

CENTER FOR MIND-BODY MEDICINE
COMPREHENSIVE CANCER CARE 2000

CONCURRENT: Funding of CAM Cancer Research

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MODERATOR: Jeffrey White, MD

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P R O C E E D I N G S

DR. WHITE: Welcome. Thank you for coming. This is a session on funding of CAM cancer research and the -- this is the second year that we've done this session.

I'm Jeff White from the National Cancer Institute, director of the Office of Cancer Complementary and Alternative Medicine there. And a large part of what I do is to try to fund CAM research. Try to develop programs for the funding of grants -- to work with the National Center for Complementary and Alternative Medicine on other projects that support CAM research.

And what I thought when I first put this together last year was that we ought to have an opportunity to introduce people that are interested in CAM research to the other funders of bio-medical research in the United States -- in cancer research in the United States. I think it's important that investigators certainly look to the NCI and NCCAM for support in this research, but there will be, I think, opportunities that you need to be aware of and I thought this would be a great opportunity -- a great time to just go over some of those and let the -- actually bring investigators to and bring the funders to the investigators. So that's what we hope to accomplish today.

So I won't actually spend much time in my introduction other than to -- just a very brief few comments about the NCI's portfolio of CAM research and then we'll just go into the presentations by the people we have today. We have Dr. Ringer from the American Cancer Society; Dr. Hottenstein from the Department of Defense; we have Elda Railey from the Susan G. Komen Foundation; and Dr. Tarver from the Pacific West Cancer Fund. And I'll introduce each of them as we come along.

So let me just first tell you a little bit about the NCI's research portfolio. It's actually not going to be much detail. It's just sort of a -- it's a qualitative look at what CAM research is being supported by the NCI. And really just to give a feel for where we are now and, perhaps, where some other opportunities might exist for other funders. So currently, there's -- the main areas that we're going to talk -- that I'll just show you are clinical trials, and epidemiology, and basic science areas.

Within the fields of clinical trials and epidemiology, we are funding -- mostly this is investigator initiated awards. The RO1s, or other -- sometimes we're talking about small business innovative awards and other -- occasionally -- I guess, actually no -- none of them are the developmental

R21s, and I'll get to that in a minute. But these are just general sort of topics that we are supporting right now.

Some clinical trials are on alternative approaches to pain management. A few in chemo prevention. Soy bean pharmoco-kinetics is an example of a specific trial that we're supporting. A randomized control trial of a plant-based diet in breast cancer recurrence -- fruit and vegetable intake and effects on smokers and increasing fruit and vegetable intake in head and neck cancer patients, and diet and genetic interactions in prostate cancer.

In basic science, we have studies in melatonin, psychoneuroimmunology, stress and tumor growth. Some of those are repeated there and then Vitamin D and prostate cancer, in vitro work, natural products with anti-cancer activity, mechanistic studies of tea in carcinogenesis, and laboratory studies of pain control. Again, this is not to go in any detail, but it's to give you a broad overview.

So -- and one other thing. We have supported conferences in alternative medicine such as this one. I just want to point out that we get many calls and many investigators interested in pilot projects, developmental type, early phase research, clinical research often, or pilot projects in basic science within which there's very little supportive data.

Currently I have to say that the NCI and complementary alternative medicine has not made this a -- this has not been well represented in our portfolio, let me say. One of the things that my office is doing is trying to develop programs that would specifically target trying to support this kind of research and, hopefully, the next time I give this to you, I can tell you more about the progress that's been made in that.

Also, some small clinical trials -- early phase clinical trials -- early phase clinical trials have been relatively under represented and there's another -- and so we are looking at opportunities to try to support that kind of research.

Often I get calls by investigators saying, I have a project that involves a particular, perhaps, dietary supplement and we'd like to get into early phase clinical trials and what do you have available? Sometime the answer is that we don't have a tremendously rapid and easy way to get someone up and running with that kind of a project. And that's one of the things I hope we might find other opportunities -- other funders that -- at least initially, as I'm saying, as we're trying to develop our program more that there will be other opportunities for supporting that kind of research. We hope to talk about some of them today.

So what I'd like to do is have each presenter make their comments and then we'll come together as a panel at the end and take your questions and answer them in that kind of format. So the first I'd like to introduce is Dr. Ringer from the American Cancer Society. He's a Ph.D. in biochemistry and master of public health and epidemiology and bio-statistics -- conducted research in chemical carcinogenesis as a member of the Oklahoma Research Foundation from '93 to '96, and as a section head at the S.R. Noble Foundation.

In addition, Dr. Ringer has lectured in areas of toxicology and biochemistry and supervised the training of graduate students at post-doctoral fellows and has over 100 publications in the area of biochemistry and chemical carcinogenesis. Dr. Ringer joined the American Cancer Society as a scientific program director in the Extramural Grants Department in 1998. We're happy to have him here today to tell us about their programs. Let me transfer this to you and then --

DR. RINGER: I would like to welcome everybody on behalf of the American Cancer Society and especially it's research department, which is located in the national home offices in Atlanta, to this program this afternoon.

I would certainly like to thank Dr. White and the sponsors of this conference for taking -- for making the effort to include ACS in participating in this -- this effort to bring what's going on in a variety of additional areas -- an area of CAM research.

I think the American Cancer Society mission statement sums up our basic goal and our basic tool that we're using to reach this goal. Obviously, we're interested in eliminating cancer as a major health problem, by preventing cancer, by saving lives and diminishing suffering, to four principal arms: Research, education, advocacy, and service. This general mission has been readapted or manifests itself now in what we call five strategic directions.

This is sort of a balanced attack with plans to reach certain goals in 2015, which I won't go into. But one of those strategic directions -- obviously, the third one is to focus high impact research and health professional training programs on the issues and to constantly update those and target those as things change.

Basically, our research program consists of about \$100 million a year and growing. Shown on this slide are -- it's just the basic breakdown of how that research program is organized. The large portion is an extra-mural grant portion -- 85 percent of our spending.

An intramural program, consisting of two components -- one in behavior and one in epidemiology and surveillance -- comprises about 10 percent of our overall program. About 5 percent of our total monies are involved in turning the dollar over, turning the donor's dollar over with regard to overhead.

What I would like to do in the next few minutes is -- ACS has been doing CAM-related research for quite some time. We don't have a focal report on it and I think it is under-emphasized sometimes in our publications. What I would like to do is just go through these three different areas of our research program with regard to CAM and explain a little bit about what our activities are, what our efforts are, and what the research opportunities are there in the few minutes that we have.

Taking a look first at our behavioral research, our smallest group -- also, our newest group. It's only been around for 5 years. It's headed by Dr. Frank Baker from Johns Hopkins. This is a very unique center. One of two in the world that we know of where the emphasis is on human behavior as it affects prevention, detection, and treatment of cancer.

The focal effort of this new group is to create a cohort and to monitor prospectively 100,000 cancer survivors -- with a variety of issues. We also have a number of other areas, but an important area of this overall effort is in the area of the study of complementary therapies used by cancer patients and survivors. This is in-house research.

We have scientists at ACS doing this and what I would like to do is give you a couple examples of the types of projects that have been initiated in this short period of time. One of the first things we did is we started the CAM use frequency study in the cancer survivors that we were looking at. This is initially a -- just about a 500-patient study, a pilot study.

But that now is ongoing -- has been expanded as we create this 100,000 cohort of cancer survivors. This is a driving force then for the other types of studies that are ongoing at ACS.

We also have been doing things in addition to looking at just patients. We've also been looking at oncology professionals and their attitudes -- and their knowledge with regard to CAM and their attitude with regard to patients who use CAM. This started in 1998 and I think the publications on this are beginning to reach in-press status. Basically, what we're finding here is that oncology physicians, nurses, and social workers have essentially comparable information with regard to CAM -- not necessarily extensive knowledge with regard to CAM -- but we're also finding that the support of patients who wish to use CAM therapy varies quite a bit among this group.

Social workers are more highly supportive of patients using CAM, followed by nurses, followed by physicians. This may not be a surprise. But there's a significant difference in the amount of support the patients are getting from oncology professionals.

There is another area that's actually being presented as a poster downstairs at this meeting. So I won't go into it except to draw your attention to it. And this the use of CAM by breast cancer survivors and what you'll see there is the report of 600 breast cancer survivors with regard to the impact and frequency of use of different -- I think 42 CAM methods were evaluated with regard to frequency of use.

Looking at them with regard to the impact that the patient's felt these CAM methods had in reducing their likelihood of a second event -- significant interest in this area. Over 70 percent of the patients -- of the participants in this survey found that this was a very important area for them and felt as though it did reduce their risk.

We're going to be expanding our studies in this area to look at specific CAM therapies with regard to efficacy and more control studies.

That's a summary then of what's going on in the area of behavioral research, intramural program, the epidemiology intramural research program -- this is an old program. It's been with the ACS for over 40 years now. Basically, this group distinguishes itself by following a number of populations in the United States with regard to their risk of cancer and doing prospective surveys over a long period of time.

Some of the studies dealing with a million or more people in the United States and then more targeted groups with regard to additional information with regard to nutrition and, more recently, we've begun to collect a inventory of bloods from this nutritional cohort -- with regard to being able to ask questions with regard to risk factors associated with lifestyle and human genetics. Something that we can do in the future here.

So this is the type of databases that the epidemiology group is primarily looking at. What types of information are they producing out of this program? Currently, one of the main efforts is to look at dietary supplements.

How do they correlate with regard to lowering risk for cancer? Three of them that are being looked at right now include multi-vitamins, Vitamin C and Vitamin E with regard to colon cancer. Colorectal cancer is an important area for the cancer -- the American Cancer Society currently is trying to bring down those numbers. The studies here are interesting. The multi-vitamin effect seems to be real, but it takes about 10 years of multi-vitamin use before we start to see a

significant decrease in colorectal cancer -- risk among men and women. These studies are in press. They'll be coming out soon.

Also, another interesting area that we're at right now, with regard to ACS, is creating our third large study group. Every 25 years we have to create a new study group of a million people to carry us forward into the new period of looking at cancer risk, and cancer mortality, and cancer incidence. This new group is -- what we're doing right now is trying to evaluate what types of areas should be followed more closely with regard to this new group that we will start in 2005. I think a lot of issues involving CAM therapies and methodologies should be, and probably will be, included in this new cohort during the next 20 years.

That takes care of our epidemiology group. Let me move on, last but not least, to our largest sector and that is looking at the extramural grants program and what's going on there. Basically, this program -- it's about \$85 million a year -- looks in -- has 14 study sections which span everything from molecular biology; and looking at carcinogenesis mechanisms; to pre-clinical studies involving drugs; to studies looking at psycho-social, behavioral, and health policy issues. So we have a whole range of areas that we're interested in with regard to research. These grants currently are awarded primarily to beginning investigators. The ACS theme is that we need to make sure we bring in the best and the brightest talent into this area. So by focusing our research dollars on beginning investigators, we think that we can help achieve this goal.

The grants currently are 4-year grants up to \$250,000 a year -- a maximum of about a \$1 million a grant -- because we have to -- because we can only give our funds to not-for-profit, non-governmental organizations, most of these funds are going to universities, medical schools, hospitals, and research institutions throughout the country -- currently about 300 to 400 institutions are receiving funding from the American Cancer Society. These are all investigator-initiated, peer-reviewed funding applications. We get about 2,000 a year and of those about 20 to 25 percent are funded across the board.

We have other mechanisms for doing research. A couple that I'll just mention are the Research Opportunity Grants. These are one-time, quick grants that can be received in 3 to 6 months and are usually targeted toward high impact areas. A novel idea, or a novel opportunity, that can have impact at the human level for which funds are needed immediately. And these are handled in a very expedited fashion.

Another type of grant that we do is in the area of research professors. ACS has long seen the need to recognize leaders in the field of cancer research no matter what era, or what aspect of cancer research that involves, and to free these individuals up from administrative responsibilities so that they can teach, do more research, or take a more public high-profile role in cancer control, cancer prevention. And so we have cancer research professorships which provide salary supplements, free to leaders in the area of cancer research so they can interact more at a public level throughout the nation.

The second arm of our research is funding health professionals and looking at post-docs. Again, this is in all 14 study sections with regard to funding people who've just gotten their M.D., or Ph.D. and are interested in creating or extending their training in the areas specifically of cancer research.

Funding those people. Making that possible. We have clinical research training grants which are specific salary adjustments for physicians who want to move more into cancer research clinical aspects, but need a salary supplement to allow them to move in that direction. There is an

important area. And we also have a whole variety of health professional training grants -- four or five of them that we won't go into in detail, which are designed specifically to support oncology nurses, oncology social workers, and primary care physicians that want to focus more on cancer control. These are all programs that are updated and retargeted on an ongoing basis as ACS sees new needs and new niches that need to be filled.

What are some examples of the type of extramural grants funded in the area of CAM? Here's a list of just four that I looked at that have been currently funded, or recently funded. They include such things as the use of pre-surgery hypnosis -- with regard to the effects of post-surgery recovery on breast cancer patients, the use of hypericin from St. John's Wort to treat tumors of the pancreas -- a very difficult cancer -- the use of vitamin -- of large doses of Vitamin A and D for biologic modulation chemotherapy of advanced breast and prostate cancers. And the application of acupuncture for pain management.

What are the application deadlines at the ACS? There's two cycles per year. The first cycle is in the spring, April 1 to April 15, depending on the particular funding mechanism that you're interested in. And then one in the fall involving either an October 1 or an October 15 date. In addition, shown here at the bottom, the health professional grants generally cycle only once a year and the exact dates when those are due you can easily find on our web page which contains all the necessary information. [Www.cancer.org](http://www.cancer.org). Just go to Research, and then Research Funding. It will have all our programs explained, all of the funding mechanisms, all of the requirements for eligibility, the types of committees that are available, as well as downloadable information with regard to instructions and forms.

ACS obviously is very interested in CAM research, as you can tell from both our intramural program and our extramural program. ACS is also very interested in the American public becoming more informed about CAM. And so -- for the last slide here -- they will be -- or the American Cancer Society, in September, will be releasing a new publication, called "The Guide To Complementary and Alternative Cancer Methods."

This is ACS's efforts to join with everyone else in trying to make up-to-date information available to both the public -- there'll be two versions of this -- both the public and to physicians. And this is going to be a 460-page book with, I think, 200 to 300 CAM methods of therapies included in it. We've had expert evaluation on these. There will be information with regard to their safety, information with regard to regulatory facts. It's being put forth in an encyclopedic format for easy use. We have taken time to go through a lot of the electronic databases and look at databases that we think are especially valuable for going to additional sources.

So ACS is very committed to looking at CAM and we'll continue to expand our research efforts in this area in the future. We certainly encourage everyone who's interested in doing high-quality research in this area to contact the ACS and send their applications in that direction as well.

Thank you.

DR. WHITE: All right. Thank you, Dr. Ringer. Okay. Next, we'll hear from Dr. Hottenstein from the Department of Defense. Dr. Hottenstein is a Lieutenant Commander, U. S. Public Health Service, and his current assignment is as Program Manager for the Neurofibromatosis Research Program of the Defense Health Research Program at the Department of Defense Office of Congressionally Directed Medical Research Programs at Ft. Detrick, Maryland. He's received his Ph.D. from Johns Hopkins University School of Hygiene and Public Health. His

post-doctoral training included neuropharmacology, pulmonary, and cardiovascular physiology fellowships at the Universities of Arizona and Colorado. As a faculty member in Neuroscience and Physiology at the University of Colorado, he taught medical and dental students while conducting a research program involving sensory and nervous system controls of gastrointestinal blood flow. And we're very happy to have him here to tell us about the DOD's program in cancer research funding.

Omar?

DR. HOTTENSTEIN: Thank you, Dr. White. We're glad to be back this year to present further information on our program with the Department of Defense Congressionally Directed Medical Research Program.

We'll discuss some of the funding opportunities for complementary and alternative medicine research with the Department of Defense. I'll give you a brief overview of our structure history of our program, the program philosophy, and the features of some of our award mechanisms, some of the innovations that we try to promote out of Ft. Detrick and extramural research nationwide, as well as internationally. And then we'll finish up with some examples of research award mechanisms and highlight some of the currently funded and also completed CAM-related research.

To date we have invested more than \$15 million in CAM-related research and we still have 12 more grants to negotiate by September 30th. Our organizational structure for the research area directorate of Congressionally directed medical research programs, including breast cancer, prostate cancer, ovarian cancer, neurofibromatosis-- Defense help in other areas that are Congressionally directed is under the Materiel Medical Research and Materials Command of General Parker and also the new MedCom Commander, General Pete.

A brief history for those of us who are not aware of it. A grass roots advocacy upwards of '92, '93, resulted in a budgetary opportunity for Congress to put \$200 million into breast cancer research. And that has been ongoing and continuing and the program was assigned to the Medical Research Materiel Command in Ft. Detrick to the Army as executive agents. And they use the Institute of Medicine as a consultant process to develop programmatic advice and also kind of engineer the program. And additional programs were brought in in '96, '97, as well as the year 2000. And again, all \$15 million to date has been invested in CAM-related research and still ongoing.

Here's a brief summary of some of our research dollars over the years to date. And you can see since '95, it's been increasing. Over here on the pink side we have the breast cancer component -- the neurofibromatosis component in red, prostate in green, ovarian cancer in yellow. And you can see annually this past year for FY -- Fiscal Year 2000 -- we had over \$275 million invested in -- these awards will be negotiated by September 30th of this year.

The central theme of this program is, in fact, innovation and eradication of targeted diseases, or the alleviation of specific components of disease within specific populations. And our mission is to foster new directions; address neglected issues; bring on new investigators and training; and expedite, if possible, breakthroughs to target disease areas; support innovative risk taking -- but also to utilize, as best as possible within our programmatic evaluation process, scientific judgment of our scientific peers.

Also to support in other ways the clinical translation awards -- and translate the basic laboratory research to the clinic and to the patient and the family thereof.

What are the unique programs of our features? We have specific areas directed on an annual basis by Congress. They're targeted and specific dollars are targeted in amounts. Say, for instance, \$15 million for neurofibromatosis, over \$150, or \$75 million for breast and prostate cancer, as an example. We have a flexible science management model a la the Institute of Medicine, which allows us to have -- capable of rapid change in our annual vision statements so we can address the needs of the community and, also, the science and infrastructure on an annual basis.

We have a two-tiered formal review process. The first tier is the scientific review process where you have tiers where each proposal is rated according to it's area. Then the programmatic review -- the second tier level is evaluated from a portfolio balance -- the needs of the community as a whole and also for the program as advertised in the program announcements. Those program announcements are available on the web site which I'll give you a little bit later.

We also have a booth here today and tomorrow. We welcome you to stop by and get a brochure, or our web site, and talk to us about how we can help fund your research. We also involve consumer participation. Those people living with the disease, or survivors -- they're out to become involved in our scientific peer review process in all panels.

Examples of the program innovations to date include our funding of high-risk, high-gain proposals such as our idea awards, our springboards to future awards, or other funding opportunities. Complementary efforts by these initial awards. These initial idea awards many times require no data, just sound logic. Scientific logic.

Then, if someone can get that work, they can get the preliminary data and then can go on to other institutions, or other funding agencies here, or elsewhere, like Dr. White would suggest.

We try to address under-funded research areas. That's the Congressional intent. The other thing is translational research, getting things moved from the lab to the clinic and pre-clinical trials and the like. Again, we felt that involving the consumers in both processes is a necessary sense of adding to the program and it's balance.

A target recruitment of researchers in specific research areas to bring them from other areas to be cross trained in new areas of research. And we also have initiatives for biomedical and behavioral research involving minority researchers and minority populations.

Examples of some of our CAM opportunities which are here today -- a goal for us is to fund excellent science. It may not otherwise have an opportunity for funding and -- it's not my fault.

New initiatives include, right now in the breast cancer area, idea awards listing -- behavioral, social, quality of life related research. So this is something new for us but it's just something that is important.

An example, again, on our idea awards -- just getting in a little more detail -- the idea awards are really look for an innovative research, unrecognized, unattempted previously, breakthrough, not having preliminary data for, say, breast, ovarian or neurofibromatosis awards, but some preliminary data is necessary for prostate award mechanism.

We also have clinical translation research award project -- try to revolutionize breast cancer prevention, detection, diagnosis. And the application of these promising laboratory leads -- preclinical insights to move them on to the patient and the patient and the population.

Where are we at? Well, in the CAM-related research, I want to give you a few examples of breast cancer research, prostate cancer research, and some abstracts of available. All of our abstracts in both lay abstracts and scientific abstracts of funded research are available on our web site. You can search with a search engine to locate what you might be interested in. Then you can find the PI, the Principal Investigator, or the institution that has conducted that particular research.

For an example, these are completed research accomplishments already in many of the -- these reports are being -- are published in the literature. In the breast cancer area, we've demonstrated -- not I, but the PI that conducted the research and his institution, demonstrated that a component of soybeans can prevent development of cancer-induced carcinogens in mammary glands.

So that's an example of research that has been funded related to CAM by this program. Also, it was determined that reduced breast cancer risk is associated with high sunlight exposure and high Vitamin D intake. So, again, that's another example. And another large trial of Hawaiian women -- they found that dietary and lifestyle factors are very important. Increased alcohol intake and/or late childbirth were at risk -- increasing the risk -- and a decrease in the risk in these women was seen by the early menopause or the high consumption of dietary fibers.

Some more examples of completed research -- okay? It's available on the web. And available from the PIs -- in breast cancer research is that environmental magnetic fields may block cancer inhibitory effects tamoxifen and melatonin in vitro. That's a very interesting study. And then there was another cohort study example here of Stage 1 tumor cancer -- found that meditation-based stress reduction programs have an effect -- decreasing the avoidance-coping behaviors that may be seen, or the feelings of hopelessness, helplessness, and distress.

They found that meditation-based stress reduction programs could increase active coping, spirituality, and emotional quality of life. Then, in other study, -- is to determine the effects that electrochemical treatment of cancer therapy was non-specific and it destroyed both tumor and non-tumor tissues.

Here are some examples of ongoing CAM-related research that's being funded by this program. The current research involving dietary seaweed and breast cancer -- it's a randomized trial. Now we have vigorous exercise and the effects on breast cancer prevention in women. The effects of green tea and polyphenols on breast cancer signaling and cells. Estrogenicity of various medicinal botanicals and also the use of citrus for mammary cancer and also another Vitamin D trial study.

With regard to prostate cancer, we have ongoing research -- again, the prostate program is only three years old so our programs last for up to three to five years. By the time the research is completed, it's seven years out, so it takes time to complete these researches and get it completed. But in the example of prostate, we have selenium and prostate cancer chemo prevention studies, fruit and vegetable intake on the outcome of prostate cancer among African American men.

Soy supplementation and PC prevention. All three effective supportive and non-supportive behaviors and the quality of life in PC patients and their spouses. And then there is also flavonoid studies among other CAM-related research which I haven't listed here today.

Just as an example, the funding opportunities that are still open -- you can see the prostate just closed in May and just a few days ago the breast cancer took receipt on Wednesday. But neurofibromatosis -- still open. Also ovarian cancer. If you follow the Congressional language and the intent and watch in the fall, you'll know what they intend to do about next year.

So we welcome your participation -- here's an example of our web site, as you pop it up on the - on your computer. It's <http://cdmrp.army.mil>. We have that brochure downstairs and you can see -- once you get to the web site, you can click onto the various research programs and get programming information at current and funded proposals, as well as search the web site for specific research interests that you want to know about, or what's been done, or what the status is, or, again, our mission, our vision statements are there. And we also have phone numbers and fax numbers if you would like to. But thank you for your attention.

DR. WHITE: This is the second year that we've had the DOD to be with us and I appreciate their involvement. We -- the other members are all here for the first time and it's -- we'd like to continue to do this kind of program. We'd like to continue to bring in different groups that are dealing with CAM cancer research.

Next have Dr. Donald Tarver from the Pacific West Cancer Fund. He's the administrator of the fund -- who's has a B.S. from Northwestern State University, and a masters from Central Washington University, and a Doctor of Education from Washington State University. And he will talk to us about his organization, which actually I'm learning about for the first time, and that is involved in cancer research.

DR. TARVER: We're happy to hear that you're learning about it. I thank you very much, Dr. White. I appreciate the opportunity to be here. We are a much less formal organization, in terms of research, than the two preceding ones, primarily because we exist for educational purposes rather than primary research. But we do have a research name, as I will point out in this short presentation.

We're located in Seattle, Washington, and I'm the administrator of the organization. I'll have this address at the end as well, so if you don't get it all here, you can get it at the end and it's a way you can contact us. We're a not-for-profit, charitable organization dedicated to cancer prevention through education, sponsorship of research, and primarily, as I indicated, it is for education.

We advocate this cancer prevention through the proper diet, exercise, medical screening, and a non-smoking lifestyle. You hear a lot of this already and we want to continue to say it until there's an absolute change with cancer education.

Over the past 12 years, Pacific West Cancer Fund has contacted over 100 million plus households with cancer information and education and direction that we hope has had some effect on change in lifestyle that may have increased their lives. Most of this was about cancer prevention, early detection through a healthy lifestyle, and regular cancer checkups.

Our research, over the past 12 years, has provided \$2,350,000 for research and new drug development, sponsored medicinal plant research, sponsored work for the sea cucumber and

sponsored educational publications which were distributed to a number of organizations -- libraries throughout the United States, or to universities and colleges that are doing particular kinds of research.

The research into the new drug development is based around the lytic peptide. It's the premier research that Pacific Breast Cancer Fund -- has resulted in the synthesis of a compound that was first found in the giant silk moths 35 years ago. It has been determined to be a protective mechanism for the moth, which attacks and destroys cells of disease of infection. A number of cancer cell lines were tested. The majority were killed with levels of peptide that left normal cells unharmed. Not only did it not harm the normal cells, but it encouraged their growth. It has been concluded, therefore, that lytic peptides may ultimately be used to treat cancers in humans. When we first got acquainted with this back in 1992, the funds that were available to the particular researcher had expired and he could not go any further with it, so we gave him a basic grant and they are now -- we hope to be able to go into human trials at the end of this year.

In the medicinal plant research, we worked with an organization called AgMed Consortium. It's composed of a group of people in M.D. Anderson; University of Texas; University of Michigan, Ann Arbor; Louisiana State University Medical School in New Orleans; and Louisiana State University Agricultural Center; and Louisiana Tech University; as well as an organization that supports for that basic research in plant applications. In addition to that, we have a relationship with a number of organizations in China. Hunan University and the Beijing Institute of Help. We are currently studying the extracts of the Gingko Biloba plant and other medicinal plants that are in the gardens at the University of Hunan Province.

And medicinal plant research -- that we multi-year medicinal plant research with Chinese organizations: Beijing Forestry College, the Forestry Research Institute of Hunan Normal University, the College of Forestry at Hunan Agricultural University. Each of these organizations are -- have a specific project to develop and bring to researchers in the United States for further study.

A new organization that we support is interested in world drug and agriculture applications -- a not-for-profit foundation that not only supports human disease eradication, but it is involved in the development of plants that are -- I can't think of the term now, but anyhow it's protected from various diseases.

And we -- as I pointed out earlier, we have some study of the sea cucumber and it's anti-cancer properties. We sponsored some educational publications. We have now the -- an encyclopedia of the woody medicinal plants of China. That's composed of 251 different species. It's written in English and in Chinese and it tells about each of these 251 species and how it's been used by the Chinese. It's intended to be used for researchers who have an interest in following that line of research.

Since 1987, we've sent out this kind of information. 142 million letters containing cancer information. We will have, at the end of this year, an encyclopedia of Chinese medicinal plants for cancer -- there'll be some 500 of those -- as opposed to the woody medicinal plants of the earlier publication. Both of those will be produced on a CD-ROM. And this is a joint U.S. and Chinese editorial and research team effort.

Our application process, as I indicated, is informal. We don't send out requests for proposals. Our interest is in providing seed money for out of the mainstream research for smaller groups

that have something that we consider needs to be boosted by seed money. We will accept a letter of intent to Pacific West Cancer Fund. You can describe any kind of research that you may have an interest in. You should include a brief statement of a proposed project and it's reviewed by the board of directors quarterly.

And as I said, we exist in Seattle, Washington, and that's our address and telephone number. We'd be happy to hear from you if you have some interest. At this moment, I couldn't tell you how successful you might be in acquiring some grant moneys from us, but we'd be certain to give it a good review.

Thank you very much.

DR. WHITE: Thank you, Dr. Tarver. All right. Our last presentation will be by Ms. Elda Railey from the Susan G. Komen Foundation. Ms. Railey is the Director of Grants and Sponsored programs for the Susan G. Komen Breast Cancer Foundation. She's been with the Foundation since 1989 and she has had several positions with the Foundation, including Controller and Director of Finance and Administration. In her position as the director of grants and sponsored programs, she oversees the National Grant Program and assists Komen Foundation affiliates in establishing their grantmaking process.

The Susan G. Komen Breast Cancer Foundation is the largest provider -- private funder of research dedicated solely to breast cancer. And she's spoken at national meetings on grant writing and principles of grant making. She's a member of the Society of Research Administrators and Grant Makers in Health and serves on the advisory board of the Texas Breast and Cervical Cancer control program.

MS. RAILEY: I used to say, when I presented on panels with the American Cancer Society and the National Cancer Institute, and all of the larger institutions, that I felt like David and Goliath. But that the enemy really wasn't the other organizations. We're working together to conquer the real giant and that's cancer. And you know, if I felt intimidated then, I'm very proud to say about the growth that the Komen Foundation has enjoyed in the past few years and I'd like to tell you a little bit about that.

If Nancy Brinker had let her intimidation conquer her in 1982, she would not have fulfilled the promise to her sister, Susan Goodman Komen, that Nancy made to Susie on her death bed. Nancy promised Susie that she would help those that were encountering breast cancer so that they wouldn't have to endure what Susie and her family had. She set about to start the Foundation and, from the very inception, the Komen Foundation has funded breast cancer research.

The research environment -- funding environment at that time was very different than it is now. The National Cancer Institute was funding a small amount of breast cancer research. The American Cancer Society was certainly out funding research. But it wasn't specific to breast cancer. Someone interested in funding breast cancer research at that time really didn't have a targeted place to go. In the last year, we have funded over \$20 million in breast cancer research at the Komen Foundation and are very proud of that.

We've structured our programs to meet research needs, but we've done it from a patient's perspective. This one's about a different perspective. See DOD has brought in consumer advocates into their review process. We started with a consumer advocate at the very

beginning, not only as part of the review process, but in structuring the program from the very inception.

The funding available for breast cancer in 1982 was very similar to what CAM research funding is now. And I think as I present some of our programs, you'll see that we are committed to creating that groundswell of information and really creating the interest to getting those programs out that are available to CAM research and understanding that our major accountability is with the breast cancer patients -- those people who are really interested in the outcome of CAM research and who really want to know the answers to the questions. And we want to be able to provide them with grounded, scientifically based answers when they come to us and ask will this really help me forget breast cancer, or will it really make it better as I'm in diagnosis and treatment -- and the ultimate question of what will make breast cancer go away.

I'd like to tell you a little bit about some of the programs that we offer. And I'm going to focus on the program structure and not on the outcome of these. We feel like we offer a very innovative program. We try to structure it to be the most innovative and responsive and we focus on research, much like some of the other programs that are innovative and have a high impact.

Our mission statement is to eradicate breast cancer as a life-threatening disease and we do this by focusing on research, education, screening, and treatment. We look at the whole paradigm of the disease, including survivorship and prevention. The hallmarks of our program are that we've innovative. We're looking for those high-impact ideas. We have a rapid response. Our application deadline, as you'll see in future slides, is April 1st and we'll begin funding those specific grants with monies that we're raising this year on in October.

We are the only organization that I know of that is conducting a blinded, or an anonymous review. We started this from the patient's perspective so that -- we felt -- would focus more specifically on the scientific merit and not on the experience of the researcher. And again, we've been funding idea grants since the beginning.

Our grants are structured into research grants and training grants. We also have a program called our step grants. These are funded through our common affiliates who are 115 strong across the nation. And these focus on screening, treatment, education projects in defined service areas in those communities across the nation. This program last year -- well, the numbers aren't in completely from 1999, but in 1998, funded over \$23 million in community-based services through that program.

Our training grants are in post-doctoral fellowships. We currently have a portfolio of about, I think, we're at 40 post-doc fellows that are in current -- period right now and in dissertation, we have 15 pre-docs that are working.

Our research grants, and this is probably the area that you're most interested in, is basic, clinical, and translational research, imaging technology, and population specifics. Because we're short on time, I will focus on basic, clinical, and translational.

This program is for grants up to \$250,000 for 2 years. I've listed some areas of interest, but I know you'll focus on complementary and probably survivorship. We have not done a targeted request for proposal (RFP) for CAM. That is something that is being considered, but right now it's considered as part of our broader RFP, as are these other areas. We do have a specific study section so that anything that we receive in the complementary, alternative, integrative area, we'll have specific expert reviews on your application. We've also been a leader in

survivorship issues and have two survivor professors. All of our grant programs, and I have mentioned here today -- deadline on April 1st -- you've been given a brochure that lists our 2000 program. That has closed now. But we brought it to you because the 2001 brochure is not out yet. Our web site still has the applications from this year -- downloadable so that you could see what those requirements are. And it also has a listing of all of our past grant fund making. You can contact us and I hope you will because if you don't apply, we can't fund you. We're very much market- driven in that respect. But you can reach us through the web site at www.komen.org through the grants and funding section. We have a toll free line that comes directly into the grants department. It's listed here and e-mail is grants@komen.org.

1-800-IM-AWARE, is our national breast care help line. This is where we field over 90,000 phone calls a year, many of them focused on complementary, alternative, and integrative methods that breast cancer patients and their families are very interested in learning more about. So we're very education-focused. We need to know what you're doing out there and we need to continue our conversations on how to approach these issues.

Thank you.

DR. WHITE: Great. Thank you, Elda.

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