they're giving, it takes a fair amount of professional courage to do that. And so far, not every profession has been willing to do that. If they were --

QUESTION: Could that be one of the reasons you're not getting people coming to the door, like Burzynsky, who got prosecuted?

DR. COULTER: We'll come back and talk about that if you want to save it till the end, because I think it's a good question, and I think it's probably one of the reasons. So the specific aims of this one then was to create a best case series for CAM providers treating cancer and to determine if there's sufficient evidence for further studies of these therapies. I guess the main thing we need to say is that in our best case series, the evidence doesn't have to be overwhelming; it has to be sufficient to suggest it's worthy of further investigation. So we're not looking for definitive evidence, but we're looking for best evidence if we can. In this case, the NCCAM identified the

CAM providers -- have identified two we've actually completed who were in the process of finishing them or that have actually done the practice part of two of them. The CAM providers are asked to identify their best cases. We visited the CAM providers, and we abstracted the patient files and the practice itself. And there are different levels of abstraction that we do. First of all, we do take the patient file and we abstract information from that. And then also, we are contacting mainstream medical providers for additional information from the patient's file, and then we also want confirmation -- particularly histological confirmation -- and so we are also abstracting information from pathologists and radiologists. So it's quite a rigorous kind of method. It involves identifying quite a lot of information and then going after it quite aggressively. The CAM provider identified the best cases. The theory was that they would do this before we turned up. As it's turned out in practice, we usually go there with myself, one nurse, and at least one medical physician -- in one clinic we had two. As it's turning out, as we sit in the clinic and go over it, we actually get into, really, a dialogue, and quite often now we guide them toward our better cases or best cases -- sometimes they give us a case they think's pretty good and we tell them why we don't think it is, and they say, "Oh, well, I know one you'll like." And so often this has become a joint discussion now about how we get their best cases. We have to de-identify all the files, which has proved out to be a bit of a problem, but has worked so successfully that I de-identified one group and then -- we are interviewing patients, which I'll tell you about in a minute -- and it turned out, one of these patients was a personal friend of mine in Australia. I didn't even know we'd looked at his file until he sent back a consent form that said I could interview him. So it works extremely successfully. This means you have to take the name off every single piece of paper in the files. On a path report, the name is on twice on every page, and you may have 10 pages. Every single one had to be de-identified. Then the provider has to contact the patients to see if they'll allow us to abstract the files, and then to see if it can be reviewed for inclusion. And then we look at the abstraction for data itself, and then where we've got permission, we actually copy the file and we bring it back to RAND. We also are doing a patient interview, and we're doing this for three reasons: One, to complete the health rated quality-of-life interview. You've heard the speakers all say this morning how important that is, and we are using standard measurement to do that. The second is to confirm the information in the file. As we found out very quickly, a lot of the information in the CAM file may not be accurate. And because we have to get the chronology of the disease and the significant events, particularly the confirmations, this turned out to be very important. And then when the record is incomplete, we also want to get permission to go to the mainstream provider and get the information. So we told you that. So this is the kind of thing that we really need to get from the mainstream providers, if you want to use that term, is we want histological confirmation; we want to be able to prove they did actually have the cancer. We want documentation or documentation of diagnosis. We want confirmation of the history of the cancer, if we can. We want documentation of the treatment, including the CAM treatment. And these are the kinds of inclusion criteria that we have for best case. It's pretty much the same as Jeff White would lay out; in fact, it's based on their criteria as well. We want histological confirmation. We want to have a starting point for CAM, if we can. We would like to have a period of exclusive treatment of CAM. I can tell you now, that's going to be happening very seldom. As most of you know in the room, if you read the literature, very few cancer patients use CAM exclusively. We certainly want documented CAM, and that has proved to be a little complicated, because in many of these cases, the medical part is very well documented but the other isn't. And we want to look at documented end point: Remission, tumor size, longevity. The first two are the ones that are the

most significant for NCI. Longevity has problems, and some of you will know about that. Well, why do we have to do so much with the patient consent? This turned out to be a major issue. The ball game has changed significantly for human protection, and so now -- it used to be that we could review medical files for research purposes without consent of the patient in most jurisdictions. It's not always true for CAM, by the way; I found one state where in chiropractic, that doesn't apply, so you would have to have patient consent. But in our case, the human subjects said we had to have consent to do this. So they had to give us consent to be in the best case series. They had to give us consent to be contacted by the research team. And they had to give consent to allow us to get their other medical records. This has really slowed the process down. As I told you, the de-identification is a major issue, because you have to go in before the study and de-identify all the files, all the ones that you think you're going to look at, and you've got to look at a lot more files than you're ever going to review, so it becomes very complex. I'm not arguing against that. It's very necessary, and it's good. I'm just telling you, it's problematic. So this is the abstraction. In terms of what we do, we document these kinds of things. I've sort of mentioned these, particularly documenting other sites. We're looking at metastases and so on. We want to look at the general medical condition, the treatment. I'm just going to show this very briefly. I'm going to flip through here. You've got it in the handout. This is what an abstraction form looks like. You can see, that gives us the criteria, and you can see the sorts of stuff we're asking. We look at ----- malignancies. We're looking at family history. And so we're collecting quite a lot of information. The two that we've done are IAT, Immune Augmented Therapy, which is down in the Bahamas. I won't go into the theory here. I put it on the handout. You can see it. It will explain what the theory is behind this. I won't make any comment on the theory. But it does have a strongly based theory, and as some of you know, it's been around for quite a long time. It's been through periods of incredible controversy. There's been a lot of sort of history with this one. There have been previous studies done on it. Clemin Burton (phonetic) had that. She published one on one type of cancer treated, then there was a survey of patients that looked at quality of life. There was a previous best-case series done by the National Foundation of Alternative Medicine on this group. This is the number of cases they did. We're doing it slightly different, and we're going for more confirmation and a lot of things that they didn't. The second one we're looking at naltrexone (phonetic), which, again, some of you may know about. It's an opiate antagonist that was used for treating heroine addiction. It has been used to treat a person with HIV and AIDS. It's also thought to cause cell death and tumor regression in some circumstances, according to people that support it, and theory is that low dose naltrexone raises levels of beta endorphins and facilitates immune function. So those are the two clinics we've done. So let me just conclude. One of the problems -- well, the problem of obtaining good cases is very challenging, and you go through a lot of cases to get good ones. And the problem is -- you probably all in this room know what the problem is -- people use so many things when they're using CAM; when people get sick with cancer, they tend to throw everything at it, so it's going to be very difficult to sort out what may look like a very good result; it's going to be difficult to know what it is. And then a lot of these people have exhausted -- gone right through conventional therapy and they have debulking, they would have had radiation, they would have had chemotherapy before they start on CAM. And so therefore, you don't know whether it's residual, effective, or what that does it rather than the CAM. So we all know the problems. But the truth is, you can get some cases with enough promise, I think, to warrant at least investigation. That's all we're trying to do. The problem of the end points is considerable. For the patients in the clinic, longevity is the end point. For hard-nosed researchers, it's tumor response,

and we all know what the issue is there. It's costly, and it involves a tremendous amount of effort. We have a team of about seven, eight people work on this, and so it's not easy to do. And then the other complication is the human subject protection, which has created a new kind of environment, which I think is a very necessary one, so I'm not complaining about that. I'm just telling you that it is problematic. Thank you.

DR. RICHARDSON: Thank you, Ian. Let's go ahead and take about 8 minutes for the questions while it's fresh, because I think we'll lose if we wait to ask questions at the end. So anybody have any questions for Ian at this point?

DR. COULTER: Can I have your question?

QUESTION: Do you have the citation from the Annals of Internal Medicine on the low back pain?

DR. COULTER: No, but if you give me a card, I will send it to you. And just write on the back of the card what you asked me to do, and I will send it to you.

QUESTION: ----- as far as practitioners coming forth, because of fear of prosecution or their being -- sort of licensure or that kind of thing in sort of providing ----- cancer care.

DR. COULTER: The question was whether maybe providers aren't coming forward to CAPCAM because of fear of one sort or another, and some you talked about -- maybe the fear of prosecution; the other might be just fear of how they may be treated. Is that reasonable?

QUESTION: Yes, sir.

DR. COULTER: Well, yeah. I mean, I'm a sociologist, so sociologists, we don't ever pretend that research is not political. It's all political, and cancer research is no exception to that. And anyone who says that this is independent is either naive or a fool, as far as I'm concerned. So this doesn't surprise us, and in my experience -- I've been doing research on chiropractors for about 25 years, and I can show you examples in chiropractic where studies were done deliberately to hurt them. And that's documented; it's in the Wilkes trial; it was in the courts now. So we know that this is the case. And so when I first started working with them, and it was a sociologist in one case that did it, they had really good reason to be fearful. And so I think -- so if I -- now, because they've known me over many years, they will now allow me to do all kinds of research on them, and they have, and particularly critical research like the programs of the care, which is the ultimate stem. So I think you have to build trust, and while I don't know the answer to your question, I'd be staggered if it wasn't part of it. I think the CAM community -- I mean, you just saw today, you know, going from a committee on quackery to a committee on integrative medicine, you know? That's a pretty short history. And I think people's memories are a bit longer than that. So there are a lot of people out there that have seen themselves attacked and called quacks and so on. So I think that may be part of the problem. It's not the only issue. I think the other issue, though, is just the magnitude of the task that overwhelms them.

QUESTION: Can you say anything further about your naltrexone research? Did you state that more data may be available?

DR. COULTER: These two projects at these two sites, we've just about completed the interviews. We're about three away from one of them. And I'm not sure how much on the naltrexone, but it's about the same. And then we're waiting for the confirmation. I told you, we're going to other providers. So my guess is that we will probably report to CAPCAM sometime in February. Now, the way this works, we have to report to AHIQ first, and we're not allowed to release results under these evidence-based practice standards. They send it to experts, and then there's a panel of reviewers, and so it's a quite involved process. My guess is that publicly, about sometime next year -- it usually takes -- the one I just told you that came out on mind-body, this is a 3-year contract, and we did that in year one, and we're just starting year three. So it's taken a whole year from the time we finished the study, went through the review, wrote it up, had AHIQ sign off on it, to its actually being published. So usually about a year. So my guess is, some time at the end of next year it would be public. And the stuff from RAND is always in the public realm. We don't do research that doesn't go into the public realm. Well, at least in the health field. In the military site, then we may do something. But otherwise we don't.

QUESTION: Thank you.

QUESTION: What are the criteria you use to ----- direction concerning some therapy? Is it one case or two or -- how do you sort out the wheat from the chaff?

DR. COULTER: There are two questions there. One is about how we choose the clinic? Is that what you're asking me?

QUESTION: Well, how you review these records.

DR. COULTER: Oh, okay.

QUESTION: ----- review the records. Where do you say, aha, there's something really worth looking at here? Is it one case, two cases, or multiple, repetitive instances of apparent response?

DR. COULTER: There's no real number. But in CAPCAM, usually if there are three very convincing cases, three to five, roughly -- and it's very roughly -- but usually what we try to do is get them to present around 20, if we can, but we've never come across one with 20 yet. So usually about -- if there are three -- and one of the very convincing would be, if the oncologist is certainly saying, well, I don't know what happened here, quite clearly the person had it, there's very good pathological diagnosis here, we know -- we can see that they had the conventional, there's no response, they still had the mass, and, wow, they go after this and 3 months later, it's completely clear -- I mean, that would be spectacular. It's very seldom that's going to happen. But on the other hand, what we try to do when we're looking at it is, we try to tell the provider what the hard-nosed criteria will be, and tumor response will be one of them, a big one, right? And then what we try to do in our mind is, we have those criteria I showed you, but also try to think, since I sit on CAPCAM, what is it that's got to move CAPCAM? Is this a case that will be

considered sufficiently indicative of further interest? And that's the criteria. QUESTION: Did you say in every case, you have a random selection of files?

DR. COULTER: Not in this case, because in a best-case series, you're asking them to give you a best case. In the chiropractor one, yes, that's a random selection of files.

QUESTION: Why did you send it off that way?

DR. COULTER: For the chiropractor one?

QUESTION: Yes. Why would you do random files even for the chiropractor one?

DR. COULTER: Well, one, because we wanted to get both a numerator and denominator for the amount of manipulation being done, and what proportion was actually being done for low back pain. I want to generalize the American population. Without taking random stacks of files, I can't do that. So it's just a straight mythological one. And we also want a random selection of providers, too. In that one, we didn't want them choosing the providers and we didn't want them choosing the files. This one is totally reverse.

DR. RICHARDSON: Okay, we'll come back and have questions at the end. Let me introduce our next speaker. As you heard from me, and now you understand why this best case is so complicated and it's been so difficult for practitioners, so I think it's great that we have this group to help. Our next speaker is Kevin Chen, Dr. Kevin Chen, assistant professor of psychiatry at the New Jersey Medical School. He has a doctorate in social psychology and statistics. And his focus has been on methodology and epidemiology of substance abuse. But he's also very interested in medical application of Qigong and these energy therapies, which is fascinating to us. He is currently working on an NIH grant to study the delay of gratification in substance use and abuse dependence, as well as several other Qigong techniques. He is actually one of the few scientists that are applying rigorous standards to evaluate this particular energy therapy. And so we look forward to hearing about your results and your research.

DR. CHEN: Thank you.

DR. RICHARDSON: Thank you.

DR. CHEN: Well, as you see in my background, the first question you may ask is, what is a social psychologist doing here with cancer care? And I have you a background of the background about how I got here, because this cause of mine ----- sitting here. And a few years ago, I read a report from the Chinese Society of Qigong Science. I was really amazed, how could that happen? What happened is that Chinese Qigong Social Science is the highest administrative organization in China to administer Qigong research and promotion. So they gave a report, say what we did is something very unprecedented in the history. They found that some people who practice Qigong completely recovered from their later-stage cancer. Some people may think it's kind of impossible, Qigong for exercise. ----- for your health. But these exercise, for cure this disease, cancer. Unimaginable. So actually in writing to just ----- go to Beijing to have it -- you know, 23 very later-stage cancer patients. They don't have much hope for conventional

therapy. This is a -----, anyway. So they gave him 23 patients and said, go with your method and see what you can do with it. So that 23 patients were isolated in one area in Beijing. They moved all the equipment -- you know, this ultrasound, MRI -- to check up with them, before and after. She had 21 days to show a result. So during that 21 days, she used this method; actually, she does not call it Qigong. She called it ----- self-recovery system. It's beyond -- she has a Qigong accent, because they have psychotherapy, they have a strong ----- mass tumor; they have all this -----, you know, fasting during this period. So at the end of 21 days, they checked out these patients, 23 very later-stage cancer patient, and 2 of them cancer-free. All of them, their cancer mark or tumor size reduced 50 percent or more. So that is, according to international criterion, or -- 100 percent effective. So rather than report it, I feel this is too good to be true. How could this happen? I lost so many friends, so many family to cancer, and they all had a combination of therapy, having nothing that cure, and these last your life longer for middle-stage cancer. So this is what has led me, a social psychologist, into cancer research, because if you --- -- what I'm going to talk, I'm going to give you some background of the background. So in case you feel ----- medicine is, so you may, ----- I hope through my unprofessional research to needing more professional research into this field to start understanding what is going on with this process, what is going on with this method. So basically, I've been doing a presentation on the format, because of his research -- he does not speak English, and I participate in the research process, so I'm presenting for him so we can save some time and present more data. So the first question you ask, what is Qigong? Some of you have heard of Qigong and pronounced it very well. So Qigong is a very ----- . There is no good definition about Qigong. You open a book, there is no definition about what is Qigong. So basically Qigong is a very general term to summarize ----- traditional Chinese exercise and therapies. So if you ask a master, he will tell you, I teach Chinese ----- Qigong medicine, the specific form he was performing, he was teaching. So he does a thousand ----- in China. But basically they all have something in common. It's a self-training process, and it's through your both mind -- both your Qi ----- of the body -- and the Yi -- that's your mind, your consciousness. So this kind of combination could reach the optimum state of both mind and body. So it's not just treating an ----- disease. It also works a lot of things in your mind and your consciousness. So I don't want to get too much into this. I just want to say that the ----- itself, you're going to see a lot of definitions if you go to the field, so people do not agree with each of them about what is Qigong, but there is something called Qigong in China has been -- for a thousand years' history, and has been used by many people in a very private or sacred way, not in public, but not in the mass teaching that we are doing today. So in China, we have many people practicing Qigong since 1980s. So there are many reports about cancer patients, actually, you know, recovering out of the practice of Qigong. But we do have many Qigong ----- who actually openly tell their students, "If you have later-stage cancer, don't come in to me." They do not want them dying in their training center. So what happens is, there's two Qigongs have spun out. One is called Gou-Lin Qigong. This one still teaching, I believe, in the United States, too. Gou Lin Qigong in the 1980s -- ----- is a lady. She survived later-stage cancer. She used this method and started teaching people. She called it new Qigong. So she stayed with a lot of people, and that's why she has been very popular where she has been studying in China. Another Qigong is -- well, I'm studying right now this master course, ----- Qigong, because since 1993 -- the story I'll tell you happened in 1993. Out of that, 23 patients being, you know, completely effective with only 3 weeks treatment -- training. So he was actually appointed as the director of a Chinese -- it's called a Qigong Anticancer Cancer Research Center. He's the director of our research center to systematically study what is going on

with the whole process. So he had hoped about 5,000-plus students with you know later-stage cancer would come therefor training and had a very impressive effective rate. So those kinds of cancer patients practice Qigong ----- a patient. I mean, as you may know, the first thing they might say is, how much psychological effect is there? So we try to get rid of those. We have this common sense that this must be possible, because, you know, this is complete remission without treatment, about 5 to 10 percent of ----- doing that. But we're talking about 100 percent. So we know that it's now completely possible. So we want to see whether we can do it in a scientific way. So I did some review in the Chinese literature. So ----- there's a clinical study. Most of it is observational, not very controlled, not proper planned, just what I described with you, like 23 patients, they just observed them and check it before and after. So this is now commencing now, because we don't know -what in the process how much is due to just the intent to be treated, how much is due to ----- himself. But the reality is there. If you open a Chinese magazine, the Qigong magazine, which you see many, many cases reported, or you -- observation reported. Even in the hospital we have a -- we have one hospital reported a thousand cases have now been followed up, having great improvement. But it's not very systematic. So most clinical study on Qigong is a combination of Qigong therapy with other Chinese herbs or acupuncture or combination therapy. The only one using Qigong alone is master ----- Qigong. Nothing else except the Qigong itself. ----- is encouraged in the patient. You use Qigong and a combination of therapies, radiotherapy and chemotherapy. So as a Chinese ----- the disease, we save a lot of people now -- the scientists are not allowing them. So those patients used chemotherapy and radiotherapy ----- Qigong separate. But most ----- Qigong when we presented to a scientist. They said, with your comments, we should look into that. So that's the basic clinical consideration is, most Qigong research has been combined with other therapies, -----, but now they're very convinced. Now they're very convinced. So now I also see some literature on individual study of ----- Qigong. What it is is, the original study is ----- Qigong is ----- master who can ----- to the patient or the subject to actually eliminate the tumor group or cancer group. So this area -- since you all have my abstract, I'm not going to talk too much, because this is not my research; I'm going to summarize -- there is not a ----- in the Chinese publication in this area. ----- individual and ----- study ----- is in there. So I want to talk ----- my study, so you can ask me questions, and ask ----- question. So we ----- study we did it so far. One, it's -----, because we think this is something psychological. So what ----- animal? We do a lot of ----- humans to start with. We know that human ----- . If you're interested in the case, I offer ----- . You're free to take a case with you. So what is this Qi, the concept of Qi exists in many cultures, but have not gotten a good understanding by the scientists, because we couldn't use our five senses to measure it, to feel it, so ----- didn't feel well. We see the signal, but we don't know what exactly that is. Actually, I just finished a review of what has been done in absolute Qi measurement. ----- it can be ----- infrared, gamma ray, you know, magnetic field, and ----- signals. But it's not a Qi. In a sense, it may be the carrier for the Qi. So we're trying to understand the phenomena. So this first study is a mice study. It's a nude mice injected with hepatic cancer, then exposed to the Qi, about 10 minutes each treatment. That means that master will use his hands and, you know, shrink the tumor or ----- --. And that's one group. And then another group will have somebody who does not know how to transfer Qi at all, also get a ----- just doing the same thing. Of course, she doesn't know what to do. She just, you know, put hands, she isn't doing any treatment. And the third group is no treatment. So this three treatments, 10-minute treatment. Every other day, there is a fourth treatments, 40 minutes in total, is close to this, while we do not what exactly is a Qi. Because Qi had both this physical Qi and the mind the Yi powers

it -- remember the definition about a Qi? So the result we had is here, and ----- you have in your package. So I'm going to show you the picture. It is more dramatic. So after the 40 minutes exposed to the Qi, and within 32 hours, we sacrificed the mice, get out a tumor, and measure the size and weigh them, how big it is. So this is the actual picture of the site. So this is 30 mice. In each one of them, there are 30 mice. The first one is the control group, no treatment at all; the second mice is the sham treatment, without Qigong training. The ----- is the Qigong master -----, and 40 minutes -----, the tumor was 70 to 79 percent smaller than the other two groups. And this study, we repeated three times. Exactly the same ----- one problem ----- with Qigong master, it is very hard to repeat, because sometimes we cannot do it the same way as we did it before. ----- some subjective status.

QUESTION: How long?

DR. COULTER: Is supposed to treat?

QUESTION: No, how long do you ----- the tumor ----- mice, right?

DR. CHEN: How long? About 48 hours before the first treatment. So now, that's 2 days after we inject the tumor -- 2 days later, you start doing the Qi treatment every other day -- that's 7 days. So ----- stop one day, one day, stop ----- every other day for 10 minutes treatment. So that is 7 more days. So next -- you know, from 10 to 12 days, we start sacrificing mice.

QUESTION: Ten to 12 days, you will kill mice, right?

DR. CHEN: Yes, ----- . That's the size. Yes, this is a hepatic cancer. Yes. That tumor size, yes.

QUESTION: -----

DR. CHEN: I believe, yes. Of the skin, yeah.

QUESTION: Two weeks -----?

DR. CHEN: Two weeks, that site, yes. It's a very fatal cancer, an evil cancer, yes. ----- . So it's 10 to 12 days, each mice, after injection. So this is one study. So basically we ----- a very consistent, very impressive finding. ----- come to this country. We did some studies at ----- . What we did was, we tried to repeat what we did in China, so we had a cancer model, but there were so many repetition of ----- review, and he was here only a very short time, so we said, we're going to take how many and ----- what do we have? We have a new ----- doing for 20 years ----- . So we did same design 10 mice in each group, three groups, Qigong, sham, and the control. And the mice ----- Qigong 10 minutes every other day, three times or four times, except this time, we started before we injected the lymphoma we had one Qigong exposed -- we think it had preventive effects ----- . Anyway, we did a new extra, ----- we did an extra, and it was three -- four to five exposures to the Qigong, because we have ----- did it more than 30 mice. We did it 90 mice at once, so we could ----- -- in a very short time ----- the difference. So what we found out is, we had ----- three groups: control, Qigong, and sham. And you can see that the Qigong group is the lowest. And one of the -- this is lymph nodes and this is the spleen in order

to see how much it has been affected by the cancer and how much it grew so that the weight of the lymph nodes the number is over body weight. So there is a ratio. It's not an exercise, because the mice, the body is about the size of ----- . So the ratio is a more accurate estimate for the lymphatic group. ----- has been very, very big. Very very -- it dropped dramatically. The Qigong group is the lowest one, and also, the most other groups we achieved statistical significance; that is, the Qigong group also grew much smaller. But in the second study, when ----- for a second time ----- we tried to repeat. It was very exciting if we could have repeated it. But we do not repeat it -- ----- like the first time, but the pattern is still there. ----- Qi group was still the lowest of them. But for some reason, specifically, we got a bigger standard deviation, if you go over them, a bigger standard deviation it was not very well controlled in terms of injection. So that was ----- to some degree. But the size -- the effective size -- is almost the same. That's the Qigong effect group, having grew mice smaller after 40 to 80 minutes exposed to the Qi, because. (Tape interruption)

DR. CHEN: -- study in our university, it's the same study, but not to animal anymore, which -- you know, we killed too many mice. So this time we decided we were doing it in just breast cancer cell, because one of master's specialty is -- he has a tremendous power. We do not understand exactly what it is. And still ----- have a laboratory you're interested in, you have access to a patient. One day we're going to try. He can make the breast cancer shrink in a few minutes. Significantly shrink. In a few cases, I observed a patient with a 3-centimeter tumor completely disappear in a few minutes. So I don't know what's going on with this -- we don't understand what's going on. But he has this power. So we gave him a breast cancer. Breast cancer -- four people that have breast cancer, you know, patient BC-123, BC 125, BC-HT-20, and BC-T47D, four people who have breast cancer. And we asked him, administer Qi for 10 minutes, and then we put in a cultivation area to cultivate it for 16 hours. This study was designed for four groups, not three groups anymore, because in our control group, it's ----- an incubator. So you just leave it in there, don't touch it at all, and then ones through at room temperature; one with Qi master for doing treatment, and one group must ----- administer Qi for 10 minutes. So after 10 minutes, what did we get? We got after 10 minutes exposed to Qi, and we have cultivated it for 60 hours, and then try to the breast cancer group, measure what's the growth rate. So what we found out is that this is -- this is not very technical. I mean, even my colleague ----- research -- what we found out is that the Qigong group is the lowest one. The group is lowest. So this is one of the ----- we repeated it twice. Trial 1, trial 2, 10 minutes. We tried to have ----- reliability in there. So we -- basically both times we repeat ----- see that the tumor hardly grew at all, because it's not a cancer, and that environment is just similar to the other group. But the ----- including Qi group, the ----- group, but the Qi group grew ----- -- it's the lowest. So on the graph, you can see very clearly. So there's something there, and there's something there we do not understand. If it eliminated the tumor group. So what do these have to do with the cancer, with our understanding patients? Because when the patient practices Qigong, the Qi flows in her body. The thing ----- she will master. Maybe the strong ----- is different. But theoretically, according to traditional Chinese medicine, it's the same ----- image ----- body. We do Qigong ----- acupuncture ----- . Stimulate the Qi flow that's the same theory behind the Chinese medicine. So here we have the implication about this kind of animal or culture cell research is maybe just something that we do not understand. Besides, we're now at this moment, in science, something ----- your own body has inhibited -- inhibitory ability for cancer. So basically, one of the first ----- I did is, there is many evidence and very consistent finding about

the inhibitory effect of Qigong from culture cell to animal to human study. I mean, it's very consistent. But not a many research has been really very well done. Not many research studies have been working in the field, because it's too efficient. It's too good to be true. It's just -- if you don't it yourself, you just -- you won't believe it. But that's it. How could it happen? We're fighting cancer for 50 years with a formula-----, but how could the human body ----- cure it? So that's the part that we've really been bothered. So I hope, you know, my presentation will bring people interested in this to come into this area and start looking into this, and maybe with your expertise -- not just a social psychologist -- with your expertise, you will do better studies. So certain things about the implication I would mention is that, if we prove ----- Qi had an effect, So we should promote more Qigong exercise for the patient, so at least they will participate in the process, in the healing process. That is ----- itself. That is ----- itself. Of course, don't mention we have this healing result. So my suggestion is that we should encourage people to find a good Qigong master, good Qigong form. Just to practice. And this way, there's also no side effects, right? -----, oh, I did this because I practice Qigong, I ----- there are no side effects, and that's one of the advantages of this practice. And it's very easy to learn. Everybody can learn this. ----- form, he could teach it in a lunchtime, if you're interested in it ----- . You know, it's very simple. There not much movement at all. It's not like you see in the Tai Chi, there are so many movements. It's basically meditation. But it's a very powerful meditation. -----, one day start diarrhea, because it detoxes the patient -- a detox process. A patient start practicing in force, they use the Koran, ----- they're relieved from that emotional depress. So this is a very powerful meditation. And also, it is very safe and reliable. You basically do not have a misdiagnosis or mistreatment, because you do not have to worry about what cancer it is. The Qigong was not created for cancer. It's a holistic ----- the whole body ----- . They did not create it for cancer. So you do not have the ----- practice; you do not have the mistreatment or misdiagnosis in there, because they don't need to diagnose what cancer it is. And also, they break the mass. The later-stage cancer is incurable. We have seen many, many later-stage cancer patients recovering with Qigong practice. So that will give patients a hope. Okay, according to American statistics, they have 30 percent chance to survive. Okay, but here, I have maybe a better chance. I may improve to 50, to 60 percent with Qigong practice. So that is the kind of message I say we're sending to the patient. And also, there's a holistic way to ----- with them, the whole body. So most of all, cancer students, when they practice Qigong, they get a kind of ----- . And the other quality that it is, diabetes, heart disease, liver disease, all disappear at the same time. So it's, in a real sense, recovery, not just treating one symptom at once. And also, ----- one is a completely new direction for future medicine. That means, actually, we're talking about self-healing here. We're talking about drug-free here. So I don't know how much we're having discussions of side effects of a pharmaceutical drug. Hey, we have an alternative here. It's free of side effects; there's something don't have side effects. So I think this maybe is the future of future medicine. I will stop here. Thank you.

DR. RICHARDSON: Thank you, Dr. Chen. (Applause) As we're setting up with this last presentation on the NCCAM research, do we have a few questions for Dr. Chen?

QUESTION: Yes, I've heard a lot about QL (?) Qigong. Is this different or the same --

DR. CHEN: It's different. QL (?) Qigong is more introductory, because there is not a movement. You cannot ----- . For introduction, Qigong is good, because you have a movement ----- . But

once you get into the introductory stage, if you want to get it -- really talking to your tumor, you want a meditative state to talk to your tumor. We are teaching our students how to communicate with their tumor. By the way, actually, I work with ----- Institute for Self-Healing. We're teaching this form in New Jersey, and we also work in Washington, D.C., too. We're going to have one week of training for next week from Monday, and if you're interested in ----- or you have a patient who is looking for an alternative, this is maybe something to look into -----.

DR. RICHARDSON: Any more questions?

DR. CHEN: Any more questions?

QUESTION: Another one. How does it compare to Tai Chi?

DR. CHEN: Tai Chi is not Qigong. Tai Chi is more like a ----- movement. ----- you do it automatically ----- . Yes?

QUESTION: ----- studies, did you have histological confirmation of the tumor --

DR. CHEN: Yes, some of them, I do have -- yes, we have all the pathological studies and ----- autopsies and biopsies done ----- . Some of them have very good ----- . But it's very hard to pull a case together -- what Jeffrey said, it's very hard to pull a case together.

DR. RICHARDSON: Thank you. Thank you, Dr. Chen. This is so fascinating to hear from practitioners in the energy medicine. It's so interesting. I mean, you don't want to talk about randomized control trials when you hear about this, but we're going to -- briefly, briefly. What I want to do is just present a very broad of what sort of research we're funding at NCCAM, the National Center now, in the oncology portfolio, for a couple of reasons: Number one, so you know what we're doing; and number two, to give you ideas, because we're certainly looking for investigator-initiated grant applications because we want to fund research in this area. Our strategic areas of focus are, of course, to invest in research, and second, to train investigators. We want to train conventional as well as CAM practitioners, expand our outreach, and facilitate integration. In other words, these therapies that are effective, we want to see that they're integrated into conventional oncology. Very briefly, the broad areas that we categorize these modalities are biologic-based -- that includes a pharmacologic and nutritional and herbal; mind-body therapies; energy therapies; manipulative body-based; and then therapeutic systems. This is just a reflection of our funding, showing how we've escalated since '92, when we were OAM, '98 to NCCAM, and we're up to 89 million. And projected with the President's budget -- before September 11th, anyway -- it was 100 million. So we'll see what happens. Now, what we've seen with the research in this area -- we jump from these anecdotal experiences, like the energy medicine in some of the cases that Ian presented, these case reports, these historical reports, and we try to jump from those, from following the standard development in clinical research, from these pre-clinical all the way to these Phase III trials. And with the Phase III trials, we risk having inadequately characterized products, as well as inadequately characterized interventions and dose. So we need to fill in the gap with some of these Phase I, II -- in other words, looking at dosing administration, those sorts of things. And that's why we've funded these botanical centers and these P50 centers across the country to do this pretesting. And this is just a snapshot. The red

reflects our centers. We have two cancer centers, one at Hopkins and one at the University of Pennsylvania. And the four stars reflect our four botanical centers across the country. I said we have two centers in cancer. I'm just going to go briefly so I can talk about the research. The botanical centers are identifying botanicals, assessing bioavailability, looking at mechanisms of action. And they're doing a number of clinical projects. As you can see, Purdue is looking at polyphenols; University of Illinois is focused on women's health with herbal supplements; the University of Arizona is doing studies of ayurvedic therapies; and the University of California is evaluating green pea, St. John's wort, some yeast-fermented rice products. And these are resource centers for us to draw and -- because we need to build collaborations. Now, the oncology portfolio at NCCAM, currently we have 51 studies that are funded. And if you look at this, the green bar is the clinical and the yellow bar is the preclinical. And across the bottom row, it shows what system we're looking at, and you see most of them are in the biologic area. And they're fairly equally divided between clinical and preclinical. Now, in that biologic area, they are also pretty much equally divided between herbal therapies and pharmacologic therapies as well. The alternative systems -- we're funding naturopathy at TCM; homeopathy; manipulation; we're funding a couple of massage approaches; energy therapies -- we're now funding, I think, three acupuncture studies and one -- no, sorry, two acupuncture studies and also a study of distant healing -- again, getting to the energy -- distant healing approaches and prayer; and then the mind-body range of approaches, with imagery, relaxation, those kinds of things. We also put our music in there. I don't know if that's the right place to put it or not. We have a music therapist here. To talk about some of the projects themselves, our NCCAM-funded center at Johns Hopkins, who we have a representative from -- Rachel's here -- their focus is on immune surveillance, which is really critical for the alternative approaches, and one of the studies they're doing is a randomized Phase II trial of PC-SPES, and I'm sure you're familiar with this, an eight-arm formula, widely used. **(WARNING: Recent developments on PC-SPES have shown it to contain estrogens and other non-herbal remedies, which have the potential to be dangerous. This info was not known at the time of this conference. When reading about PC-SPES, keep this information in mind. For more information, see the [Washington Post Article from September 5th, 2004](#)[may require registration].)** They're looking at tart cherry and soy in a rodent model for reducing pain. And the other, third, very interesting clinical study is prayer in African-American women who have breast cancer. So I just want to talk briefly about this PC-SPES herbal study, because we really see this as one of the prototypes of how we're going to evaluate these herbal complex mixtures. This has eight herbs in it -- chrysanthemum, licorice, ginseng, saw palmetto, skull cap -- and actually, Sophie Chen is going to be here and talk about her research. She developed this. It's used widely for advanced prostate cancer. There have been a number of Phase I and II trials showing that it is effective; it causes dramatic drops in PSA, reduces pain, improves quality of life. It does have similar side effects as you would see with the estrogen therapies among men. But the Hopkins study will be conducting a double-blind, placebo-controlled trial comparing PC-SPES versus DES and estrogen therapy. Three groups of men -- they'll either get the PC-SPES or the placebo DES, the DES, or placebo PC-SPES, or they'll get neither treatment. I think this is right. Am I right, Rachael? And they have an arm in Singapore that's going to recruit a subset of patients to be able to look at the differences in diet, because we know the Asian diet is very different. Another study that we've just funded, a basic science study with the PC-SPES at the University of Oregon, is going to be looking at the androgen and anti-androgen effects of this product, applying a lot of the basic science, because in some of his preliminary work, he showed that there's been reduced prostate weight and testosterone levels with the PC-SPES administration. So his objective, as you can see, is looking at the time and the dose-dependent effects of the SPES,

and he also looked at the interaction with this androgen-signaling pathway, and he's going to correlate that with markers. And finally he's going to look for interactions, because we're becoming very concerned about the possible drug/herb interaction. So he's going to be evaluating the effect of PC-SPES on this P450 metabolism pathway. He's just started. Now, another popular herbal product that's widely used by the cancer patients is this noni juice. Have you heard of this one? Very popular. It comes from this; this is the plant, and it grows these seeds, and they harvest these berries, and they extract it and compress it and make juices. And so many patients use this. It's one of the five most common approaches used in the Pacific Islands, along with aloe and some other herbs. They have identified some novel glycosides in it, trisaccharides, and it has been shown to have some anti-tumor activity in some animal models. So it looked promising. Patients are using it like crazy. And so Brian Issel stepped up, who is an oncologist at the Cancer Center at the University of Hawaii, and he's proposing a Phase I study -- remember, I talked about it in the drug development? We need to fill in the intermediate areas with the Phase I, II. So he's going to conduct a Phase I trial with the freeze-dried fruit extract, and these patients will be noncurable cancer patients with a life expectancy of at least 6 months, no prior treatment within 4 weeks, and he's looking at the maximum tolerated dose, standard drug development toxicity, as well as anti-tumor effect and symptom control. And he's also going to be applying all these pharmacokinetic studies as well to look at how this is absorbed in the body, eliminated, excreted, metabolized, and those sorts of things, the kinds of things we need if we want to move forward. This is just a list, and I'm going to move quickly. This is just a list of some of the things we're funding, and you can read these: Antioxidant; angiogenesis of green tea; we're looking at plant estrogens and their possible contraindications with breast cancer; in vitro skull cap for skin cancer; burbeen (phonetic), an extract for glioma cells; ginkgo biloba -- actually, someone at George Washington University is doing a study with ginkgo biloba for brain cancers; and then angiogenesis inhibitors with shark cartilage. A couple of studies -- I said we were funding some massage, and this is a massage study at the University of California at San Francisco. Again, fatigue is a big problem, as you know, in cancer, and so they will be randomizing patients to receive six massages or sham treatment or usual care, looking at quality of life and fatigue. We just funded about nine studies, just in September, for patients at the end of life for cancer. And this is one of the studies that has been funded, and it's being conducted at the Dana Faber Cancer Center, and Dave Rosenthal, I think, gave your plenary talk. Anyway, Dave has proposed this, and wrote a very good application -- acupuncture for pain, nausea, quality of life as palliative care. And he will take ovarian patients, advanced ovarian cancer patients, and assign them to acupuncture. They will all get the acupuncture, and he will look at the pre-test scores and the post-test scores. So it won't be a randomized controlled trial, but it will be a pre-post design. They will get acupuncture twice a week for 4 weeks and then once a week for the following 4 weeks, and then he will follow these patients up for 12 weeks. We have a couple of acupuncture studies -- again, soy isoflavones. At Stanford, they're going to be evaluating those with prostate patients. Soy phytoestrogens is -- this is an animal study with monkeys, and they're looking at the possible interactions of soy phytoestrogens with hormone replacement therapies. And these are all critical issues for women. You might have heard about the complex nutritional regimen. This is something that came along the best-case series route. It took about 10 years, but it came along, and he presented his best case -- he's Nick Gonzalez, who will be presenting here -- presented his best cases to the NCI, and the NCI said we should look at this further, and he conducted a pilot study, treated 10 patients prospectively with his complex nutritional regime, which is lots of pancreatic enzymes, the mainstay nutritional supplements, and the controversial

coffee enemas daily. So we're actually funding a study at Columbia Presbyterian. Karen Atman's (phonetic) group is conducting the study. We had a couple of studies of shark cartilage, again, because they are so widely used and so popular, we felt we had to invest in a definitive study of that. This large placebo-controlled Phase III trial is being conducted through the CCOP (phonetic) group at the N.D. Anderson Cancer Center, randomizing patients with non-small-cell lung cancer. We're receiving this frozen liquid extract shark cartilage, or a placebo, again looking at it for the hard outcomes, survival, quality of life, and this is ongoing. As you know, there are many shark cartilage products, and so the other very popular product that's available over the market -- now, the frozen liquid extract is not. But this product is available over the market, and it's going to be studied, again in a placebo-controlled fashion, a Phase III trial, through the Mayo Clinic, with a different population: colorectal patients and breast patients, around 600 advanced cancer patients. Again, placebo-controlled, and they'll look at the hard outcomes: Quality of life, survival, toxicity. I just want to mention in closing that we're very interested in the topic of antioxidants with comparing chemotherapy and radiotherapy, and hope to organize a state-of-the-science workshop on that next year. And I think I'm going to close there and open it up so we can have some more time for questions. Key principles of CAM research, you would know, are standard. And setting priorities: We want to look for credible preliminary data, simple study designs, how can we move the science forward and address issues of the patients. And those are really our primary areas of interest. This is our website. It's one of the best websites in 2000. It probably will be again this year. So anyway, that's it, and I'll be here to answer questions if you have any questions.

DR. COULTER: I was supposed to make some comments here, but if you have questions, I'd prefer to listen to you than to listen to me, but -- I guess my comment would be, then, just looking at what's happening, is that, for me anyway -- and I've been doing research in CAM for about 30 years now, and in fact, like everyone else I have a story to tell. I was at the faculty of medicine, University of Toronto, where some colleagues told me we would not be permitted to do any research on chiropractic; that it was beyond the realm of serious investigation, which for a sociologist was a strange experience, because there's nothing in society that's beyond the realm of sociology. So I would tell you, my comment would be that what's encouraging for someone like me is to see the incredible diversity and approaches to investigating CAM. And I'll always remember the article -- Weinberg in *Academic Medicine* in '94 published a very interesting article looking about the problems of focusing research, and he actually talked about breast cancer and our understanding of the role that cells and proteins in cells play within breast cancer. And he pointed out at that time that if you look at the major breakthroughs in breast cancer, some of the work had come from the brains of rats, some had come from the vulva of worms, the retina of the fruit fly had, again, given a major insight, and the last part was actually a virus and warts on the backs of cows. And his kind of argument was that if we get obsessed about focusing research, you know, we would have missed most of that. So it's going to be someone pumping away in some field that doesn't even look highly relevant to cancer at all that may actually make the breakthrough in cell research. So I think if you look at what's happened in this session, and particularly if you look at the sort of range of things that are being supported, for me it's very encouraging, because on the one hand, we're trying to do this messy kind of best-case series; on the other, we're taking things like Qigong and actually trying to put it into a laboratory setting, and then we're trying to move to Phase III cancer trials. All of it's important. What we need, of

course, is to encourage more people doing it, and of course to get more funds. So thank you for attending. If there are any other questions -- and there are. The gentleman in the back first?

QUESTION: -----.

DR. COULTER: I think you raised a really good issue, and it's one that concerns me greatly, because I'm in an evidence-based practice center, and most of the thrust of evidence base is efficacy. So if you look at the systemic reviews, we're looking for efficacy. I just published an article in Dentistry that makes a claim that I don't think you can do evidence-based practice without effectiveness studies. So I think there has to be a move to looking at -- I mean, it's sort of a two-prong approach. On the one hand, efficacy will be sort of reductionistic. I mean, that's for sure. We want to know exactly what it is about shark cartilage that works, and if we could reproduce that, and because you have problems getting the dosage correct and constant and so on, then we'll be way advanced on that. So that's efficacy. You need to do that. On the other hand, if we take, say, the best-case series, we're practitioners actually combining a whole bunch of things, but seem to get the patients well, then I think we need to be funding that kind of research as well. So I think a lot more effort and focus now needs to be on effectiveness and looking at real-life practices and saying, what people are getting results with patients? And out of that, for me, anyway, that would set a priority of what we may actually pursue in terms of efficacy.

DR. RICHARDSON: I would just add that I totally agree with that. And one of the things that we have done to try to address the practice-based approach is, we have funded research in integrative medicine, in looking at the barriers and the facilitators of that. And at the same time, they'll be looking at effectiveness of these practices to try to -- because clearly that's what we need to look at. But as Ian mentioned, I mean, you really need to show evidence. You have to show evidence, effectiveness of these approaches. And it's difficult when you have a whole group of things, and --

QUESTION: Just a corollary to Ray's excellent comments. My thoughts are that insurance coverage, legislation, policies can be driven by outcomes research, and outcomes research is eventually going to be practice-based. It seems to me that RAND or NCCAM can be instrumental in bringing together multi-center studies where we have small groups of patients, like he's got 10 Qigong patients here and you've got 10 in San Francisco or whatever. And is there that kind of thrust to pull together multi-center studies that really aren't going to require huge funding, because you're doing it in smaller groups, but people can participate in real-life situations? DR. COULTER: Tom has a really good point. I'll give you an illustration with the chiropractic research. The first piece of research we did in chiropractic at RAND was to do the systematic review, which we did -- made analysis on the manipulation of low back pain. Now, what did that do? Well, what it did was -- I hope, anyway -- establish once and for all that there's some efficacy for manipulation. So I mean, up until that point, there's this big debate -- is it useless, does it do anything? So now the next question is, okay, in whose hands is it more effective? So now you can go from there, saying, well, we've got reasonably -- and there are about 70 trials on manipulation now for low back pain, so it's quite -- when we did it it was 34, I think, but that's more than we had done on any other medical procedure at RAND at that time. So it was a pretty substantial body of literature. Not all great quality, but even if you look at the

best-case ones, it was pretty good. So now you want to go on and say, now we can do a ----- . In whose hands, for what kind of patient, for what kind of condition is it most effective? Now, it could be that a medical doctor manipulating may not get as good a result as a physical therapist versus a psychiatrist versus a chiropractor. Who knows? So now you get to what I think is the real interesting question, which is the heart of what you're asking -- is effectiveness, right? So that's an example where an efficacy kind of focus clears the deck for you to go ahead now and say, okay, it's worth putting the time and effort now to look at effectiveness. But if you had no efficacy, you probably are wasting your resources and may go down a lot of blind leads until get there. So I think that's one. The other one about, as I understand it, in the CAM community we have to move toward setting up practice-based networks, and NCCAM does fund one. They are establishing one on chiropractic, where they're trying to -- because there's not hospitals -- I say, you've got to set up a data collection system, which is ----- -- NTI has this beautiful structure, because when they want to do research they have these models of science, right, and they've got all these patients. Now, if you want to do NCAM, where do you go to get there?

DR. RICHARDSON: Right. Actually, we are hoping that the naturopathic community will come together so we can establish some of these centers. Is there a question?

QUESTION: Yes. A comment, actually. I've been observing outcome studies ----- psychology for quite some time. But I was encouraged yesterday by Dr. Tripathy's cross-over. The medical establishment tends to think that reductionistically and, necessarily, in terms of replication. But replication doesn't have to come first. Efficacy, as you say, can come first, and you can demonstrate efficacy from exceptional practitioners. In outcome studies in psychology, we've had some sort of a two-prong progress in our field, which is a little different than in medicine. In medicine, it's always efficacy and replicability, cash in hand. In interpersonal, less concrete, less materialistic interventions, it's possible to find exceptional practitioners. And you'll have no way of defining the mechanisms of their effectiveness, but you'll have indisputable evidence of effectiveness, and from there, then you can begin to pare out the mechanism's effect. And I hope that you're funding research which is in this inequitable area -- somebody said too that you'll give some consideration to exceptional practitioners ----- if they have an efficacy, then break it down to reducibility.

DR. COULTER: And I guess when they choose best-case clinics for us to go to -- I mean, I don't how they choose them, because they NCAM them. But that's one where you could say, "Well, this ----- exceptional practitioner," right? But just a comment further on what you said, you know, we get into this big debate all the time about the methods of rigorous medical research applied to CAM. Well, the truth is, all the problems at CAM are no different than all the research problems of social sciences. Psychology and sociology have been living with this stuff for a hundred years. We get the same attacks -- is sociology scientific, isn't it, you know. And we have developed methods of doing very good research that are unique, but are equally scientific. So I think sometimes we get a little overwhelmed in CAM about we've got to get this -- you know, reduction is biomedical kind of paradigm, because it's only ----- science. Well, if that was true, you just wiped out the whole of social sciences, including economics, by the way. So I think we shouldn't be too apologetic about the fact that there are other ways of doing research, and we should use them. And I think your model from psychology is a good example.

DR. RICHARDSON: Right. Thank you all for coming, and we'll be here for you to ask any questions.

(Whereupon, the PROCEEDINGS were continued.)

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