THE ROLE OF EARLY DETECTION AND COMPLEMENTARY AND ALTERNATIVE MEDICINE IN WOMEN'S CANCERS

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

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THE ROLE OF EARLY DETECTION AND COMPLEMENTARY AND ALTERNATIVE MEDICINE IN WOMEN'S CANCERS

THURSDAY, JUNE 10, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:37 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton, (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Horn, Mica, Biggert, Ose, Chenoweth, Waxman, Mink, Norton, Cummings, Kucinich, Schakowsky, and Sanders.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; Barbara Comstock, chief counsel; David Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, professional staff member; Mark Corallo, director of communications; Carla J. Martin, chief clerk; Lisa Smith-Arafune, deputy chief clerk; Laurel Grover, staff assistant; Nicole Petrocino, legislative aide; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; Jean Gosa, minority staff assistant; and Andrew Su, minority research assistant.

Mr. BURTON. Good morning. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written opening statements be included in the record. Without objection, so ordered.

We will have other Members—I see some of them coming in right now—joining us, so they will be coming in just a few moments.

We are here today to talk about a subject that has probably touched every family in America, cancer. Specifically, today we are going to talk about women's cancers. At hearings in the future, we will be talking about some of the major concerns that men have, prostate cancer. I have talked to Michael Milken's staff. We are going to be talking to Senator Dole's staff. We will be talking to the minority also about people that they might want to have testify about men's problems, prostate cancer and other issues, as well as diets that might assist men in fighting this dreaded disease as well.

But today, we are going to be talking about women's cancers. In this country, every 64 minutes a woman is diagnosed with a reproductive tract cancer. One in eight women today will get breast can-

cer, one in eight. It is an absolute epidemic. Some people believe that that figure will grow to as many as one in three or four.

This is turning out to be a very busy week in Washington for cancer issues. Last Sunday, over 60,000 people participated in the National Race for the Cure, sponsored by the Susan B. Komen Breast Cancer Foundation. This foundation has done a phenomenal job raising awareness of breast cancer and raising money for research and treatment. I applaud their work, and my colleagues do as well.

Today the Government Reform Committee will receive testimony from researchers, health care providers, and patients on the role of early detection and complementary and alternative health practices in women's cancers. This coming weekend, the Center for Mind, Body, Medicine, and the University of Texas, Houston Medical School, in cooperation with the National Cancer Institute and the National Center for Complementary and Alternative Medicine is conducting the second annual comprehensive cancer conference. They will bring together researchers, practitioners, and patients, to discuss research advances and patient needs in both conventional and alternative medicine.

This week, this same week, 1,355 women in America will lose their lives to one of these cancers. Overall, more than 10,000 men, women, and children, will die from cancer in America this week, 10,000. We say to their families and loved ones, we in Congress recognize that the war on cancer declared by President Richard Nixon in 1971 is far from over. We cannot, after 28 years and tens of billions of dollars in research declare victory, because we are not yet close.

My wife suffered from breast cancer several years ago. Thankfully, she is a 5-year survivor. Last year, I lost my mother and my step-father to lung cancer. So I know, as well as many of my colleagues, what families go through when loved ones have to fight cancer. Every additional year a patient lives is a victory. Every new treatment, drug, or surgical technique is a potential victory. However, we have not won this war on cancer. But we will not give up.

The committee has been working to break through barriers of institutional bias to get more research done in complementary and alternative therapies for cancer, and to improve the information available to the public from the Federal Government on treatment options. We cannot abide by institutional biases within the Government that says something is not acceptable because it is alternative or unconventional. We must ensure that there is a balance between genetics, drug development, natural product development, and alternative therapy research within the National Cancer Institute.

To combat this bias, I am introducing the "Inclusion of Alternative Approaches in Cancer Research Act." This bill, my bill, would ensure that every advisory group of the National Cancer Institute would have at least one member who is an expert in complementary and alternative medicine. One leading drug treatment for breast cancer and ovarian cancer, Taxol, was originally derived from the yew tree and was developed through the natural products program. It is important to continue to look to nature for other opportunities for drug development. It would be a shame if reductions

in funding for the natural product drug program resulted in missing the next Taxol that might save lives.

I have previously mentioned that less than 1 percent of the National Cancer Institute's $2.7 billion annual budget goes to research in complementary and alternative medicine. That is very disappointing. Unfortunately, the director of that institute does not see the need to change that ratio, and told me in December that he has no plans to extend that, even though half of America's cancer patients will include a complementary or alternative treatment in their plan to fight cancer. I believe that since we are giving them $2.7 billion, 1 percent is not enough. We will do everything in our power to make sure that more of those funds are given to alternative and complementary research.

Taxol, Tamoxifen, and other drugs are important tools in the fight against cancer, so are pap smears and mammograms, and so is an integrated treatment plan. We have been pleased with the assistance we have received from several of the professional medical associations involved in these areas, including the Society for Gynecological Oncology, and the American Society of Clinical Pathologists.

Dr. Edward Trimble will present information on the National Cancer Institute's research in early detection and the integration of complementary and alternative health practices in women's cancers. Cancer is a disease, but its victims are heros and heroines. They are people, real people with families, jobs, and communities. They make a difference in our lives. People like Sally McClain, from Indianapolis, IN, who lost her life to breast cancer that metastasized to her spine. Sally was a friend of Claudia Keller on my staff. She also was the daughter of a man who taught me in high school, who was a good friend of mine. It is a shame that one so young should die so young because of a disease like this. But Sally didn't give up the fight, not one single day. Or Lynn Lloyd, a high school English teacher in Montgomery County, MD. After two bouts with breast cancer, she is now hospitalized with cancer in her brain and her lungs. Even when she was receiving chemotherapy last year, she scheduled it around her classes so she could keep teaching and stay involved with her students. Now that's real dedication. Most of her students didn't even realize that she was battling cancer until her most recent hospitalization.

We are honored today to have another one of those heroines with us, a lady that's a very, very good friend of mine. Her husband and I were elected to Congress together back in 1982. We are going to miss Senator Mack in the U.S. Senate. His lovely wife, Ms. Priscilla Mack, is the executive co-chair of the National Race for the Cure. As a breast cancer survivor, she knows from personal experience the importance of early detection. She has worked hard to raise awareness about women's cancer issues. With the energy that Ms. Mack brings to this fight, we will hopefully begin winning more of these battles, saving more lives, getting research funded that will get the answers about prevention, early diagnosis, treatment, and hopefully one day very soon, a cure.

Biomedical research already knows that there is not a magic bullet cure for cancer. What we do know at this time is that the earlier cancer is diagnosed, the greater the chances of long-term sur-

vival. That is why pap smears are such an effective tool in saving lives. We do know from good research and practice, that when someone develops a holistic cancer treatment plan, including attention to mind, body, and spirit, then recovery is more likely, with better quality of life and extended life as well.

Dr. James Gordon, director of the Center for Mind Body Medicine here in Washington, and an internationally recognized leader in the field of complementary medicine and alternative medicine, will be testifying also about advances in complementary and alternative medicine cancer research.

When Jane Seymour, a very prominent movie star, testified before our committee in February, she shared the story of several of her friends who had gone the conventional route of cancer treatment and then been told by their doctors that they had done everything they could and it was in essence hopeless. They were basically told to go home and die. These women did not accept that death sentence. They sought other healthcare professionals and advice from friends and family on other approaches to treating cancer. They learned, as many others have, that in order to survive the conventional treatments for cancer, radiation and chemotherapy, that a body needs to be strengthened through good nutrition. I am delighted that Michio Kushi is here today to talk to us about the macrobiotic diet, and that the importance of nutrition is essential in cancer patients. Mr. Kushi is recognized throughout the world as the foremost authority in this field. The Smithsonian Institute has just opened the Michio Kushi family collection on the history of macrobiotics and alternative and complementary health practices at the National Museum of American History.

We'll also be hearing from Susan Silver of the new Center for Integrative Medicine at George Washington University. This center has developed a program for women in cancer treatment with an integrative approach.

Dr. Daniel Beilin is here today to update us on a new tool in the arsenal of early detection, regulation thermography. This low cost test can be used as a complement to mammography for early detection of changes in breast tissue. It has been used in Germany, I believe, for about 10 years extensively. It is also proving to be a valuable tool in detecting other cancers like ovarian cancer and prostate cancer. We are looking into advances in research in prostate cancer, as I said earlier, and we plan to have a hearing early this fall.

We expanded this investigation to cover all women's cancers because there is so much that needs to be done in breast cancer and other areas as well. For example, there is no reliable early detection test for ovarian cancer; 75 percent of ovarian cancers are not detected until the late stage, three or four, and there is only a 25 percent survival rate of more than 5 years. However, of those that are discovered in early stages, there is a 95 percent survival rate of more than 5 years.

The symptoms of ovarian cancer are vague. They are bloating, sudden weight gain, gas, pressure, and lethargy. There is research to indicate that eating lots of meat and animal fats may increase a woman's risk of ovarian cancer. We need more good research in these areas to find solutions. The members of this committee on

both sides of the aisle are very involved in these areas, including Congresswoman Mink, who introduced H.R. 961, the Ovarian Cancer Research and Information Amendments of 1999.

Linda Bedell-Logan's sister died from cancer. During her battle, Linda's sister, like many cancer patients, suffered with lymphedema. Linda, who was involved in healthcare, researched her sister's treatment options and learned about combined decongestive therapy. As a result of this experience, she has helped many cancer patients gain access to this treatment by getting their insurance companies to cover the costs. Lymphedema is a serious complication for many cancer survivors. It causes swelling, usually in an arm or leg. It can be very painful, and it reduces a cancer survivor's quality of life.

We are also going to hear from two cancer survivors. Their stories show the struggles that women face with cancer and how they go through them, the need to develop an individualized treatment plan to find reliable information on all treatment options, and to be comfortable with the treatment choices they make. Lee Gardener and Carol Zarycki are two more cancer heroines. I hope I pronounced your names correctly. If I didn't, correct me when you come forward. Even though they have faced the most daunting enemy you can imagine, they have recovered, returned to living and to helping others face cancer.

The hearing record will remain open until July 25th for all those who wish to make written submissions on the record.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement

Chairman Dan Burton
Committee on Government Reform

"The Role of Early Detection
and
Complementary and Alternative Medicine
in
Women's Cancers"

Thursday, June 10, 1999

10:30 AM

2154 Rayburn House Office Building
Washington, DC 20515

We are here today to talk about a subject that has probably touched every family in America -- cancer -- and specifically women's cancers. In this country, every 64 minutes, a woman is diagnosed with a reproductive tract cancer. One in eight women today will get breast cancer. Some say that number will grow to one in three unless we do a better job of understanding the causes of cancer and preventing it.

This is turning out to be a very busy week in Washington for cancer issues. Last Saturday, over 60,000 people participated in the National Race for the Cure, sponsored by the Susan B. Komen Breast Cancer Foundation. This foundation has done a phenomenal job raising awareness of breast cancer and raising money for research and treatment. I applaud their work.

Today the Government Reform Committee will receive testimony from researchers, health care providers, and patients on the role of early detection and complementary and alternative health practices in women's cancers.

This coming weekend, the Center for Mind Body Medicine and the University of Texas - Houston Medical School, in cooperation with the National Cancer Institute and the National Center for Complementary and Alternative Medicine, are conducting the Second Annual Comprehensive Cancer Conference. They will bring together researchers, practitioners, and patients to discuss research advances and patient needs in both conventional and alternative medicine.

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Every additional year a patient lives is a victory. Every new treatment, drug, or surgical technique is a potential victory. However, we have not won this war on cancer and we will not give up!

The Committee has been working to break through barriers of institutional bias, to get more research done in complementary and alternative therapies for cancer, and to improve the information available to the public from the Federal Government on treatment options. We cannot abide by institutional biases within the Government that says something isn't acceptable because it is "alternative" or "unconventional"! We must insure that there is a balance between genetics, drug development, natural product development, and alternative therapy research within the National Cancer Institute.

To combat this bias, I am introducing the "Inclusion of Alternative Approaches in Cancer Research Act." My Bill would insure that every advisory group of the National Cancer Institute has at least one member who is an expert in complementary and alternative medicine.

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I have previously mentioned that less than one percent of the National Cancer Institute's 2.7 billion dollar annual budget goes to research in complementary and alternative medicine. That is very disappointing. Unfortunately, the Director of that Institute does not see the need to change that ratio, and told me in December that he has no plans to extend that -- even though half of America's cancer patients will include a complementary or alternative treatment in their plan to fight cancer.

Taxol, Tamoxifen, and other drugs are important tools in the fight against cancer. So are pap smears and mammograms. And so is an integrated treatment plan. We have been pleased

with the assistance we have received from several of the professional medical associations involved in these areas including the Society for Gynecological Oncology and the American Society of Clinical Pathologists. Dr. Edward Trimble will present information on the National Cancer Institute's research in early detection and the integration of complementary and alternative health practices in women' cancers.

Cancer is a disease, but its victims are heroes and heroines -- they are real people with families, jobs, and communities. They make a difference in our lives. People like Sally McClain from Indianapolis, Indiana, who just lost her life to breast cancer that metastasized to her spine. She didn't give up the fight, not one single day. Or Lynn Lloyd, a high school English teacher in Montgomery County, Maryland -- after two bouts with breast cancer, she is now hospitalized with cancer in her brain and lungs. Even when she was receiving chemotherapy last year, she scheduled it around her classes so she could keep teaching and stay involved with her students. Most of her students didn't even realize that she was battling cancer until her most recent hospitalization.

We are honored to have another one of those heroines with us today -- Mrs. Priscilla Mack, the Executive Co-Chair of the National Race for the Cure. As a breast cancer survivor, she knows from personal experience the importance of early detection. She has worked hard to raise awareness about women's cancer issues. With the energy that Mrs. Mack brings to this fight, we will hopefully begin winning more of these battles -- getting research funded that will get to answers about prevention, early diagnosis, treatment, and hopefully, one day very soon, even a cure!

Biomedical research already knows that there is not a "magic bullet" cure for cancer. What we do know at this time is that the earlier cancer is diagnosed, the greater the chances of long-term survival. That's why pap smears are such an effective tool in saving lives. We do know from good research and practice, that when someone develops a holistic cancer treatment plan -- including attention to mind, body and spirit -- then recovery is more likely, with better quality of life and extended life as well.

Mr. BURTON. I now recognize my friend Mr. Waxman, for his opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I am pleased that we are having this hearing on such an important issue. Breast cancer is the second leading cause of cancer death among women. Cervical cancer will kill close to 5,000 women this year. At least another 20,000 women will die this year from uterine and ovarian cancers.

The real issues before us are how can we safely and effectively prevent, detect, and treat cancer, and how can we make sure that all women have access to good treatments and to accurate information about their treatment choices? Proper screening techniques can and have lowered mortality rates for breast and cervical cancer. We must continue to work hard to ensure that women have access to the screening techniques currently available, and we must continue to educate women about the importance of being screened for these cancers. But this is not enough. We also have to make sure that healthcare providers follow up with women, notify them of their test results, and encourage them to return for further tests if necessary. We also have to make sure that quality treatments are available to all women.

At the same time, we need to continue to research better ways to detect cancers. Currently there is no good test for ovarian cancer, the fifth leading cause of cancer death among women in the United States. While mammography has been proven to reduce the number of breast cancer deaths in women over 50 years old by at least 30 percent, it has not been as effective in reducing cancer deaths among younger women. We need to continue to research screening techniques.

We should also be looking at ways to prevent cancer. In 1993, I sponsored legislation that mandated a study of why certain localities were experiencing elevated incidence of breast cancer and elevated mortality rates. Studies such as these are important tools in understanding why women get cancers and how to prevent it. We need to know whether the causes are environmental, genetic, dietary, and any other plausible theory. We need to understand what is going on, and why some localities, for no reason that we can otherwise understand, seem to produce an extraordinarily high number of breast cancers.

We must concentrate our efforts on developing safe and effective ways to prevent cancer, to detect cancer, and to cure cancer. We need to make sure that these therapies are available to all women. We have an extraordinarily high rate of Americans who lack insurance; 42 million was the last figure of uninsured people in this country. No one is served by battling over the relative merits of alternative versus traditional medicine. Instead, our goal should be to develop the most safe and effective therapies possible, regardless of how they are classified.

Mr. Chairman, I am pleased that we are going to hear from so many important witnesses today. I want to apologize in advance, because I have a conflict in my schedule. There is a markup in another committee, so I won't be here to listen to all of the witnesses. But I will have an opportunity to review the testimony, and, I look

forward to doing that, and to working with you and our colleagues to accomplish the goals that we all share.

Mr. BURTON. Thank you, Mr. Waxman.

Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman. I don't have a formal opening statement, but I want to congratulate you on conducting this hearing, and again reminding us of the importance of early detection, prevention, and treatment. I again compliment you on this, and also reserve some time to introduce one of our witnesses. Thank you.

Mr. BURTON. Thank you, Mr. Mica.

Mr. Sanders.

Mr. SANDERS. Thank you very much, Mr. Chairman. Mr. Chairman, I think you know as well as anybody that this has been a very contentious committee over the last couple of years. You have heard that, I know.

Mr. BURTON. You're kidding.

Mr. SANDERS. Yes, I know. You and Mr. Waxman know that. It is very nice to see us getting away from that type of partisan hostility to focus on an issue of enormous concern to every man, woman, and child in this country. I thank you very much and the staff very much for putting on this hearing.

The remarks that you have made and Mr. Waxman have made cover a lot of what my opening statement was going to be. But I just want to say a few additional words. You know, first of all, the fact that we are having a hearing on cancer today, probably 30 years ago, there would never have been a hearing like this because people said well cancer, we don't know why it happens. God strikes somebody and that's the way it goes. There is no cause for cancer. In fact, we don't even talk about cancer. It's such a terrible thing. We use the "C" word, but we don't even talk about it because there is just nothing that can be done about it.

So as a result of the work of a lot of people, we have come a long way. We are now beginning to take a rational look at the causes of cancer and how we can effectively treat it. Just think, not so many years ago, when you and I were younger, we watched on television and we saw physicians telling us the particular brand of cigarette they smoked. Remember that? Telling us that they liked this brand of cigarette. That was physicians advertising cigarettes. Well, we have come a long way from that "conventional" wisdom of doctors telling us about which cigarettes to smoke.

Twenty or thirty years ago, forty years ago, breast feeding was told to women and mothers as to be a terrible thing. You certainly don't want to do that. That was physicians. That was the norm. That was what doctors were telling mothers.

I can remember 15 years ago in the city of Burlington, talking to one of the leading physicians at our local hospital. I said, "Well what do you think about diet and disease?" "Oh, there's no connection between diet and disease. It doesn't matter what you eat." Now I think every American understands the important connection between diet and disease. Every day, we are learning more and more about the relationship between indoor air, between pollution in general, between stress and disease, the fact that there is not a huge gap between mind and body, as you indicated. People who

are depressed, people who are under stress are more likely to come down with a variety of illnesses than other people.

We have also learned in recent years that some of those therapies and treatments that people around the world have been practicing for thousands of years are not quite as crazy as some of our "leading specialists" have told us. It was maybe 20 years ago—I may be wrong, it was James Reston of the New York Times ended up in China, and he was ill. They practiced acupuncture on him. Suddenly acupuncture became acceptable in the United States, where for years our leading specialists had told us what a quacky and ridiculous idea that was.

My point is that we are learning more and more about causes and treatments. I think this hearing is an important part in that process. I agree with you that we should be doing a lot more in expanding the Office of Alternative Medicine, for example. I should tell you that we had Wayne Jonas, who was the very capable head of that office in Vermont a couple of years ago. Five hundred people came out to a town meeting on alternative health in the State of Vermont on a snowy day in the central part of the State.

I am working on legislation, I know many other people are, to begin expanding complementary healthcare, making sure that Americans have access to that type of care. The other point I would make is that one of the very sad aspects of what is going on in this country today is even when there are treatments available for cancer, we have millions of people who do not have health insurance. So I would hope that we will join the rest of the industrialized world, and on this issue you and I may disagree or we may not, but the time is now that the United States should join the rest of the world and have a national healthcare system, guaranteeing healthcare to all people. What is the sense of having treatments out there if you have millions of people who cannot afford that treatment?

Where we do agree is I think we should expand and broaden our knowledge in terms of complementary healthcare. Europe is already way ahead of us, maybe less dependency on some powerful drugs if there are natural cures out there. Mostly as I think you have indicated, let's study what's going on out there. Let's learn. Maybe the treatments don't work, fine. But there is nothing wrong with exploring all of the options that are out there.

So I really do appreciate your holding this hearing, and look forward to working with you.

[The prepared statement of Hon. Bernard Sanders follows:]

TESTIMONY OF REP. BERNIE SANDERS (I-VT) BEFORE THE GOVERNMENT REFORM COMMITTEE

HEARING ON ALTERNATIVE AND COMPLEMENTARY TREATMENTS FOR WOMEN'S CANCER

June 10, 1999

Mr. Chairman, thank you for calling this important hearing today on an issue of great importance to American women and their families – women's cancer. I have long been an advocate of prevention and treatment for illnesses, including complementary and alternative treatments.

While more conventional treatments for cancer, such as chemotherapy, radiation, and drug therapy are needed and should of course continue to be an option for anyone suffering from this terrible disease, we should also look to other less intrusive and less expensive treatments.

The National Cancer Institute estimates that there will be 175,000 new cases of breast cancer diagnosed this year. Additionally, 12,800 new cases of cervical cancer; 25,000 new cases of ovarian cancer; and about 35,000 new cases of endometrial cancer are diagnosed each year. In my home state of Vermont, 330 new cases of breast cancer were diagnosed in 1997. Cancer in fact accounts for approximately 26 percent of all deaths in Vermont.

While some tests are in place to detect early forms of cancer, such as Pap smears, mammograms, ultrasound and self-exams, we need to find other reliable, safe testing methods. For example, there is no reliable early detection for ovarian cancer, and 75 percent of ovarian cancers are not detected until late stage, at which time there is only a 25 percent survival rate. And even though mammograms certainly help detect many breast cancers, many tumors also go undetected. Thermography is an alternative low-cost and non-invasive procedure that can detect changes in breast tissue earlier than mammograms. I am interested in hearing more about this procedure from our panel today.

With regard to cervical cancer, I want to state how important it is to provide access to Pap smears to younger women. My state of Vermont has done a good job in lowering the eligibility age for low-income women to have access to Pap smears. However, those age 18 to 40 still do not have access. I hope that we can increase the Medicare reimbursement rates for these tests and encourage more insurance plans to cover them for younger women.

I want to spend a few minutes talking about complementary and alternative treatments for cancer, as well as access to clinical trials. Often, a clinical trial is the only treatment available to women with certain forms of cancer. Once the therapy is found to be safe and promising, a study can be opened up to see how well it treats patients. However, while these clinical trials can be lifesaving, there are often barriers to patients' participation. One barrier is lack of insurance coverage, both with private insurance and under Medicare. Legislation has been offered this year, which I am supporting to allow Medicare coverage of clinical trials. However, problems still arise even if an insurance company is willing to pay for treatment.

One of my constituents is suffering from ovarian cancer. She and her physician found out about a clinical trial for a drug therapy that could potentially benefit her. However, even when she agreed to sign a liability waiver, pay for the treatment herself, and be exempted from the actual study, the pharmaceutical company sponsoring the trial refused her admission. Even though her congressional representatives, physicians, oncologists, and others advocated for her, the pharmaceutical company refused to let her in. Thankfully, she was able to receive other treatment, but the bottom line is that she should not have had to try so hard to get the treatment she needed.

Several forms of complementary therapies for cancer have been used by many Americans suffering from this disease. These therapies can include meditation, massage therapy, certain teas to help with nausea, biofeedback, and acupuncture. All of these treatments have been effective in treating symptoms of cancer.

I hope that the National Center for Complementary and Alternative Medicine (NCCAM) will continue to receive support to conduct

research on complementary and alternative therapies for cancer and other ailments.

Again, I thank the chairman for calling this hearing to investigate what measures are being taken to try to find new and effective prevention and treatment measures, both in the fields of "traditional" and complementary and alternative medicine, to try to put an end to these terrible women's cancers and in fact, all cancers.

Mr. BURTON. Thank you very much, Mr. Sanders.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. I want to thank you also for holding this important hearing. During my tenure in Congress, I have been very actively involved in women's health issues, as you know, as a member of the Congressional Caucus on Women's Issues, and former chair. I have been working with my colleagues very diligently to increase the funding for women's health, including breast, ovarian, and cervical cancer research. As Chair of the Technology Subcommittee of the Science Committee, I have been working to facilitate technology transfers between Government agencies and the private sector. Efforts such as missiles to mammograms, that project between the Public Health Service, the Department of Defense, the intelligence community and NASA, are critically important in applying new technologies to the fight against breast cancer.

The Congressional Caucus for Women's Issues has spent a great number of years attempting to address the neglect of women's health research at the National Institutes of Health, which as you know, is in my district. The caucus asked the General Accounting Office back in 1989 to investigate the NIH policy regarding the inclusion of women in clinical studies. Women had been routinely excluded from many studies, such as the physicians health study, which studied the effects of aspirin on heart disease on 22,000 male physicians. Just this week, however, I found it astounding. I read in the Washington Post that "drinking at least two cups of caffeinated coffee a day lowers a man's risk of developing gallstones." Now more than 46,000 men took part in this study that spanned a decade. But what about women?

In 1990, the caucus introduced omnibus legislation, the Women's Health Equity Act, which included the establishment of the Office of Research on Women's Health, and the requirement that women and minorities be included in all the clinical trials and protocols wherever appropriate in research studies funded by NIH. That has been working. In the fall of 1990, in a meeting of caucus members, NIH announced the formation of that office and quite frankly, we codified it in Congress, so it is a permanent office. Since that time, great progress has been made in funding for women's health concerns, particularly breast, ovarian, cervical cancer, osteoporosis, and the Women's Health Initiative. For example, breast and ovarian cancer funding at NCI, the National Cancer Institute, has more than quadrupled since 1990.

Recently, I initiated a letter to the House Subcommittee on Defense Appropriations, asking for continued funding for the Department of Defense peer-reviewed breast cancer research program for fiscal year 2000. You know that we have 223 Members of this House who have signed onto that letter.

However, our job is far from over. Despite great strides in women's health research, we still have to be vigilant, have to address issues that aren't receiving public attention and research priority that they deserve. That is why I think we are all open to the suggestions and enhancing alternative medicines too.

More than 14,000 women will die of ovarian cancer this year. Early detection is essential in the treatment of ovarian cancer. Yet

there is no reliable early detection test. We know that if diagnosed and treated early, the survival rate for ovarian cancer is 95 percent. However, there are no obvious signs or symptoms until late in its development, and only about 25 percent of all cases are detected at the localized stage. Congresswoman Mink has been very much involved in that project.

There are 2.6 million women living with breast cancer in the United States today. Each year, approximately 175,000 women are diagnosed, 43,300 women will die of breast cancer, which is the leading cancer among women. Despite these frightening statistics, there are only three methods for detecting breast tumors, self examination, a clinical breast exam by a physician, and the mammogram.

I do want to comment that the first panelist is Priscilla Mack, as you mentioned. I am just very proud of the fact that she is the executive co-chair of the Susan G. Komen Race for the Cure. I have a picture of Priscilla that was taken of my running in the race just last Saturday. It was the 10th anniversary; 67,000 people ran in that race, bringing in a great deal of money which will help with all the research projects. I am sure you will tell us about that.

As an aside, since we are all affected in some way by cancers that affect women, my sister died 23 years ago of cancer. At that time, we began raising her six children, I think successfully.

Lung cancer kills more women than breast cancer. Yet there has been very little emphasis on lung cancer in general. In 1998, 23,000 women died of lung cancer. Between 1974 and 1994, there was a 147 percent increase in women diagnosed with lung cancer. Lung cancer tends to be a silent disease, and there are no good early detection programs in place for women or for men.

So, Mr. Chairman, I applaud you for holding this important hearing on the early detection and alternative treatment of women's cancers. I look forward to the testimony from the experts and from those who have had some experience. Again, I applaud you. Thank you. I yield back.

Mr. BURTON. Thank you, Mrs. Morella. I was looking at this picture of you in the race. What was your time? [Laughter.]

Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman. Thank you for your continuing leadership in this area and for the participation of members on this panel, as well as our guests here today.

Over 500 years ago, people thought the Earth was flat. It caused many not to want to go on a voyage that could cause them to fall off the corner of the Earth. Today there are still people who think that illness and disease is something that's outside of us and that we can turn our health over to other people who will then tell us how we can be healthy. But through the work of people like Michio Kushi, who is one of the panelists today, we have learned that we have the ability to take responsibility for our own health. What a miracle that is. Think about that for a moment. That the conditions which create disease may come from things that we do. So if that is in fact the truth, how empowering it is that we can have some control over the conditions which are internal to our disease and which become externalized and can cause us to have a debilitation in our quality of life.

Mr. Kushi, in joining this panel today, brings to it a tremendous amount of experience in his work as one of the foremost proponents in the world of macrobiotics. As all of the students of Greek and of medicine know, macrobiotics comes from the word "macros" and "bios" in Greek, which means a great life or long life. That was a term that was coined by Hippocrates about 2,500 years ago.

Today people know macrobiotics in a much more popularized way through foods like brown rice and seitan, which is a wheat cutlet, whole wheat sourdough bread, vegetable sushi, and rice cakes. The standard macrobiotic diet has been practiced widely throughout history by all major civilizations and cultures. The diet centers on whole cereal grains and their products and other plant qualities.

Over the last 30 years, Michio Kushi has taught throughout the United States and abroad, giving lectures and seminars on diet, health consciousness, and the peaceful meeting of eastern and western philosophies. In 1978, Mr. Kushi and his wife, Adaline, founded the Kushi Institute, which is an educational organization for the training of future leaders of society, including macrobiotic teachers, counselors, and cooks. The Kushis in 1986 founded One Peaceful World. It is an organization which provides information on macrobiotics and helps to guide society toward world health and world peace.

Now one of the things that I think ought to be called to the attention of the Members before we begin hearing from the witnesses because many of you are already aware of this, later this year, the National Institute of Health is expected to issue a long-awaited study on the macrobiotic approach to cancer, which is currently being completed by researchers at the University of Minnesota and at Harvard University. Another report, which is a case control study from Italy, shows that macrobiotics can significantly lower the risk of breast cancer. That report is awaiting publication.

The American Cancer Society describes macrobiotics as "the most popular anti-cancer diet" today. On its Internet site, the American Cancer Society states,

> Macrobiotics may help prevent some cancers. It may reduce the risk in developing cancers that appear related to higher fat intake such as colon cancer and possibly some breast cancers. The macrobiotic diet, like other fat free diets, can lower blood pressure, and perhaps reduce the chance of heart disease. Taking part in a macrobiotics program may provide some sense of balance with nature and harmony with the total universe, and as such, promote a sense of calmness and reduce stress.

So when we think in terms of health today, perhaps rather than thinking in terms of simply winning a war with cancer, we can also look toward changing the analogy and talk about prevention of cancer, because some see cancer as a lack of balance. As we bring our bodies more into their natural harmony, as Mr. Kushi I'm sure will be testifying about, we can find that conditions of health can be created where some may have thought previously it was impossible to do so.

So this hearing today, through the testimony of the witnesses and through the testimony of other experts, such as Mr. Kushi, will be an exercise in raising the Nation's consciousness over the importance of looking at alternatives to healthcare, the importance of finding better ways to treat disease, and the importance of giving individuals an opportunity to reclaim power in their own lives to

improve the quality of their lives, and through their courage and example, give others hope that they can do the same.

So, with that, Mr. Chairman, I thank you very much for your efforts in calling these hearings. I look forward to the testimony of the witnesses. I am awaiting a call to go to the floor for the debate on the Kosovo spending bill, so I may not be able to be here the whole time, but I appreciate being here now.

Mr. BURTON. Thank you, Mr. Kucinich. You have been a big help. I appreciate your continued assistance.

I might just hold up before our next member speaks, that these are some of the books that Mr. Kushi has, co-written by Mr. Alex Jack. Here's a book also, "Let Food Be Thy Medicine." There are a number of books out like this. I am not just touting these particular books. I don't get a commission. But I think it's really important for anybody who is watching on television, who is in the audience, to take a look at some of these books because change in diet I think has been proven, and will be proven in the future, to be a real help in preventing various forms of cancer.

With that, Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman. May I, like my colleagues, thank you and compliment you on your initiative in holding this hearing. As a Chair last year, along with Nancy Johnson of the Women's Caucus, I am particularly appreciative for this effort.

The Women's Caucus has perhaps devoted more of its time to cancer, and especially breast cancer but other forms as well, including ovarian cancer, than it has to any other women's issue. Last year, when Tamoxifen was announced as a drug that had proved so effective in treating breast cancer that they were stopping the trials and letting it go forward, we held a whole hearing on that with the Surgeon General, the FDA, and others coming in, including women who had participated in the trials.

The progress in dealing with women's cancers is so extraordinarily hopeful today. Just yesterday a major controversy resurfaced that arose last year about whether women should begin to have mammograms at 40 or 50, where the women in Congress took the position that they should begin at 40. Where there is some difference among the experts, then for goodness sakes, let's err on the side of the expert that may save the most lives. Now there is an additional study just announced yesterday that affirms 40 as the age that you should start mammograms.

Just today, I believe—again, I'm thinking it was yesterday, perhaps reported yesterday—a study again reported confusion among women and families about the role of estrogen. We are told that estrogen in fact does tend to be a factor in some breast cancer, but those are the breast cancers that are easiest to combat, and that apparently it is not as much of a factor as we thought.

We all know that the most effective thing that a woman and a family can do to prevent breast cancer is early screening, and that an early mammogram could not be more important. We had come to the point where breast cancer was breaking down along income lines and insurance lines. I am very pleased at the way in which mammograms, or mammography, has become available to low income women and minority women who were being left out, and

therefore, being subjected to discovery of their cancers much later, when they are often not curable.

The fact is that breast cancer, for example, and ovarian cancer are becoming curable diseases based almost entirely on early detection. Therefore, the emphasis on prevention in this hearing could not be more important. We are learning that cancer is many different diseases that act like, or at least a disease that acts like many different diseases. I am going to say for that reason, cancer is nothing to play around with. Prevention and, once the disease sets in, responsible treatment is going to be very important. The notion of alternative medicine, it seems to me, is critical here. If you believe that prevention is the best cure, the developing science on the role of fat and diet must be taken very seriously, not only with respect to women's cancers, but generally.

What I would like to leave the hearing with—and I hope to be able to stay through most of it, I am going to have to come and go because of other hearings—is with what I regard as the great need. That is a word that I will take from what the chairman said. He used the word "integration." That is to say the integration of so-called alternative medicine with traditional medicine as is practiced largely in the West. The fact is, that the reason that we are able to cure so much cancer has to do with the genius of American medicine. Now if we look further into alternative medicine, we may find the genius that enables us to help prevent cancer. Then we will be able to bring the two together in a successful integration.

I would hate to see the development of polar notions of medicine, that there's alternative medicine, and then there's the other medicine. That is a tragedy. That is a false dichotomy. Moreover, we should not allow different sets of standards to develop for testing what is effective. Women have a right to know from their government what is effective, whether it comes out of nature in some pure sense or whether it is manufactured by a pharmaceutical company, and the role of government is to make sure that somehow, we can do our best work by finding safe, economical ways to integrate so-called alternative medicine with more traditional medicine so those words disappear and it's all medicine.

Finally, Mr. Chairman, let me say that with the members of the Women's Caucus, I went to the Labor, HHS, Appropriations Committee where we go every year. Instead of talking about the diseases of women, I proposed a new program which I call LIFE. I chose that acronym for lifetime improvement in food and exercise, because I am appalled at the way in which, particularly the baby-boomers and children, are setting themselves up for cancer, diabetes, arthritis, and every deadly disease known to man through overweight and obesity. The notions of fat and diet are very important, but they are important because of the natural ways in which they prevent disease.

I look forward to what our witnesses will have to say about not only their experiences, but also about these ways of preventing similar experiences. If I could just say on a personal note that I particularly am pleased to welcome Mrs. Connie Mack, because her husband and I have worked as closely together as I have with any Member of the Senate or the House. He is not of my party. He has been extraordinary in the way in which he has used his problem-

solving skills to work with me on tax matters. I know any man that is as good as that must have an awfully good woman for a wife.

Thank you, Mr. Chairman.

Mr. BURTON. I am sure that Priscilla guides him in everything he does.

Mrs. Mink.

Mrs. MINK. Thank you, Mr. Chairman. I, too, want to join my colleagues in commending you for calling these hearings on such an important matter as the discussion on the needs for early detection and discussions of other kinds of preventive measures that could be taken with respect to women's health issues.

Mr. Chairman, for 8 years I have been trying to get the Congress to focus on the one issue that I thought was terribly neglected, having to do with the research necessary for finding some way in which we could detect the presence of ovarian cancer early enough to assure that the life of the woman could be saved. I discovered in 1991 through efforts by researchers at NIH and elsewhere, that only $8 million of the entire NIH budget was devoted in any respect to the research needed in ovarian cancer. Notwithstanding efforts of hundreds of women on this specific issue, we have only risen to a paltry level of $40 million. I have legislation, and Mr. Chairman, in which I invite your cosponsorship, calling for a budget of $150 million, which even by itself is modest if we are to really put the research efforts that are there to discover a reliable early detection test that could save lives.

It is important to talk about prevention and all the other aspects of your hearing today, but it seems to me that with the scientific knowledge and the intelligence and training and research capabilities of our health researchers throughout the country, that we ought to be able to find a reliable test that could save thousands of lives of women who are diagnosed today, too late to have their lives saved. So many of these women are young, just beginning in their life situation. It is something which I feel very, very strongly about that has been neglected.

Mr. Chairman, this is really the first hearing in all these years of effort to call attention to this deplorable situation and neglect, that we have allowed. I have been to the Appropriations Committee, as my colleague here has indicated, every year, asking for earmarked money for this research effort. The Appropriations Committee has refused to earmark any money for ovarian cancer research. They have included report language, but never any earmarked money.

So I urge my colleagues to consider the legislation that is before this body, and join me in cosponsoring. I believe it is essential, and I believe that we are on the threshold of a research breakthrough. What is required is a commitment on the part of this Congress to steer our health research industry to focus on this very, very pathetic neglect. If we can clone sheep and mice and other things with our incredible intellectual capability, it seems to me that within a few short years, we ought to be able to come up with a reliable

test that could save thousands of lives each year. I implore this committee to continue this effort in calling attention to this serious health research neglect.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Patsy T. Mink follows:]

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DEMOCRATIC CAUCUS EDUCATION AGENDA TASK FORCE, CO-CHAIR

STATEMENT BY CONGRESSWOMAN PATSY T. MINK
COMMITTEE ON GOVERNMENT REFORM
JUNE 10, 1999
FULL COMMITTEE HEARING ON THE ROLE OF EARLY DETECTION AND COMPLEMENTARY AND ALTERNATIVE MEDICINE IN WOMEN'S CANCERS

Mr. Chairman,

First, I would like to commend the Chair for scheduling a hearing on this very important subject of early detection and complementary and alternative medicine in women's cancers. This is truly a subject that deserves more attention.

I will focus my statement on a cancer that is often overlooked and is known as the "silent killer" – Ovarian Cancer. Ovarian cancer is the leading cause of death from gynecologic cancers in the U.S. Although it accounts for a quarter of all gynecologic malignancies, it is responsible for half of all gynecological cancer deaths.

I emphasize the need for additional ovarian cancer research because the woeful fact is that while we have been pouring billions of dollars into cancer research, and although we have made significant gains in the detection of certain cancers, death rates for ovarian cancer have remained the same for the last 50 years because we have failed to produce an early detection method for ovarian cancer.

Although the five-year survival rate for ovarian cancer patients diagnosed in the early stages is near 90 percent, very few are diagnosed at this stage. The vast majority of all ovarian cancer patients, a whopping three-fourths, are diagnosed in the later stages when the five-year survival rate is only 15 to 20 percent.

After an early detection method was developed for cervical cancer, its mortality rates decreased by 70%. With a 90 percent five-year survival rate for ovarian cancer if detected in the early stages, and more than 25,000 new ovarian cancer cases diagnosed each year, imagine how many lives we could save if only we developed an early detection method for ovarian cancer.

In an attempt to stimulate research in ovarian cancer, I have introduced legislation to increase research efforts for ovarian cancer in each Congress since 1991 when a mere $8 million was spent at the National Institutes of Health on this research. In 1999 that level was more than $40 million but that is still not enough.

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My most recent legislation is H.R. 961, the Ovarian Cancer Research and Information Amendments of 1999. H.R. 961 has three components. First, it authorizes $150 million for ovarian cancer research. One half to be spent on basic cancer research and one half for clinical trials and treatment.

Of this research, the bill requires that priority be given to: developing a test for the early detection of ovarian cancer; research to identify precursor lesions and research to determine the manner in which benign conditions progress to malignant status; research to determine the relationship between ovarian cancer and endometriosis; and requires that appropriate counseling, including on the issue of genetic basis, be provided to women who participate as subjects in research.

Second, the bill provides for a comprehensive information program to provide the patients and the public information regarding screening procedures; information on the genetic basis to ovarian cancer; any known factors which increase risk of getting ovarian cancer; and any new treatments for ovarian cancer.

Finally, it requires that the National Cancer Advisory Board include one or more individuals who are at high risk for developing ovarian cancer.

I would encourage all of my colleagues to cosponsor this bill if that haven't already done so.

Although I am disappointed that we do not have any ovarian cancer survivors on the panel today, I am believe many of the panelists are familiar with ovarian cancer and I am hopeful they will include references to it in their remarks as well.

Mr. Chair, I thank you for this opportunity to express my views and for calling this hearing.

Mr. BURTON. Thank you. I will be happy to cosponsor your legislation. I think Dr. Beilin may have some information that might be helpful in the research toward these cancers.

Mrs. MINK. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Are there any other Members that wish to be heard? Mr. Ose. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. As I look down our list of witnesses, it makes my heart glad to know that they are all in this room. They are special people who have decided that they want to touch other people's lives and are doing so every day. So I thank them for being with us today. I look forward to your testimony.

Mr. Chairman, I am also pleased that this hearing regarding detection and treatment of women's cancers has been scheduled today. The medical and scientific community has made tremendous breakthroughs in the early detection and treatment of women's cancers in the past few years. Even with all the options currently available for the early detection and treatment, the estimates for new incidences of these cancers are unacceptable. The National Cervical Cancer Coalition estimates that 2 million American women will be diagnosed with breast or cervical cancer in the 1990's, and half a million will lose their lives. A disproportionate number of deaths will occur among minorities and women of low income.

It is interesting that in my district in Baltimore, sits Johns Hopkins Hospital. Johns Hopkins does a tremendous job of outreach, but at the same time, I know many women who are dying of these cancers every year. Virtually all of these deaths can be prevented by making life saving screening services available to all women at risk. Common barriers to early detection screening include, and this is very interesting, women attempting to escape knowledge that they have cancer, prohibitive costs and unawareness of the availability of low cost programs, lack of access to transportation to screening locations, communication barriers, lack of physician referrals, and lack of childcare.

The Breast and Cervical Cancer Mortality Prevention Act of 1990 authorized the Center for Disease Control to implement a national cancer screening program. Through September 1996, the CDC has provided more than 1.2 million screening tests to low income, uninsured, or under-insured minority women.

Alternative and complementary approaches to treating these cancers have also gained momentum. In 1998, the National Center for Complementary and Alternative Medicine was established within the National Institutes of Health. This has effectively engaged traditional biomedical research in the evaluation of alternative medical treatment using scientific models. However, until more is known about the many alternative and complementary treatments, conventional treatment methods hold the most promise. We hope for a cure in the near future. In the absence of a cure, the ability to implement a national program to detect and treat women's cancers depends in large part on the involvement of various partners in State and local governments, physicians, national and private sector organizations, and consumers.

In the spirit of greater understanding and education of varied treatments of this disease, I look forward to hearing the experiences and opinions of today's witnesses. Thank you.

[The prepared statements of Hon. Elijah E. Cummings, Hon. Edolphus Towns, and Hon. Louise Slaughter follow:]

Alternative and Complementary Treatments for Women's Cancers

Statement - Congressman Elijah E. Cummings
Thursday, June 10, 1999

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Virtually all of these deaths can be prevented by making lifesaving screening services available to all women at risk. Common barriers to early detection screening include:

- women attempting to escape knowledge that they have cancer;
- prohibitive costs and unawareness of the availability of low-cost programs;
- lack of access to transportation to screening location;
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We hope for a cure in the near future. In the absence of a cure, the ability to implement a national program to detect and treat women's cancers depends in large part on the involvement of various partners in state and local governments, physicians, national and private sector organizations, and consumers.

In the spirit of greater understanding and education of varied treatments of this disease, I look forward to hearing the experiences and opinions of today's witnesses.

Opening Statement of the Honorable Edolphus Towns
Subcommittee on Government Reform and Oversight
" The Role of Early Detection and Complementary and Alternative Medicine in Women's Cancers"

June 10, 1999

Mr. Chairman, I want to thank you for holding this hearing on "Early Detection and Complementary and Alternative Medicine in Women's Cancers."

It is obvious that part of our overall mission is to ensure the protection of the nation's health to the best of our ability. With the assumption of this premise in mind it is only natural that we direct our attention to the leading proponents which prevent us from achieving our objectives. From my own work with this committee, I know that early detection is particularly important to a disease like breast cancer. The Human Resources Subcommittee, established through a series of hearings, that the early detection of this disease is vital in reference to the parallel mortality rates of those diagnosed with breast cancer.

From 1989 until 1993 recommendations were made on the part of the National Cancer Institute toward the necessity in biennial mammography for women between the ages of 40-49. The aforementioned recommendation was constructed with the combined efforts of both the National Cancer Institute and 12 other major cancer research organizations. At the conclusion of 1993, the National Cancer Institute revised its prior recommendation, restricting the necessity of mammography to include only those women beyond the age of 50. It should be noted that this revision was not done with the consensus of the nation's leading cancer societies that had played an instrumental role in the initial

recommendation.

The American Cancer Society has recently delivered statistics, which have only served to confirm the need for this country to continue with any and all mandates condoning methods which assist in the earliest possible detection of breast cancer. Their estimates show approximately 46,000 breast cancer deaths in 1994, of those 13,800 could have been saved with early detection. Women have a 93% chance of five-year survival when the cancer is diagnosed at the earliest stage, yet this rate dramatically plummets with each subsequent stage. The five-year survival rate drops to 18% for those whose cancer has reached the distant metastases stage at the time of diagnoses.

The American Cancer Society, and Howard University, have both confirmed that African American women are not only more prone to develop breast cancer, but more likely to develop the disease between the ages of 30 and 40, ten years prior to their white counterparts. Howard University Hospital shows that 30% of all breast cancer cases diagnosed in African American patients occurred in those under the age of 50. In addition, of those 30% diagnosed while less than 50 years of age, *40.4% were under 40.* Considering the consistency of African American women developing breast cancer at an earlier age, as well as the statistics regarding the rapidly increasing mortality rate with each passing stage of the cancer, it becomes obvious that African American women are in need of mammograms early on in their lives. With the National Cancer Institute pushing for more lenient mammogram implementations, it is no surprise that the African American, breast cancer mortality rate is 25% higher than the national average.

The facts upon which the cancellations of earlier mammography screenings were based, came from Randomized Clinical Trials known as RCT's. These trials include a diverse pool of different demographic groups, and ages, lending to a very general overview of mammography effectiveness. These trials, which were used by the NCI for justifying their recommendation revision, did not adequately concentrate their studies toward answering questions toward mammography effectiveness on women between 40-49. There has never been a study concentrated solely on this age group other than a Canadian Study(conducted by the Canadian National Breast cancer Screening Study) which has been blasted for wrongful analysis due to faulty screening methods.

Experts agree that routine mammogram screening is presently the most effective way of decreasing the breast cancer mortality rate. The above statistics show that any rise in the recommended age for regular mammograms will have a significant, detrimental effect on the minority female population in particular, as well as the entire female population in general. The initial recommendations made by the National Cancer Institute have sent a very direct message to the female population, - that early, and frequent mammograms save lives. To date there is so solid evidence to the contrary, and until there is, a change in policy would have only confused the population, leading to further insecurities, not to mention a lack of faith in the recommendations of the National Cancer Institute. To say that women do not require testing before reaching age 50, is to ignore the realities of this disease. The National Cancer Institute revision did not conduct adequate research in the direction of women between 40-49 and by no means should they have allowed women to

possibly be at risk until they could solidly prove otherwise. That is why I introduced H. Res. 40 in the 104th Congress which urged the National Cancer Institute to ensure that mammograms remain accessible to the 40,000 women between the ages of 40 and 50 who are expected to be diagnosed with breast cancer each year. This resolution ultimately resulted in NCI reinstating its recommendation for mammograms to begin at age 40. Mr. Chairman, I am hopeful that today's hearing will further highlight the need for early detection in the treatment of breast and other cancers.

Testimony of Rep. Louise M. Slaughter
before the House Government Reform Committee Hearing,
"Winning the War Against Women's Cancers"

June 10, 1999

Mr. Chairman, I thank you for the opportunity to submit testimony at this timely hearing, "Winning the War Against Women's Cancers." I commend you for bringing attention to this vital issue and applaud your leadership.

As you know, Mr. Chairman, I am proud to have a long history of activism in Congress on women's cancer issues. As a member of the Budget Committee, I was responsible for proposing that Congress earmark the first $500 million specifically dedicated to breast cancer research back in 1990. During the early 1990s, I served as the official spokeswoman of the Strang Cancer Prevention Center and I have spoken out in dozens of forums in support of women having regular mammograms, Pap smears, and other cancer screening exams.

Today I would like to take this opportunity to call the Committee's attention to two lesser-known women's cancers: colorectal cancer and clear cell cancer of the vagina. The former is quite common, while the latter is very rare. Yet both have in common a great need for increased education and awareness among American women.

Colorectal cancer is the third most common cancer diagnosis among American women, with an estimated 67,000 new cases expected to be diagnosed in 1999. Many women still consider colorectal cancer to be a man's disease, when it actually strikes men and women at equal rates. Over 28,000 women will die from this cancer in 1999, despite the fact that colorectal cancer is completely preventable and highly treatable when detected early. It is a public health tragedy that so many women die from this disease each year -- most because their cancer was not detected until a later, less treatable stage.

We need to bring colorectal cancer "out of the closet," just as we did with breast cancer a decade ago. American women should not be dying simply because they are unaware that everyone over the age of 50 should have an annual colorectal cancer screening exam. If polyps are detected in the colon, they can be removed before they ever become cancerous, making colorectal cancer one of the only totally preventable cancers. When colorectal cancer is detected at its earliest stage, it is 91 percent curable. Yet only 37 percent of colorectal cancer cases are detected at this early, highly treatable stage. Despite the fact that simple, effective, affordable colorectal cancer exams exist, fewer than 20 percent of Americans engage in regular colorectal cancer screening.

Clearly, we must do more to educate American women about the need for regular colorectal cancer screening. Last year, I worked closely with House Appropriations Labor, Health and Human Services, and Education Subcommittee Chairman John Porter to obtain language in his subcommittee's Fiscal Year 1999 report directing the Secretary of Health and Human Services (HHS) to implement a nationwide education and awareness campaign on

colorectal cancer. I am pleased to report that HHS and the Centers for Disease Control and Prevention kicked off this campaign in early March. This effort will use many of the same tools that were so effective in educating women about the need for regular mammograms. I look forward to seeing this initiative bear fruit in the form of higher rates of colorectal cancer screening and, consequently, much lower death rates from this disease.

I would now like to turn your attention to a very rare women's cancer known as clear cell cancer of the vagina. Virtually every case of this cancer in the United States can be traced back to a single cause: exposure to the drug diethylstilbestrol, or DES. DES was prescribed to pregnant women between the late 1930s and the early 1970s in the mistaken belief that it would prevent miscarriage. Not only did DES fail to impact miscarriage rates, but it had serious health consequences for many of the children exposed in utero. For girls exposed in utero, perhaps the most devastating effect was the risk of developing clear cell cancer of the vagina. Until recently, this cancer was diagnosed almost exclusively in young women under the age of 25. Treatment involved a radical hysterectomy and removal of part of the vagina -- and, obviously, meant an end to fertility and childbearing.

In recent years, DES has continued to make its impact felt on DES daughters as they aged. Women in their 30s and 40s are now being diagnosed with new cases of clear cell cancer. Recurrences of this cancer continue to be untreatable, a certain sentence of death. Further, DES daughters face a range of other health consequences, including an increased risk of ectopic pregnancy and other pregnancy complications, infertility, and abnormalities in the shape of the vagina, cervix, or uterus. It remains unclear whether DES daughters or mothers have an increased risk for breast cancer.

As in the case of colorectal cancer, increased education is needed to inform American women about DES-related cancers and other disorders. The majority of DES daughters are not even aware that they were exposed. Some pregnant mothers took DES without ever knowing what it was, simply acting in the faith that their doctor was providing the best possible care. Some mothers have passed away without ever telling their daughters they took DES, or even knowing they needed to do so. It does not occur to most women to ask their mothers about this issue, given that so few people are aware of the health risks associated with DES exposure.

I was proud to author the DES Research and Education Act of 1993, which established the first permanent DES research and education efforts at the National Institutes of Health. Congress passed my legislation reauthorizing this statute in October. Pilot projects established under the 1993 legislation have yielded a wealth of information about the most effective methods of educating women about DES issues. HHS is now poised to expand these education efforts to more sites across the nation, informing women about the risks associated with DES exposure and the steps they need to take to safeguard their health.

Colorectal cancer and DES-related vaginal cancer are just two examples where we are making progress toward "winning the war against women's cancers." While these are important steps in the right direction, much more remains to be done. I look forward to working with you, Mr. Chairman, and with your committee toward that day when we can declare our final victory against women's cancers. Thank you.

Mr. BURTON. Thank you, Mr. Cummings.

We have two votes on the floor. We should be back here in about 15 minutes. I apologize to the people who will be giving testimony, but we will get right to you, just as soon as we get back. So please excuse us. We stand in recess to the call of the gavel, about 15 minutes.

[Recess.]

Mr. BURTON. The committee will come to order.

Sorry for the delay. We had some votes on the floor of the House. I am sure Members will be coming back in here as they leave the floor.

I would like for our first series of witnesses, Ms. Mack and Mr. Kushi, to come forward please and take their seats. Ms. Mack, you can sit on the left. Mr. Kushi can sit on the right.

I think I will recognize my colleague from Florida for an introduction.

Mr. MICA. Thank you, Mr. Chairman. I am, indeed, delighted to have this opportunity to introduce someone very special to me. For the past two decades, I have known the Mack family. I had an opportunity to be a friend and also recently to be a colleague of Senator Mack. I think that there have been several comments already about the Mack family. Certainly Senator Mack is a gentleman. We have a gentlelady with us today, his wife. Both are very accomplished in their particular areas of endeavor.

The Mack family, like many American families, and we have also heard that among our Members of Congress cited today, have been afflicted by the rages and ravages of cancer. Their family, the Mack family, has been victimized by this disease. Mrs. Mack, Priscilla Mack is a cancer survivor. What is great about Priscilla Mack is that she took this adversity and this disease and she turned it into a personal campaign of public awareness, a public education effort to have millions and millions of American women become aware of the need for prevention, self-examination, and the problems that are related to breast cancer.

So I am, indeed, delighted and privileged to introduce a leader in our State and in our Nation. She is really our first lady in Florida in the fight against cancer, and really our first lady in the Nation who has brought to the public, to the American women, the need again for early prevention, detection, and treatment.

So, Mr. Chairman, thank you for this honor and welcome, Mrs. Mack.

Mr. BURTON. Thank you, Mrs. Mack. I can recall back when Connie and I first got elected in 1908.

Mrs. MACK. It seems that long.

Mr. BURTON. It was 1982. Connie came over to my condo over in Alexandria. We sat on the floor and watched Chariots of Fire. You were down in Florida at the time. So Connie and I have been good friends for a long time, as well as you. I remember watching your boy grow up. So I am really happy you are here today.

Mr. Kushi, we are very happy you are here today. I am going to read your book. Hopefully that will save my life for a couple of years.

So we will start off with you, Mrs. Mack.

STATEMENTS OF PRISCILLA MACK, EXECUTIVE CO-CHAIR OF THE NATIONAL RACE FOR THE CURE; AND MICHIO KUSHI, THE KUSHI INSTITUTE, BROOKLINE, MA

Ms. MACK. Mr. Chairman, members of the committee, I would like to thank you for the opportunity to appear before the Committee on Government Reform, and I commend you for holding this important hearing. I am here both as a breast cancer survivor, as well as executive co-chairman of the Susan G. Komen Breast Cancer Foundation's National Race for the Cure.

In October 1991, I was diagnosed with breast cancer. Prior to the time of my diagnosis, I had followed all the recommendations with regard to having annual mammograms and clinical breast exams. However, it was through breast self-exam that I discovered my lump in my left breast. I underwent a modified mastectomy, followed by 6 months of preventative chemotherapy, 5 years of Tamoxifen. In May, the following year, I completed my reconstructive surgery.

I also want to note that I had had my mammogram 9 months before I found my lump. I had had my clinical exam 3 months before I found my lump. Early detection saved my life through my breast self-exam. Today I am a breast cancer survivor.

My goal is to share with as many women as possible the lessons I have learned as a breast cancer survivor. The most important lesson is a simple one, educate yourself. When confined to the breast, the 5-year survival rate is more than 95 percent. But women have to do three things, and through the American Cancer Society, of which I work also in Florida, we call it triple touch. You'll see when I mention these three things, why triple touch saved my life. One is your breast self exams monthly. Two, mammograms, as indicated by your physician. Three, your clinical exams. My message to women is simple but important. Early detection saved my life, and it can save yours too.

One of my efforts to help in the fight against breast cancer is my work on behalf of the Susan G. Komen Breast Cancer Foundation's National Race for the Cure. Since its inception 10 years ago, the race has grown to the world's largest 5K walk/run. The 10th Anniversary Komen National Race for the Cure took place this last Saturday, June 5, with the record number of 66,148 participants. I also found out that 43,000 crossed the finish line. I believe Congresswoman Morella was 1 of those 43,000.

We were honored that Vice President Al Gore and Tipper Gore served as our honorary chairs for the race. Breast cancer survivors took part in a special salute to survivors which began with an inspirational walk at the foot of the Washington Monument. We also had a large bipartisan contingency of Washington lawmakers and more than 2,500 participants from 72 countries around the world. Most importantly, thousands of my breast cancer survivors, wearing pink T-shirts, all participated from all across this great land.

Last year, the Komen National Race for the Cure awarded $1.8 million in grants to 24 Washington, DC, area hospitals, research centers, breast health organizations, and the national grant programs of the Susan G. Komen Breast Cancer Foundation. These grants provide funding for breast health programs including research, screening, treatment, and education programs.

This year, we are pleased to announce that we will give approximately $2.5 million in grants, to be awarded from this year's race. Since its inception, the Susan B. Komen Breast Cancer Foundation has raised more than $136 million through the work of its local affiliates in more than 100 communities across the country.

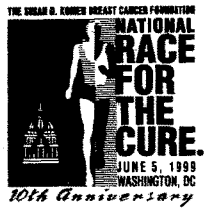
Once again, let me offer my heartfelt thanks to the many Members of the Senate and the House of Representatives who participate in the Komen National Race for the Cure series throughout the year. With each advance we make in finding a cure for breast cancer, we are one step closer to winning the race.

I would like to, before I close, mention to you all how cancer has touched our lives personally. Through this all, I want you to keep in mind that many of us are alive today because of early detection. My husband's mother was a 25-year breast cancer survivor. My husband's brother died of melanoma at the age of 35. His was not detected early. My daughter is a 10-year survivor of cervical cancer. Early detection saved her life. Because it was detected early, we now have a third grandson after the fact. She is in perfect health. My husband was diagnosed with melanoma right after he was elected to the Senate. Early detection and due to the profound experience we had with his brother, early detection saved my husband's life. Then I was diagnosed with breast cancer. Early detection saved my life. Unfortunately, Connie's mother died of renal cancer. Connie's father died of esophageal cancer. My stepmother died of ovarian cancer.

When we say early detection until we find a cure saves lives, meaningful things like this hearing and all that the doctors and the researchers are doing, I pray to God we'll end this dreaded disease.

Mr. Chairman, I thank you for the opportunity to appear before this committee.

[The prepared statement of Ms. Mack follows:]



STATEMENT OF MRS. PRISCILLA MACK
BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM
June 10, 1999

Mr. Chairman and Members of the Committee, I would like to thank you for the opportunity to appear before the Committee on Government Reform, and I commend you for holding this important hearing.

I am here both as a breast cancer survivor as well as Executive Co-Chairman of the Susan G. Komen Breast Cancer Foundation National Race for the Cure®.

In October of 1991, I was diagnosed with breast cancer. Prior to the time of my diagnosis, I had followed all of the recommendations with regard to having annual mammograms and clinical breast examinations. However, it was through breast self-examination that I discovered the lump in my left breast. I underwent a modified mastectomy followed by six months of preventive chemotherapy. In May the following year, I completed reconstructive surgery.

Today, I am a breast cancer survivor.

My goal is to share with as many women as possible the lessons I have learned as a breast cancer survivor. The most important lesson is a simple one: educate yourself. When confined to the breast, the five-year survival rate is more than 95%. But women have to do three things: self-examinations, mammograms and clinical examinations. My message to women is simple but important: early detection saved my life, and it can save yours too.

One of my efforts to help in the fight against breast cancer is my work on behalf of the Susan G. Komen Breast Cancer Foundation National Race for the Cure®. Since its inception 10 years ago, the Race has grown to be the world's largest five-kilometer run/walk.

The 10th Anniversary Komen National Race for the Cure® took place on Saturday, June 5, with a record 66,148 participants. We were honored that Vice President Al Gore and Tipper Gore served as Honorary Chairs for the Race. Breast cancer survivors took part in a special "Salute to Survivors," which began with an inspirational walk at the foot of the Washington Monument.

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Early detection saves lives: Complete a breast self-exam monthly. • www.natl-race-for-the-cure.org

INTERNATIONAL PAPER Printing by PEAKE

We also had a large bipartisan contingency of Washington lawmakers and more than 2,500 participants from 72 countries. Most importantly, thousands of my fellow breast cancer survivors wearing our pink T-shirts also participated.

Last year, the Komen National Race for the Cure® awarded $1.8 million in grants to 24 Washington, DC area hospitals, research centers, breast health organizations and the National Grant Program of the Susan G. Komen Breast Cancer Foundation. These grants provide vital funding for breast health programs including research, screening, treatment and education programs.

This year, we approximate that more than $2.5 million in grants will be awarded. Since its inception, the Komen Foundation has raised more than $136 million through the work of its local affiliates in more than 100 communities across the country.

Once again, let me offer my heartfelt thanks to the many Members of the Senate and the House of Representatives who participated in the Komen National Race for the Cure® events throughout the year.

With each advance we make in finding a cure for breast cancer, we are one step closer to winning the race.

Mr. Chairman, thank you for the opportunity to appear before this Committee.

Mr. BURTON. Thank you very much, Priscilla. It is good seeing you again. I was not aware of all the tragedies that your family had to endure. We have had some ourselves, but, that's a lot. So you are to be commended, and Connie is to be commended, for all the extra efforts you put forth to help out.

Mr. Kushi.

Mr. KUSHI. Thank you very much for this opportunity, Mr. Chairman and committee members, I very much appreciate the fact that conventional medicine has developed its technology with the goal of diagnosing and treating various illness. We desire the continuous support of the physical and the other approaches that conventional medicine offers for the treatment of sickness.

On the other hand, the conventional approach is a symptomatic approach, and therefore, does not focus on revealing or applying understanding of the cause which underlies disease. No. 2, professionals engaged in the practice of conventional medicine often lack an understanding and support of other healthcare approaches. No. 3, conventional treatment, including its methods of diagnosis has always produced side effects. This is especially true when treatments are over-applied, and often results in the severe suffering of those who receive such treatments. Four, conventional methods of diagnosis and medical treatment are always expensive and often beyond the average person's income. As a result, costs often become the responsibility and burden of the government, the public, and the insurance systems.

Based upon these points, the tendency of individuals to search out these alternative approaches, so-called alternative and complementary health practices, has increased over the past many years beginning, commencing from about 40 years ago. Currently, approximately 50 percent of those who are suffering from disease are searching for and receiving unconventional methods of treatment.

As a demonstration of these trends, consider the example of cancers that affect women. One, over the past 40 years, it has been my experience, as well as that of my associates, that many women are hesitant to receive chemotherapy, radiation, and the other intensive treatments. Two, many women who receive conventional care seek alternative methods as a result of intense suffering, both physical and emotional, that they experience by conventional medical treatment. They seek out milder approaches. Three, many patients desire to know the cause of the cancer from which they are suffering, yet they do not receive satisfactory answers.

The causes of women's cancer, as is true of the majority of physical and emotional sicknesses, lie in daily lifestyle and dietary practices. For example, in the case of breast cancer, the major causes are over-consumption of high-fat foods, including dairy food and simple carbohydrates such as refined sugar and sweets. In the case of ovarian cancer, the major dietary factors are the over-consumption of eggs and poultry, as are high fat, high cholesterol animal foods.

In the case of uterine cancer, dietary causes include over-consumption of animal foods and heavy dairy fats such as those found in cheese. In the case of cervical cancer, similar to prostate cancer in men, the primary dietary factors are the over-consumption of

oily and greasy foods, salty foods, hard baked flour products, and heavy animal foods. In the case of thyroid cancer, the primary causes are the over-consumption of eggs, poultry, dairy fats, and hard baked flour products. In the case of pancreatic cancer, consumption of poultry, cheese, shellfish, and hard baked flour products are contributing factors.

In the case of skin cancer, causes include over-consumption of oily foods, sweets, and dairy fat, high-fat foods. In the case of leukemia and lymphoma, dietary causes include over-consumption of dairy fats, sugar, and sweets, as well as oily and greasy foods. Over-consumption of stimulants and aromatic substances, such as hot spices, alcoholic beverages, and caffeine, accelerate the spread of the cancer condition.

Other lifestyle factors, such as cigarette smoking, physical inactivity, exposure to high levels of electromagnetic fields or radiation, and the consumption of chemically treated foods and water also contribute to the development of cancers. Non-organic chemically cultivated agriculture, irradiation, microwave cooking, and similar methods of unnatural food production and artificial processing, as well as daily unnatural lifestyle, are potential factors as well.

The macrobiotic approach, which attempts to correct these undesirable characteristics of the current American lifestyle and dietary behaviors, has been practiced by many individuals since the 1960's. Beginning as a grassroots movement, the macrobiotic approach has led to the initiation of the natural food movement and organic agriculture. The macrobiotic approach continues to gain popularity, and currently influences many millions of people. As a healthcare practice, this approach has helped to prevent disease and speed recovery times associated with numerous sicknesses, including many types of women's cancers.

Among those in today's audience, the following six or seven ladies are present that have experienced various types of cancer and also have recovered through the macrobiotic approach: Chris Akbar, a former physicist from Pennsylvania, who recovered 14 years ago from inflammatory breast cancer, which is predicted to have a lifetime of 2 or 3 months; Marlene McKenna, a mother of five, radio/television commentator, and investment broker from Rhode Island, who recovered 16 years ago from malignant melanoma spread to the small intestines; Judy MacKenney, a clothing designer from Florida, who recovered 8 years ago from non-Hodgkins lymphoma, stage 4; Kathleen Powers, Stone Mountain, GA, diagnosed in 1985 with endometrial cancer, stage 4, and diagnosed in 1993 with non-Hodgkins lymphoma, stage 3, terminal; Debora Wright, Athens, GA, diagnosed in 1995 with infiltrating ductal cancer, stage 2B; Lynn Mazur, Arlington, VA, diagnosed in 1989, Hodgkins lymphoma, stage 4B; Lizzz Klein, Tampa, FL, diagnosed in 1985, 30 various kinds of symptoms, including brain damage and breast cancer, suspected results due to breast implants; Mr. Norman Arnold, a business leader and philanthropist from South Carolina, who recovered 17 years ago from pancreatic cancer spread to the lymph and liver.

These ladies and gentleman will be available for interview later, if you wish. Not only have they survived their illnesses, but they have actively contributed to society for many years following recov-

ery, without recurrence of cancer. The majority of those cases were all terminal. These people are only a few examples of many who have recovered from cancer. In addition, many hundreds of women and men have received benefits from the macrobiotic approach.

The National Institutes of Health made a small grant of about $30,000 to the School of Public Health at the University of Minnesota. This fund was applied for the collecting of data and gathering of medical records. The data are now under review by a research group from Harvard Medical School and oncologists from Beth Israel Deaconess Medical Center in Boston.

In contrast to the conventional approaches, the macrobiotic approach also includes—not denying the conventional approach also, but also such practices as oriental herb medicine, acupuncture, moxibustion, and shiatsu massage, as well as other physical body care, emotional meditation, and psychological therapy practices, as they are necessary.

We highly recommend that the Government support the following: One, please make available public education regarding a proper healthy way of eating, mainly using grain and vegetable bases; and more natural lifestyles.

Two, increase funds available for research regarding the effectiveness of alternative and complementary approaches for both prevention and recovery, including diet and lifestyle as the base.

Three, make recommendations to all health facilities and medical schools to accommodate healthful menus and cooking instructions, as well as to teach a proper healthy lifestyle.

Four, advise selected hospitals or healthcare centers to establish a pilot plan for macrobiotic diet or similar diet and lifestyle, together with data creation as a clinical trial.

Five, please advise medical and healthcare professionals of simple, practical ways of diagnosis, based upon oriental diagnoses of the face, pulse, meridians, and vibration, in order to effect low-cost, early detection.

Six, establish community-based and school-based educational programs, including school lunch programs and high school home economics classes, to recover home cooking and healthy lifestyles.

Seven, we would be happy to cooperate with such governmental efforts or public efforts by dispatching or sending well-experienced macrobiotic educators, counselors, and cooking instructors to any potential facilities. We recommend the funding of educational training centers at the level of college or professional schools.

Women are, in my humble opinion, strong opinion, the center of love, beauty, health, and longevity, and happiness among humankind. Home and family are the base for health and happiness. If this country establishes these ways of health and happiness, and prevents and treats physical and emotional disorders in a more natural way, America will become a symbol of health and happiness for the entire planet. America will become a leading light for all humankind, beyond the establishments of power, politics, and economies. This is the way of a great America, to open a new era

of humanity for the 21st century. In this way, America will become the creator of one peaceful world for a healthy mankind.

Thank you very much for this wonderful opportunity.

[Applause.]

[The prepared statement of Mr. Kushi follows:]

The Role of Early Detection and Complementary and Alternative Medicine in Women's Cancers

Full Government Reform Committee Hearing
U.S. House of Representatives
2154 Rayburn House Office Building
10:30 a.m. Thursday, June 10, 1999

Testimony of Michio Kushi
62 Buckminster Road, Brookline, MA 02445
TEL: (617)566-6785 FAX: (617)734-0635

Dear Honorable Chairman and Government Reform Committee Members,

I appreciate the fact that conventional medicine has developed its technology for the diagnosis and treatment of various sicknesses, which are ever increasing and becoming more complex. We desire for the continuous support of its physical and chemical approaches for the treatment of sickness.

On the other hand, among people, and especially among those more intellectual, there has been rapidly increasing awareness of the limitations of conventional medicinal care. Such limitations can be summarized as follows:

1. The conventional approach is a symptomatic approach, not revealing and applying an understanding of the cause of these sicknesses, until very recent times.

2. Professionals engaged in conventional medicine often lack an understanding and support of other healthcare approaches.

3. Conventional treatment, including its way of diagnosis, has always produced side-effects, especially when treatments are over-applied, often to the extent of severe suffering of those who receive such treatments.

4. The conventional ways of diagnosis and medical treatment are expensive, often beyond the average person's income; this results in government or public or insurance systems needing to be applied.

Based upon these points, those who are dissatisfied with conventional medical approaches have searched for other health care approaches, which are comprehensively called "alternative and complementary health practices." Such tendencies have been increasing for the past forty years, and now about fifty percent of those who are suffering are searching for and receiving unconventional methods.

Let us use examples such as women's health, especially today focussing on the problem of cancer.

1. According to the experience of my associates and myself for the past forty years, many women are hesitant to receive chemotherapy, radiation, surgery, and other intensive treatments.

2. Many women who are under conventional care want to seek other ways because of their intense suffering experiences, both physically and emotionally. They seek other milder approaches.

3. Many patients wonder what is the cause of the cancer from which they are suffering, and yet they do not receive satisfactory answers.

The causes of women's cancers, as of most physical and emotional sicknesses, lie in daily lifestyle and dietary practices.

1. In the case of breast cancer, the major causes are over-consumption of fatty food, including dairy food, and simple carbohydrates, including refined sugar and sweets.

2. In the case of ovarian cancer, the major dietary factors are the over-consumption of eggs and poultry, as well as other high fat animal food.

3. In the case of uterine cancer, dietary causes include the over-consumption of animal food and heavy dairy fat, such as that in cheese.

4. In the case of cervical cancer, similar to prostate cancer in men, the primary dietary factors are the over-consumption of oily and greasy foods; salty foods; hard baked flour products; as well as heavy animal foods.

5. In the case of thyroid cancer, again eggs, poultry, dairy fat such as cheese, and hard baked flour products are the primary causes.

6. In the case of pancreatic cancer, poultry, cheese, shellfish, and hard baked flour products contribute.

7. In the case of skin cancer, the causes include oily foods, sweets, and fatty foods.

8. In the case of leukemia and lymphomas, the dietary causes include the over-consumption of dairy fat, sugar, and sweets, as well as oily and greasy foods.

Over-consumption of stimulants and aromatic substances, such as hot spices, alcoholic beverages, and caffeine, accelerate the spread of a cancer condition.

Of course, lifestyle factors, such as exposure to high electromagnetic fields or radiation or smoking may accelerate the development of cancer, as does consumption of unnatural chemically-treated food and water. Non-organic chemically-cultivated agriculture, irradiation, microwave cooking, and other such methods of unnatural food production and artificial processing, along with daily unnatural lifestyle, are seriously questionable as well.

The macrobiotic approach, which tries to correct these undesirable points of current American lifestyle and dietary practice, has been practiced by many people since the 1960's, beginning from the grassroots. It initiated the natural food movement and organic agriculture, and now is spreading to many millions of people. As a healthcare practice, this approach has helped to prevent and to effect recovery from many, including many kinds of women's cancers.

Among those in today's audience, the following ladies and gentlemen are present:

Christine R. Akbar
A former physicist from Bethlehem, Pennsylvania, who recovered 14 year ago from Inflammatory Breast Cancer, 2 to 3 months predicted lifetime

Mr. Norman J. Arnold
A business leader and philanthropist from Columbia, South Carolina, who recovered 17 years ago from Pancreatic Cancer spread to the Lymph and Liver

Lizzz Klein
A businesswoman and inventor from Tampa, Florida who was diagnosed in 1985 with 30 various symptoms, including Brain Damage and Breast Tumors, suspected due to breast implants

Judy MacKenney
A clothing designer from Nokomis, Florida, who recovered 8 years ago from Non-Hodgkins Lymphoma, Stage IV

Lynn Mazur
A public relations professional from Arlington, Virginia, who was diagnosed in 1989 with Hodgkins Lymphoma, Stage IV-B

Marlene McKenna
A mother of five, radio/television commentator, and investment broker from Providence, Rhode Island, who recovered 16 years ago from Malignant Melanoma spread to the Small Intestines

Kathleen Powers
A real estate professional originally from Ft. Myers, Florida, who was diagnosed in 1985 with Endometrial Cancer, Stage IV; and diagnosed in 1993 with Non-Hodgkins Lymphoma, Stage III, terminal

Debora Wright
A graphic designer/yoga teacher from Athens, Georgia, who was diagnosed in 1995 with Infiltrating Ductal Breast Cancer, Stage II-B.

Later, if you wish, these ladies and gentleman can be interviewed. They have not only survived, but have been actively contributing to society for many years after they recovered, without recurrence of cancer.

These people are only a few examples of the many who have recovered from cancer. In addition to them, many hundreds of women and men have gotten benefits from macrobiotic practice.

The National Institutes of Health made a small grant of about $30,000 available through Department of Public Health of Minnesota University. This fund was to be applied for collecting of data and gathering of medical records. The data are now under review by a research group of Harvard Medical School and oncologists working at Beth Israel Deaconess Medical Center in Boston.

Sharply contrasting with conventional approaches are oriental herb medicine, acupuncture and moxibustion, shiatsu massage, and other physical body care, emotional meditation, and psychological therapy practices.

We highly recommend the government should support the following:

1. Public education for a proper, healthy way of eating with a grain & vegetable base; and a more natural lifestyle.

2. Making more funding available for research of the effectiveness of alternative and complementary approaches, for both prevention and recovery, including diet and lifestyle as the base.

3. Making recommendations to all health facilities and medical schools to accommodate healthful menus and cooking instructions, as well as teaching of a proper healthy lifestyle.

4. Advise selected hospitals or healthcare centers to establish a pilot plan for macrobiotic diet and lifestyle, together with data creation, as a clinical trial.

5. Advise medical and healthcare professionals of simple, practical ways of diagnosis, based on oriental diagnoses of the face, pulse, meridians, and vibration, to effect low-cost, early detection.

6. Establish community and school educational programs, including school lunch programs and high school home economics classes to recover home-cooking and healthy lifestyles.

7. We would be happy to cooperate with such governmental efforts by dispatching well-experienced macrobiotic educators, counselors, and cooking instructors to any possible facilities. We recommend funding of educational training centers at the level of college or professional schools.

Women are the center for love, beauty, health, and longevity among mankind. Home and family are the base for health and happiness. If this country establishes its way of health and happiness, reducing in a more natural way various physical and emotional disorders, America will become a symbol of health and happiness for the entire planet.

And America will become a leading light for all mankind, beyond power, politics, and the economy. This is the way of a great America, to open the new era for humanity for the 21st Century. In this way, America will become the creator of One Peaceful World for a healthy mankind.

Thank you very much for this opportunity for presenting my humble statement.

The Role of Early Detection and Complementary and Alternative Medicine in Women's Cancers

Testimony of Michio Kushi

Addendum

Recovery Stories of Macrobiotic Patients Present at the Hearing on June 10, 1999

1. Christine R. Akbar	Inflammatory Breast Cancer
2. Norman J. Arnold	Pancreatic cancer spread to the Lymph and Liver
3. Lizzz Klein	Breast Tumors and suspected Breast Implant Poisoning
4. Judy MacKenney	Non-Hodgkins Lymphoma, Stage IV
5. Lynn Mazur	Hodgkins Lymphoma, Stage IV-B
6. Marlene McKenna	Malignant Melanoma spread to the Small Intestines
7. Kathleen Powers	Endometrial Cancer, Stage IV; and Non-Hodgkins Lymphoma, Stage III
8. Debora Wright	Breast Cancer, Stage II-B

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A former physicist from Pennsylvania, who recovered 14 year ago from
Inflammatory Breast Cancer

My twin sister Kathy and I were born on September 27, 1952 in Easton, PA to our parents, Francis and Arlene Riley. Our ancestry was Irish and Pennsylvania Dutch (German), and our food was typical postwar American fare: chicken, eggs, lots of dairy, some beef; ice cream, chocolate, cheese, sugar, cakes, refined white flour, canned or frozen vegetables. We ate almost no whole grains and never heard of mineral-rich sea vegetables.

From an early age, I from suffered from hypoglycemia and its subsequent overweight, because I craved sweets my whole life. I tried many diets in order to slim down, and on one protein-sparing example, I ate protein pills at every mealtime, and consumed 48 eggs in a single week! At age 30, I adopted a lacto-ovo vegetarian diet, choosing not to kill any more animals. But then my diet consisted mainly of cheese omelets, pizzas, ice cream, and chocolate. By this time I was working very hard on a Ph.D., and was staying up working all night at least twice a week. My weight had peaked at about 170 pounds.

My background in mathematics and science, including a master's degree in high-energy physics, had led to employment in the newly emerging computer field. I had worked in the United States and Europe as a programmer, analyst, technical writer, and consultant. In the mid-1980's, I worked as a teaching assistant in the physics department of my fourth graduate school. I had become very disillusioned with Western science, because I had never met an advisor whose ideas made real sense to me, and in vain I was searching for something more meaningful.

In early July 1985 at age 32, I developed what looked like mastitis. In 2 weeks, about one quarter of my left breast had become swollen and painful, hard under the skin from 3 to 6 o'clock, with red, hot edema of the skin over it. The classic symptoms of peau d'orange and a ridge between normal skin and the most distal border of the inflammation were also evident. Penicillin-type drugs had no effect, and neither mammogram nor ultrasound revealed anything conclusive. On July 22 a surgical biopsy confirmed Inflammatory Breast Cancer. there was extensive intraductal and infiltrating duct carcinoma, with severe chronic inflammation and extensive lymphatic invasion in the 6x6 cm mass; and the skin had multifocal lymphatic permeation by carcinoma and perivascular chronic inflammation. Fortunately, there were no palpable axillary lymph nodes. Estrogen receptors were 2 and 0.

I undertook extensive Medline computer searches of the current medical literature at Yale Medical School library. All confirmed that practically no woman was alive 2 years after this diagnosis, despite mastectomy, chemotherapy, and/or radiation treatment. My kind but pessimistic oncologist told my husband I may have only 2 or 3 months to live, even with medical treatment. I was young for this ailment: the average patient was age 52 years at onset, and postmenopausal. All medical literature I consulted said "etiology unknown" for this type of cancer. My oncologist suggested that it was genetic, yet no one in my family ever had had breast cancer before. Therefore, he said, it must be a latent gene. This was not very satisfying for me.

The day after diagnosis, my oncologist started chemotherapy treatments for me once a month, for four months: Cytoxan, Adriamycin, and 5-Fluorocil (CAF) both

intraveneously and pills by mouth. Side effects included loss of hair within 3 weeks; nausea; early drug-induced menopause; heart palpitations; weakness; and extreme loss of white blood cells. The inflammatory skin component became better after 1 or 2 treatments, but the hardness of the diffuse tumor remained. By October, my WBC count was 1600/μL, and it was dangerous for me to proceed with further chemotherapy. Even though I asked the hospital dietician for a special diet to reduce my great weight, I was told by medical doctors that since I was taking chemotherapy, I had to maintain my weight. I should eat anything, especially high protein foods, and was recommended a high calorie chocolate drink. I knew Western doctors had almost no training in nutrition, and they had no idea about food causing cancer. My intuition told me that I should eat completely oppositely from the doctors' recommendations.

In September 1995 my twin sister had given me Dr. Anthony J. Sattilaro's book *Recalled by Life* about a physician and chairman of Methodist Hospital in Philadelphia. He had recovered from medically terminal prostate cancer that had metastasized to the bones using a Macrobiotic Diet. By weaning himself off extensive medical treatments and switching from a gourmet French diet to simple fare of whole grains, vegetables, beans, and sea vegetables: medical tests declared him disease free in less than 1 year. According to macrobiotics, cancer is caused primarily by a long-time imbalance in our diet and way of life. This made complete sense to me. All my life it seems that I knew my diet was very wrong, and I would become deathly ill at an early age. I intuitively felt that I would somehow recover, and lead a life totally different from that of my first 33 years.

At home, I immediately threw away all the cheese and chocolate in my kitchen and read every book I could find on macrobiotics, beginning with *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Prevention and Relief of Disease* by Michio Kushi, with Alex Jack. I also started to take cooking classes and counselling from a local macrobiotic center in Middletown, Connecticut. Very carefully I studied the concepts of yin (expansion) and yang (contraction), the complementary opposite energies that make up all things.

I discovered that to recover from this extreme form of breast cancer, I needed to first eliminate the dairy food whose protein and fat primarily made up the mass of the tumor. Macrobiotics held that dairy goes naturally to the milk-producing part of a woman's body, while sugar, oil, and other stimulants cause the tumor to spread like wildfire. I also had to stop the eggs, cheese, and baked flour products which had stagnated in my pancreas and caused the chronic hypoglycemia that drove me to eat all the relaxing sweets and dairy. I began to see food and the body in terms of the oriental concept of energy, which was easy with my physics background. If the energy of improper food could cause energy blocks or stagnations like tumors in the body, then proper food could also release these blocks and eliminate the symptoms of cancer. I determined to let food by my medicine. I carefully avoided all sweets, oils, and excessive fat and protein, as well as all refined flour products, and I ate only foods recommended in the Breast Cancer chapter of *The Cancer Prevention Diet.*

I went for a second opinion at Tufts New England Medical Center, and found a group that advocated only chemotherapy and radiation therapy, without surgery. My research indicated that at M.D. Anderson Cancer Center in Houston, radiation therapy twice daily for six weeks could help tumors of this type temporarily, so I asked my radiologist to do this, until January 1986. He confessed that all medical treatments in this case were more art than science, but he would try his best. I found in seeking further opinions that there were as many recommendations as there were doctors; so I asked those whose opinions with which I agreed to write letters to my own doctors to direct treatments. In particular, I found a surgeon opposed to surgery, and in this way I

convinced my own team of physicians not to do a mastectomy. I tolerated the radiation treatment well, especially because I balanced the very "yin" treatment with additional miso soup and sea vegetables once I started macrobiotics.

Finally, my oncologist was pressuring me into six months more of chemotherapy. Medicine practically guaranteed me that I would die if I continued and I had decided that I would rather die than bear more torture of the drugs. On January 28, 1986, I met Michio and Aveline Kushi for my first consultation at a "Way of Life" seminar in Boston. Aveline kindly presented me with an autographed copy of the newly published *Aveline Kushi's Complete Guide to Macrobiotic Cooking*, which I treated as my new *Bible*. Michio told me in his light and amusing, yet provocative, way that I would commit suicide if I ate one more piece of chocolate.

He recommended a version of the Standard Macrobiotic Diet tailored for my condition, including four special home remedies to be prepared from household foods:

1. **Grated Carrot and Daikon Radish** - to dissolve my excess body fat and help lose weight
2. **Sweet Vegetable Drink** – a tea made from cooking onion, cabbage, carrots, and winter squash, to help clean the egg and cheese fat out of my pancreas, which had been causing my extreme hypoglycemia and chocolate binges
3. Ume-Sho-Kuzu – a Japanese salty & sour drink made from a thickening root starch, an alkalinizing pickled plum, and soy sauce to strengthen my intestines and relieve the chronic constipation that is a root of many upper body ailments; and
4. **Barley and Cabbage Breast Plaster** - a paste made from cooked Pearl Barley (Job's Tears) and raw green Cabbage worn nightly for 2 months. This plaster was most effective: after just 4 or 5 days, I found that old hard breast calcifications that I had had for many years were beginning to soften and dissolve.

As my disease was so far advanced, even Michio Kushi was cautious, and he gave me two diets to chose from: one based on diet alone, and the other with diet combined with additional chemotherapy. Although my husband preferred more drugs, he supported my decision to only use macrobiotic food as my medicine, and he created a "nest" at home where I could just cook, make special remedies, take walks, sing happy songs, and just sleep. He also kindly kept away anyone who brought my energy down, including my kind and well-meaning, but pushy, oncologist. And my parents and sisters offered their heartfelt support with their weekly phone calls and their switch to natural foods diets.

For the next 2 months I observed the healing diet that Michio had recommended. Every second of my time I spent trying to save my life, because if I did anything else, I felt I could easily lose my life. I never once doubted that I would recover: macrobiotic philosophy enabled me to understand the energy that had caused the tumor to grow, and to create the energy of food that would cause it to be balanced and dissolve. I learned how food transmutes into blood, and what we eat becomes our body, mind, and spirit. With each new meal, I felt that my blood was made into a cleansing solvent that could penetrate my remaining tumor and dissolve all the heavy dairy fat and protein of which it was composed. And with my cleaner body and clearer mind, my intuition became sharper, and I could experience the power of the universe, heaven' s and earth's forces, healing me directly.

At the end of March 1986, on Good Friday, I was awakened at about 4 a.m. by nearly uncontrollable diarrhea. I had read that the body sometimes "discharges" excess animal food in such strong ways, so I was not so concerned. But the next morning, to my happy surprise, I realized that the remaining hardness of my breast tumor was suddenly and

miraculously gone! This was just two months after starting a serious practice of macrobiotics under the guidance of Michio and Aveline Kushi. In the time that modern Western medicine had said that I would probably die, a traditional Eastern diet had helped save my life. I was so grateful.

I began and still continue to record what foods I eat daily, and to record the condition of my body each morning. This self-research has confirmed for me the cause and effect relationship between diet and health. For example, I found that cosmetic use of small amounts of sesame oil on my face for 6 weeks in June 1986 seemed to bring back the redness on my breast. It appeared that the oil entered my bloodstream as if I had eaten it, and it was like throwing oil on a flame. Following Michio's advice, I stopped the oil treatment and again ate Grated Carrot and Daikon: the inflammation disappeared with diarrhea after about 5 days. After this, I stayed very strict with my diet and lifestyle, for more than 2 years. I widened to include fruit, bread, and oil only when I was told it was safe by my counsellor. I gradually widened to the Standard Macrobiotic Diet, which I follow to this day.

My salvation, I think, lies in the following facts:

1. The initial chemotherapy was "yang" to balance my extreme "yin" condition.
2. I took only a modest amount of drugs to control the acute initial symptoms of inflammation, and then stopped.
3. Carefully I avoided all foods that resembled those that caused the tumor to grow, and I never cheated on my "healing" macrobiotic diet.
4. I stopped my graduate studies and quit my consultant job to just get well.
5. At all times I felt in control both of the Western and Eastern treatments.
6. Everyday I spent cooking like a pharmacist to save my life.
7. I had a supportive and loving family, who had blessed me with a strong constitution, changed to a macrobiotic diet with me, and even studied Shiatsu to give me massages.
8. Still I had a little intuition left to know what was good for my recovery.
9. I did not believe I would die just because the doctors said I would.
10. I had a strong imperative to live and a Big Dream for my life.

About 2 ½ years after recovering, I began to study formally at the Kushi Institute in Becket, Massachusetts. It seemed to me that, with my newly found knowledge, I had to change my life to help others who were also unfortunate enough to have a diagnosis of cancer or other serious disease. I see so very many people making the same mistakes with diet and way of life that caused me so much pain and suffering. I served as a coordinator of the Way to Health Program, a one-week seminar designed to help people, primarily cancer patients and their families, begin macrobiotics. Because of my science background, I was often called upon to coordinate medical research and teaching for the Kushi Institute. For the last several years, I have served as an assistant to Michio and Aveline Kushi at their home in Brookline, Massachusetts. My duties have ranged from assisting with consultations to gathering medical records for a pending best case series report in the *Study of the Macrobiotic Approach to Cancer*. Lawrence H. Kushi, son of Michio and Aveline Kushi and professor of nutritional epidemiology at the University of Minnesota School of Public Health, served as a principal investigator for this research, supported with a small grant from the former Office of Alternative Medicine of the National Institutes of Health.

It is now 14 years since I was diagnosed with cancer. I am returning to my old passion, high-energy and nuclear physics, but from the macrobiotic vantage point of "Alternative Science." We are conducting experiments in low-energy nuclear

transmutation, attempting to form heavier elements such as iron, from lighter elements such as carbon and oxygen. We are also investigating natural, alternative methods of energy generation and storage, including directly harnessing cosmic energy received from heaven, and centripetal energy generated from earth. Just as cancer, heart disease, and other illnesses can be healed with peaceful, gentle means, it is our hope that someday unlimited sources of energy and scarce elements will become commonly available, and help heal the planet and promote peace in this world.

I am very, very grateful to be alive. I am grateful to my family for giving me life and eternal support. I am grateful to medical doctors for their original diagnosis and for controlling the inflammation at the beginning so the cancer did not spread. I am grateful to Michio and Aveline Kushi and other teachers for bringing the traditional wisdom of the unifying principles of nature to America, for teaching me the cause of my cancer, and for bringing foods and recipes that helped save my life. And I am very grateful to the patients and champions of Alternative medicine who helped add both quality and quantity to the precious years of my life.

Adapted from *Women's Health Guide: A Natural Approach to Breast Cancer, Heart Disease, Fibroids, PMS, Bulimia, Childbirth, Menopause, and Osteoporosis*, edited by Gale Jack and Wendy Esko, ©1997 by One Peaceful World Press, with permission.

Thank you very much to all members of the Committee on Government Reform for so kindly allowing us to testify about macrobiotics at this hearing on "The Role of Early Detection and Alternative and Complementary Treatment for Women's Cancers."

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A business leader and philanthropist from South Carolina, who recovered 17 years ago from **Pancreatic Cancer spread to the Lymph and Liver**

Norman J. Arnold, a resident of Columbia, South Carolina, was in the prime of life. President and chief executive officer of Ben Arnold Company, he directed the largest wholesaler of wine and alcoholic beverages in the Southeast, and among the ten largest in the nation. Active in community affairs, he headed up local chapters of the Boys Club, the Zoological Society, and the Heart Fund. Appointed to several state commissions, he served as the committee chairman for the Governor's Economic Task Force. With his wife and family, he was active in educational, philanthropic, and synagogue activities.

On July 28, 1982, Norman underwent routine gallbladder surgery at Providence Hospital in Columbia. During the surgery, his surgeon, Dr. Dan Davis, discovered that he had a primary cancer in the head of the pancreas. He also found a smaller tumor in one of the lymph nodes, and three cancerous lesions on Norman's liver. The tumor was biopsied and sent to pathology where it was diagnosed as adenocarcinoma, a highly virulant form of cancer. Dr. Davis realized that Norman was beyond remedial surgery, so he removed his gallbladder and closed Norman's abdomen.

In the consultations with the surgeon, and gastroenterologist, Norman and his wife, Gerry Sue, were told flatly that there was no cure for this disease, nor was there any hope of recovery. They were told that he had from three to nine months to live. Pancreatic cancer is one of the most devastating of all malignancies; it is thoroughly intractable to standard chemotherapy protocols and patients do no live long following diagnosis.

Even though the prospects of surviving pancreatic cancer are about null, the doctors advised him to start chemotherapy and/or radiation as a way of "possibly gaining more time." Dr. Phillip Schein, at the Vince Lombardi Cancer Center at Georgetown University recommended a very potent chemotherapy treatment, involving three chemicals, for "as long as my body could take it."

Norman had always been an active, energetic, and above-average amateur athlete, and a very optimistic and positive person. The five chemotherapy treatments made him weak and tired, and gave him a deep feeling of helplessness and hopelessness. The effects of the drugs were devastating: weight loss, chronic fatigue, muscle wasting, nausea, and total loss of body hair. His weight dropped from 160 to 112 pounds. He looked like a refugee from Auschwitz. "This debilitated feeling was more painful to me than the actual pain I endured," he later recalled. "This miserable existence combined with the fact that I did not want my growing incapacity to be a physical and psychological burden to my three sons (twins and a three-year older boy) and my wife. I also did not want their last memory of me to be that of an invalid."

Not being accustomed to taking bad news passively, Norman investigated all the medical and alternative cancer therapies, including interferon, hyperthermia treatment, radiation therapy, and a variety of experimental drugs. He subscribed to medical journals, newsletters, and computer information services. He searched the medical literature for every possible alternative to death. He also had the help of several physician-friends who assisted him in gathering research. Of this varied and uncertain list of alternatives, two emerged to provide some hope. One was an experimental cancer treatment called monoclonal antibodies.

Norman's cousin and boyhood friend, Dr. Charles Banov, an allergist and immunologist, was searching for medical treatments that might be of help to Norman. Dr. Banov soon discovered a highly experimental approach called monoclonal antibodies.

Monoclonal antibodies are proteins produced by the immune systems of mice to fight the type of cancer being dealt with by a human patient. The method works by injecting blood from the human patient into a mouse; the mouse creates an immune response, which doctors hope will be effective against the particular kind of cancer affecting the human patient. Once the immune system of the mouse has responded to the cancer, scientists extract the mouse antibodies and inject them into the patient in an attempt to stimulate the patient's immune system to produce an effective antibody against the malignancy.

In 1982, monoclonal antibodies had not been shown to be effective against any type of malignancy. (Monoclonal antibodies remain an unproven therapy against cancer to this day. No study has proven they are effective in the treatment of cancer.)

In September 1982, he was given an injection of the monoclonal antibodies, which were produced by scientists at Wistar Institute in Philadelphia, Pennsylvania, a branch of the University of Pennsylvania Medical School. There would be only one injection. He simply had to wait to see what effect the antibodies had, if any.

The second treatment Norman chose was macrobiotics, a diet and philosophy based on ancient principles developed in China some 2,500 years ago. During the eight-week period in which he took five chemotherapy treatments, Norman learned about macrobiotics, made inquiries through a medical doctor who had relieved his own cancer on the diet, and arranged to meet with Michio Kushi. As he lay in his bed, someone had given him a copy of the August 1982 issue of *Life Magazine*. In it was an excerpt from a forthcoming book entitled *Recalled by Life*, the story of a medical doctor's use of a macrobiotic diet to successfully treat his own prostate cancer metastasized to the bones.

"I had heard there were those who promoted certain non-conventional cancer treatments in order to financially exploit cancer victims," Norman noted later. "I was therefore very skeptical of Mr. Kushi at the outset, but my concern proved to be totally unfounded."

Norman investigated macrobiotics and discovered that there were numerous accounts of people using the diet and lifestyle to overcome cancer. He was dubious, but intrigued. He decided to have a friend, attorney John Rainey, investigate the claims. Mr. Rainey went through the files of the Kushi Institute and East West Foundation – both macrobiotic educational institutions located then in Boston. He also searched the records of an Illinois medical doctor who used macrobiotics in his practice to help numerous people recover from serious illnesses, including cancer. Mr. Rainey then personally visited each person on record as having successfully dealt with cancer through the use of macrobiotics. Remarkable, the lawyer discovered that the vast majority of the claims were true: these people had in fact been diagnosed with terminal cancer, and had used macrobiotics as their principal means of treatment.

Norman had long been fascinated by nutrition, though his previous interest focused exclusively on vitamin therapy. The macrobiotic idea that diet and lifestyle were the leading factors in both the onset and recovery from disease struck a deep chord in him.

The macrobiotic diet is composed chiefly of whole grains, land and sea vegetables, beans, fish, and fruit. The diet is low in fat and cholesterol and rich in all essential nutrients, including fiber. The philosophy includes the age-old concept of yin and yang, the ancient view that two opposite forces combine to create all phenomena. It is through balancing these two primordial forces that health is achieved. The macrobiotic

philosophy maintained that the typical American diet, rich in fat, cholesterol, sugar, refined grains, and chemicals, provides an onslaught of poisons that, once inside the body, accumulate into masses. These accumulated toxins prevent adequate blood flow to organs and tissues, suffocating and deforming cells. A variety of illnesses begin to manifest as a result, including heart disease, diabetes, and arthritis. By depriving tissues of oxygen and, at the same time, polluting the cellular environment with toxins, the daily diet also affects the DNA, or genetic material, of cells. Once the DNA is altered, cells often begin to multiply out of control, thus becoming cancerous.

Kushi maintained, however, that by eating a diet that is free of these toxins, and at the same time rich in nutrients, the body can throw off the accumulated poisons and restore balance and health. This throwing off of waste was typically referred to in macrobiotics as "discharging."

Norman started eating a macrobiotic regimen, modified for his particular condition, in August 1982. In October he received his fifth and final chemotherapy treatment. On Thanksgiving holiday, Norman decided to quit chemotherapy and commit himself exclusively to the macrobiotic regimen. On his own initiative, Norman decided to discontinue the chemical injections because he "preferred a more acceptable quality of live, even if that meant less time alive, rather than a questionably longer existence as a cripple." On the macrobiotic diet, he gradually began to recover his vigor and energy and positive, cheerful attitude.

Meanwhile, in November, Gerry Sue and Norman attended a five-day seminar at the Simonton Clinic in Dallas, Texas, famous for its successful use of mental imagery in the treatment of cancer. Under the direction of Stephanie Simonton, wife of the clinic's founder, Dr. O. Carl Simonton, Norman and Gerry Sue learned the importance of the mind in the maintenance and enhancement of the immune system. Mental imagery became a fundamental part of Norman's daily health routine. Among the images he used was the picture of his tumor being eroded by his blood, being strengthened by his macrobiotic regime.

Once he began the diet, Norman did indeed begin to "discharge." He lost weight and suffered a variety of passing cold symptoms. One of the most frightening of all was that his tongue turned black. He awoke one morning, opened his mouth to brush his teeth, and notices that his tongue had turned black. Gerry Sue was aghast. She called Michio Kushi in a panic. Mr. Kushi calmly reassured her that Norman's tongue would regain its normal color, and that it was a good sign. Norman's system was deeply cleansing itself. In fact, the tongue's normal color did return, but the experience was terrifying.

Gerry Sue was regularly calling Michio to say that Norman was steadily losing weight. Mr. Kushi reassured her each time that eventually Norman's weight would stabilize and he would even regain a few pounds once he reached optimal weight. This, too, came to pass.

"In time, I found that I had more energy and vitality that I had had for twenty years. My wife Gerry Sue, who also had adhered strictly to the macrobiotic diet with me, had positive results both physically and psychologically. My then sixteen-year-old son, who played first-string center on his high school basketball team, discovered that the macrobiotic diet greatly increased his strength and especially his endurance. My then thirteen-year-old twin boys demonstrated more concentration, mental agility, and stamina in their schoolwork when eating macrobiotically, as they do alternate with the "standard teenage junk food diet outside our home."

On June 24, 1983, just nine months after he was diagnosed and began the macrobiotic diet, the various CAT scans and ultrasound tests showed the pancreas tumor

and the "spots" on the liver decreasing in size. On December 21, 1983, further CAT scans, ultrasound, and blood tests, and liver tests showed no evidence of disease. His doctors were baffled. Norman was triumphant.

Having already outlived his original prognosis by two years in 1984, Norman said he was then mentally and physically relaxed and functioning better than he had for many years. "I played vigorous, singles tennis matches almost every day and found that I had much more strength and endurance than I had had for a very long time. I beat my forty-one-year-old gastroentgerologist in a 6-4, 7-5, 6-8, 8-6 match!"

On his sixtieth birthday in January 1990, Norman climbed Mount Kilimanjaro, whose peak stands at 19,600 feet above sea level. He continued to be an avid tennis player and scuba diver. In July 1999, seventeen years after his cancer diagnosis, he is still in excellent health and cancer-free.

Sources:
Letters from Norman Arnold to Congressman Claude Pepper, Chairman of the U.S. House Subcommittee on Health and Long-term Care, January 18, 1984.
Adapted from *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Prevention and Relief of Disease*, ©1993 by Michio Kushi with Alex Jack, with permission;
And
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A businesswoman and inventor from Tampa, Florida
who was diagnosed in 1985 with 30 various symptoms, including
Brain Damage and Breast Tumors, suspected due to Breast Implants

I was a real go-getter! I became successful at an early age by using my admittedly Type-A personality to acquire several businesses and even co-invent and patent a product. I pursued a very productive and dynamic lifestyle.

While living in the fast lane, I had to have breast reconstructive surgery in 1985 followed by silicone breast implants. Afterwards, I was plagued with colds and flus that would not quite so away, extreme fatigue, headaches, and sleeplessness. These immune deficiencies were the first signs that something was not right.

My body continued to deteriorate. The doctors couldn't figure it out. My hair started to fall out, I lost eyebrows and most of my eyelashes, and my sight began to decline. I lost my sense of smell and taste, and started to gain weight at alarming rates, unrelated to my caloric intake. My memory lapsed, night sweats and insomnia were commonplace, and muscle fatigue set in. Over the next few years, I became a candidate for the person with the most symptoms in the *Guinness Book of Records*. They included chronic fatigue, bowel problems, urinary and bladder problems, irregular heartbeat, depression, neuromuscular seizures, hormonal imbalances, and finally breast lumps that led to tumors. My whole body was breaking down.

At the end of seven and a half years, I deteriorated to the point that I was confined to a wheelchair. I lost the use of my left arm, then left leg, right leg, and finally most of my right arm. Medical testing found damage to the left lobe of my brain, and my thinking processes were impaired. Like a stroke patient, I could understand what people said to me but could not communicate back. For a talker like me, this was torture!

Medication didn't seem to be able to touch the pain. My connective tissue was on fire, an extreme form of fibromyalgia, and migraine headaches lasted until I almost passed out. Certain areas of my skin felt like a burn victim's, and I couldn't tolerate even light clothing. A frame was built over my bed to lay the covers on so I didn't scream in pain with the pressure of the blankets on my overly-sensitive skin.

I could find no relief. I could not find my spirit. I prayed for the only relief I could imagine: to pass away peacefully, quickly. I was dying a slow, agonizing death.

As my sicknesses multiplied, I lost or sold all my businesses, investments, homes, and possessions. The doctors did the best they could but were really at a loss. I learned of the problems of breast implants and had them removed, but by this time my body was already too far gone. The doctors finally told me I might have two or three weeks left and I should plan my funeral.

I'll never forget that judgment. But I was ready and wanted to die at home. I went home, planned my funeral, and waited for the end to come. Among the few personal items left were my books. My bed was surrounded by reading material—books on healing, cancer, and every illness imaginable. There were medical books, self-help books, herbal books, and books on prayer and meditation. My nurse thought I was crazy. Although I was virtually blind, unable to communicate, and could hardly turn a page,

some primitive impulse to survive remained. My financée was a scientist and had taught me the value of research.

One day as I lay there, crying in pain and using my one good arm to slowly turn the pages of a book on alternative health care, the words "macrobiotics" and "natural healing" suddenly came into focus. That instant is vividly engraved in my mind to this day. Something about those unfamiliar words made me place my hand on the page and wait for my fiancée to come home. He picked the book up, started reading, and then I heard my first miracle—a scientist snapping his fingers and exclaiming, "That's it! It makes sense!"

Over the next few weeks we continued to read up on macrobiotics—the miracle of "great life." My helpers cooked for me; plastered, ginger compressed, massaged, and body-scrubbed me; and sang silly songs to lift my spirits. Three weeks later, I stood up from the wheelchair! We were stunned, then elated, crazed with relief.

Over the next few weeks and months, my body continued to rejuvenate with healthful foods: brown rice and other whole grains, miso soup, beans and bean products such as tofu and tempeh, fresh garden vegetables, and small, daily amounts of sea veggies.

My hair started growing back, overall pain lessened, and my eyesight returned. Soon the seizures stopped, and the ability to talk returned. (You can't shut me up now!). Thinking processes normalized, all bodily functions strengthened, and the tumors naturally melted away.

I got up from my deathbed (and the wheelchair) in 1994 and have not stopped since. My macrobiotic practice has gone forwards, backwards, and even upside down! But I continue to make progress and keep healing. I have gone through many physical and emotional discharges, especially to release the old animal food, dairy, sugar, and chemicals that; from the macrobiotic view, were the underlying cause of my manifold ills.

I have seen and felt many miraculous things on my macrobiotic journey. Moments of pain, strength, fear, and surrender. But most of all, as my health returned, I experienced more moments of unbridled joy than I can count!

Lizzz Klein went on to study in the leadership training program at the Kushi Institute, managed the Way to Health Program, and is presently Associate Director of the K.I. She is networking with many individuals and organizations around the country to promote macrobiotic education. She can be reached by E-mail at Lizzz@macrobiotics.org.

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A clothing designer from Florida, who recovered 8 years ago from
Non-Hodgkins Lymphoma, Stage 4

Seven years ago this January, I began the greatest challenge of my life. My husband, Larry, our oldest daughter, Lauren, and I were sitting in an oncologist's office at a prestigious cancer hospital in Boston, being told I had non-Hodgkin's lymphoma, an inoperable, metastatic, incurable disease of the lymph system. It would develop to Stage IV within a few weeks! The tumor was situated on the right side of my abdomen, surrounding other organs. Lymph nodes were swollen on the left side of my neck and cancer cells were found in my bone marrow. We were numb.

CANCER! The diagnosis sounded unbelievable to us. My mind was saying, "There must be some mistake," but my heart knew that the myriad of tests I had been through had uncovered a life-threatening condition. The thought came to mind that God never gives you more than you can carry. I prayed He would give me the strength to rise above my health challenge. We had so many questions. Good health had always been so important to me. I never smoked and drank minimally, only on special occasions. I was rarely sick, and ate what I considered a healthy diet.

The doctor called me "Superwoman" when he learned of my lifestyle. I was busily juggling the activities of a family and managing my home business as a fashion designer. I was a nurturer and saw to the care of both my parents. My dad had died of heart disease seven years earlier after several years of illness, and my mother had died of breast cancer, like her mother, the previous January. I had cared for several other members of my family, too. Family is very important to me. I realize now that I made a grave mistake in overextending myself. I didn't take the time to listen to my body and care for my own needs!

At the urging of the oncologists, I agreed to take oral chemotherapy, chlorambucil, a non-curative cancer drug. I remember seeing fear frozen on many of the patients' faces in the hospital clinic waiting room, everyone there trying to make sense of their afflictions, desperately seeking a ray of hope and a miracle cure.

It was only a matter of days before my body and soul were telling me that the chemicals were not right for me. I watched my body swell and contort with sickness as I continued the oral chemotherapy. It was supposed to be a mild treatment but would be proceeded by a more potent protocol later, when my disease reared its ugly head and recurred, as the doctors anticipated it would. I donned my old maternity clothes. Nothing else fit. What does one do? Buy a whole new cancer wardrobe? I was so uncomfortably bloated through my abdomen and my stomach was burning with pain. I had to sit upright in bed to sleep at night. I was exhausted, my nervous system a mess, walking was difficult, and I developed ulcers. The side effects were devastating. The doctors gave me numerous prescriptions and elixirs to take care of my digestive tract, but nothing seemed to work.

One of my dreams was to vacation with my friends in Aruba again. In May, for my birthday, four of our favorite couples chipped in and gave Larry and me an all-expense-paid trip to join them in Aruba that October. When my registered nurse friend asked the doctors if I would be capable of making such a journey, they disclosed to her

that my disease was terminal, and I would not live long enough to take the trip, which was five months away.

In October, we made that miraculous vacation with our friends! The week after returning from that memorable trip, I got good news and bad. I was admitted into the hospital and placed in quarantine for five days due to a painful case of shingles on my face and body. The good news was that the cancer was "in remission" and I had ingested my last dose of chemotherapy.

I was inspired by Dr. Bernie Siegel, founder of ECaP, a support group for exceptional cancer patients. I lived in eastern Massachusetts, at the time, and drove more than three hours each way to attend his Monday support group in New Haven. My immune system was very depleted from the chemotherapy so, when I got fatigued on the drive down and back, I would pull off to the side of the road several times to "power nap." I respected the power of positive thinking. I had read over 30 books in the library on cancer. Every article I had read on non-Hodgkins lymphoma said it was incurable. The ECaP lending library offered many books on alternative and complementary therapies. One title stood out, *The Cancer Prevention Diet: Michio Kushi's Nutritional Blueprint for the Prevention and Relief of Disease.* The book stated that compared to other forms of cancer, lymphoma was relatively easy to relieve. I joyously brought the book home, read it, and proceeded to search for a macrobiotic counselor.

To my good fortune, I was able to locate Marc van Cauwenberghe, M.D., a well-respected counselor. My nursing friend and I met with him and were very impressed with the encouragement he gave, his explanation of macrobiotic healing, and whole food nutrition. "You will heal yourself," he declared.

Life is too precious to just lie there and have it taken away. I had to CHANGE—that was the key word in my healing. In my weakened state, every waking hour I researched, read, meditated, visualized, cooked, and prayed. It was a full time job to heal. Allotting myself the time to heal was the best gift I ever gave myself. I had so much to live for and so much still to give in my life.

For 11 months after I was diagnosed, I had struggled with chemotherapy, its insidious side effects, and the standard American diet. Now I threw out all the drugs and elixirs and started to take natural remedies. The sweet vegetable drink stabilized my blood sugar and cured my ulcers. The ume-sho-kuzu tea strengthened my digestion and restored my energy. The ginger compress on my kidneys dissolved stagnation and stimulated blood circulation and energy flow. After eating macrobiotic food for only two weeks, I began to feel noticeable improvement. The pain in my joints and feet disappeared. My innards embraced the nourishing whole food and I started to discover energy I had not felt in years and I was experiencing peaceful sleep at last. I felt strong enough to take walks with my friends, deep breathing oxygen and blowing the toxins out. I chewed my food thoroughly and listened to joyful music.

I attended the Macrobiotic Winter Conference in Miami in 1993, where I heard Michio Kushi, Bernie Siegel, Deepak Chopra, and other highly respected healers lecture. The conference was an educational and inspiring affair. I also assisted Aveline Kushi in a macrobiotic cooking class in a private home and attended a spiritual and healing workshop with Michio. I then participated in his group consultation. Michio was amazing, diagnosing people and offering them helpful suggestions on how to improve their health in a natural way. It was a turning point. I had to get well and teach others this lifestyle.

I had endured a year of cold weather in Massachusetts since my diagnosis. I was perpetually cold because my immune system had been depleted by the cancer and chemotherapy. Larry came home from work one day and announced that he had been

downsized. It was a time of recession and no jobs were available. All of our income and health insurance would soon be terminated.

We drove to Florida and discovered a beautiful area on the west coat. We sold our home of 27 years and took the plunge. We packed our gas camping stove and propane tanks, organic grains and beans, and bought farm fresh vegetables on the way. We rediscovered who we were, walking beaches, healing together, embracing the universe and nature. We felt the glow of love our family and friends had given us, appreciating every precious moment we had together.

We settled in beautiful Nokomis. Since there were no macrobiotic counselors nearby, I made an appointment with a doctor for advice on another health concern. During the visit, I told her about my illness and she laughed, "Jackie Onassis has the same thing you do. You have the 'in' disease and, not to worry, they'll find a cure for it." One week later, Jackie succumbed.

Miracles do happen and I am one of them! I've learned that quality of life is the important issue, not quantity of years. There are no gimmicks in practicing this lifestyle, just properly preparing and consuming quality, organic, blood-building, whole foods that will protect you from disease.

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Judy had a chest/abdominal and body CAT scans, with and without dye, plus full-body X-rays in the Spring 1999, and no trace of disease was found. Judy and Larry MacKenney recently attended the Macrobiotic Career Training (MCT) program at the Kushi Institute. They manage Harmony Haven, a macrobiotic wellness center and retreat on Florida's Gulf Coast near Sarasota. For further information, please contact them at 712 Quail Court, Nokomis FL 34275 (941) 488-9509.

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A public relations professional from Arlington, Virginia, who was diagnosed in 1989 with **Hodgkins Lymphoma, Stage IV-B**

In December of 1987, Lynn Mazur, a 30-year-old public relations professional working in Washington, DC, first decided to consultant a doctor for persistent bouts of fatigue following a series of head and chest colds that occurred throughout the fall of that year. Lynn, an exercise and sports fanatic, who walked 3 to 4 miles daily, practiced yoga regularly and taught aerobic exercise classes three times per week, was rarely ill. Adult on-set diabetes was prevalent in her family history and Lynn suspected the change in her energy level could indicate early warning signs of the disease.

That initial doctor's visit was the beginning of a thirteen-month odyssey in search of a diagnosis for relief from an ever-growing list of symptoms. Numerous specialists were consulted, multitudes of medical tests were conducted, while the long list of symptoms expanded and robbed pleasure and vitality from her days. Fevers, night-sweats, skin rashes, viral and bacterial infections, excessive thirst, erratic appetite, weakness, dizziness, extreme fatigue, unexplained pain, burning and itching sensations, and mysterious lumps that surfaced, lingered, then disappeared were among the symptoms that eclipsed her once good health.

Lynn's lifestyle involved international travel to remote third world countries. Malaria and rare infectious diseases became the focus for health care providers determined to get to the root of her symptoms.

In January 1989, following the surgical biopsy of a lymph node, Lynn was diagnosed with Hodgkins Lymphoma, Stage IV-B.

The cancer diagnosis came as a shock since lymphoma had been ruled out by doctors on several occasions when suspicious lumps prominent in her neck disappeared on their own. "Cancer doesn't disappear without treatment," doctors insisted. Yet, with the lymphoma diagnosis, one doctor believed Lynn had experienced no less than 10 "spontaneous remissions" due to a strong and active immune system response.

The conventional treatment for Stage IV Hodgkins Lymphoma in 1989 was MOPP/ABV chemotherapy followed by radiation. Lynn's oncologist was anxious to move forward with that protocol immediately because of the advanced staging of the disease. While Hodgkin's disease is often seen as curable, the prognosis for Lynn's condition was identified as only a 38 percent chance for survival.

Lynn was hesitant to submit to chemotherapy that would suppress an immune system credited with fighting disease and creating natural remissions of cancer. She decided to take three weeks to explore alternative therapies that might support her body's natural defenses. During that three week period of research, she was unsuccessful in finding an alternative course of treatment that she felt addressed the immediacy and seriousness of her situation. In February 1989, Lynn began the first of eight cycles of chemotherapy.

In October of 1989, having completed the chemotherapy, Lynn's cancer was in remission. Unfortunately, the news was not all good. The chemotherapy, specifically the drug Bleomyicin, had created a new problem -- a rare collagen vascular disease that had no known cure and had proven unresponsive to experimental drugs. The condition

was attributed to the "rebound" response of her highly active immune system once the immune suppression drugs were discontinued. Lynn was given just two months to live.

While a course of radiation was advised to follow the chemotherapy, and experimental drugs were encouraged to combat the new disease, Lynn declined those methods of treatment, determined to find an alternative therapy that had eluded her earlier.

Convinced she should work with her immune system rather than against it, Lynn began exploring "detoxification" diets to rid her body of the residual effects of the chemotherapy. Working with a homeopath and naturopath, she began to modify her diet but still feared that diet modification alone might not be enough. Then, a friend in California gave Lynn a book about the macrobiotic approach to healing entitled, *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Prevention and Relief of Disease* by Michio Kushi, with Alex Jack. Instantly, she knew she had found the stronger "healing" solution, a way to health that could work for her.

Within ten days of starting the macrobiotic diet, significant changes in Lynn's blood tests were evident. Her doctors were amazed. Within thirty days of following the diet, the condition began to show signs of reversing. Within ten months of following the macrobiotic approach to healing, the "incurable and terminal" disease that threatened to take her life had disappeared. Today, nearly a decade later, Lynn is still cancer-free and healthy. She credits the macrobiotic approach to saving her life and she continues to follow the diet to support health, happiness and wellbeing.

Lynn Mazur is currently the Director of Public Relations for the Kushi Institute. For further information, please contact her at TEL: (413) 623-5741 ext. 107, FAX: (413) 623-8827, or Website: www.macrobiotics.org.

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A mother of five, radio/television commentator, and investment broker from Rhode Island, who recovered 16 years ago from
Malignant Melanoma spread to the Small Intestines

In 1983, Marlene McKenna was diagnosed with malignant melanoma. "As a working mother of five children, radio/TV commentator, and investment broker, I was living a very unbalanced life," Marlene explained in an interview in *The Providence Visitor*.

In August 1985, she began to complain of severe stomach pains, and in January 1986, doctors discovered that five tumors had spread throughout her body. Two feet of her intestines were removed, and Marlene was told she had six months to a year to live.

Declining all treatments, Marlene turned to macrobiotics at the suggestion of her brother and visited Michio Kushi in Boston. In addition to changing her diet, she brought in a gas stove in place of her electric stove, and began to meditate and practice yoga. A devout Catholic, she also did a lot of inspirational reading and praying.

"I promised God that if He walked me through this and helped me live, I would give Him life with life," she recalls.

Within a year, she was on the way to recovery, and doctors found no evidence of further cancer. Feeling well enough to return to public life, she ran for state treasurer in Rhode Island. During the campaign, she discovered that she was pregnant. Because of her previous illness and age (forty-two), doctors encouraged her to get an abortion. Marlene refused. "I realized that (having the baby) was part of my promise to give life with life," she explains. Though she lost the election, she gave birth to a healthy baby boy, keeping her promise to God and proving her physicians wrong.

She is helping people around the country who have heard of her remarkable recovery by her lectures and public appearances.

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Adapted from *Cancer-Free: 30 Who Triumphed Over Cancer Naturally*, ©1991 by East West Foundation, with permission.

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A real estate professional originally from Ft. Myers, Florida,
who was diagnosed in 1985 with **Endometrial Cancer, Stage IV**
and diagnosed in 1993 with **Non-Hodgkins Lymphoma, Stage III, terminal**

In April of 1985, my doctor called to report I tested positive for Endometrial Cancer and he wanted to know what I wanted to do about it. At that same time, I had also been diagnosed with Rheumatoid Arthritis. I was a real estate professional and project manager at a luxury condominium in Naples, Florida and I didn't have time to be sick or undergo massive, debilitating treatment.

I immediately went to my local health food store (Gulf Coast Nutrition) and told the owner, Yen Bell, a Vietnamese woman, what was happening to me. She gave me three books: *You Are All Sanpaku* by William Dufty; *Zen Macrobiotics* by George Ohsawa; and, *Recalled by Life*, by Anthony J. Sattilaro, M.D. I went home, read the books, and designed a whole grains and vegetable diet to heal myself.

Yen Bell gave cooking classes on Saturdays. I went to those classes and I read everything I could find on the macrobiotic approach to healing. I began to feel better; nausea and flu-like symptoms disappeared.

I was being monitored by my OB/GYN physician and soon, he began reading the same books. Often, we encountered one another in the health food store and I enjoyed seeing him purchasing macrobiotic food items.

That summer, I had a D & C. This would be the only conventional medical intervention I would allow. By November 1985, I was completely cancer-free. I liked my life, I loved my job and especially enjoyed my success (In 1989, I was a candidate for Who's Who of American Women and was listed in the 1992-93 edition. Later, I would also be listed in the Who's Who in Finance and Industry). I faithfully followed the macrobiotic way of eating, and remained happy and healthy until May of 1990, when, at the age of 49, I would encounter difficult challenges.

On May 20, 1990 at 2:00 p.m., I was at work, showing a condo to prospects. It was a rainy day and my shoes were soggy and wet from walking the property. I returned to the clubhouse through the front door and stepped in briskly. The carpet had been removed for cleaning and the bare tile floor was wet. I began sliding and skidding and eventually hit the floor hard. The injuries were horrendous, as were the resulting surgeries: two cervical hemi-laminectomies to remove ruptured disks on both sides of my spine at the neck; two rotator cuff repairs to reconstruct left and right shoulder tears; two total knee joint replacement operations; and one lumbar laminectomy for lower spine injuries. I also sustained substantial damage to my left hip.

I was out of the job market and the ensuing melodrama was frightening. I began a medical odyssey that would compromise more than aid my physical and emotional health. I believe my broad insurance coverage coupled with the "good ole boy" network of conventional medical doctors and their practice of continual "specialist referrals" were responsible for much of my agonizing journey.

The surgeries that began in 1990 would repeatedly send me home to bed for recuperation with prescription bottles of painkillers, sleeping pills, and Valium. I lived alone and was at home alone. I cried a lot and I swallowed a lot of pills. I lived in a small

condo hotel room in Naples, Florida and was unable to prepare my macrobiotic food. I knew I was getting sick and I gained 20 pounds.

My surgeon sent me to a neurologist who put me on a liquid, high-protein diet. I lost 17 pounds. However, I had become dependent on the prescription medications and the neurologist sent me to a psychiatrist. I was feeling suicidal and I didn't know who I was. In less than two years, doctors and drugs had destroyed my health. I was taking Zanarx, Haldol, Codeine, uppers, downers and sleeping pills. I was admitted to a two-week de-tox program and placed on Methadone -- the drug of choice to de-tox.

Prior to de-tox, the psychiatrist administered an MMPI (personality inventory) test. From the results, I was diagnosed as schizo-effective reaction. Stellazine, Klonapin and Benedryl, and Lithium were prescribed. I could not believe I was suffering from such emotional illnesses when I had never had trouble before. I had worked and supported myself most of my life, yet now, this doctor was insisting I could never "make it out on the street" without all this medication.

The psychiatrist threatened me with the "Baker Act" if I did not take the drugs. (The Baker Act allows a psychiatrist to approach a judge and have a patient institutionalized in the State Hospital where drugs can be force-fed.) I was terrified and actually moved out of the county to another jurisdiction to be free of the threat.

While I followed the doctor's orders, I also consulted with a psychotherapist. This gentleman presented me with research indicating that for neurological patients, MMPI test results were highly suspect and often erratic. He encouraged me to get off the drugs.

Declining recommended medical treatment can create havoc with insurance coverage. I was forced to contact my insurance carrier. Mark Rhoers of Liberty Mutual was my adjuster. He was truly supportive. He recommended a psychiatrist, recently approved by the insurance company and more appropriately matching my needs and interests.

In July of 1993, I began working with Robert J. Mignone, M.D., a psychiatrist and medical acupuncturist. He immediately began a titrating process to get me off all medications and began a series of acupuncture treatments which the insurance company allowed. The doctor believed my reactions and behaviors were completely drug-related. He was correct. It took nearly two years to de-tox from the effects of the medications and to regain normal brain functioning.

During the time I worked with Dr. Mignone, I noticed I was having recurrent bouts of flu-like symptoms including fever, aches and pains, loss of appetite and weight loss. In December of 1993, during a beach weekend with friends, I experienced severe chills. The following Monday, I consulted my GP and he ordered blood workups.

On December 22, 1993, I received results from blood tests. Neutrophils at 9920, platelets at 1472 hundred/cu mm, sed rate at 102 mm/hr and differentiated MCH at 35. The blood work indicated non-Hodgkins Lymphoma. A second opinion confirmed this diagnosis and advised treatment, but suggested I would not live beyond 90 days.

I was weak and thin but unwilling to submit to any drug therapies. I knew I would retreat to nature and sunsets before I would ever consider a hospital bed. I went home and prayed and came to believe Macrobiotics would once again pull me through. Dr. Mignone increased the acupuncture treatments and I knew these two therapies would make me well.

The Oak Feed Restaurant in Miami was sponsoring a Macrobiotic Conference at the Eden Roc Hotel in early February of 1994. I registered immediately and arranged a consultation with my first macrobiotic counselor, Lino Stannich. Lino would become my food coach and recovery guide. I still recall some of his early advice, "You have a strong body and a strong constitution and you are not going to die." And, I didn't!

For the next 10 months, my GP monitored my blood work every 21 days. While at times there would be "spiked" results, by May of 1994, my blood work was clearly changing for the better. By May of 1995, blood tests had returned to the normal ranges.

I relied on other alternative practices including a silent retreat in October of 1994 at the Lama Foundation in Taos, New Mexico. Fasting and colonics were part of that experience. I found such approaches were strengthening to mind, body and spirit.

I learned a lot from these health challenges. The most important lesson, I believe, is to select health care professionals carefully and build a team. If the team is not working well, move quickly to create a better match. Finding open, caring, supportive and involved physicians is extremely important when engaging conventional medical solutions. Complementary and alternative practices were crucial to my healing. By choosing the macrobiotic approach to healing as my primary medical modality, I know first hand that health can be achieved without high levels of pain and suffering --- there are simple ways to wellness and peace.

Today, cancer-free for more than four years, I look back on my story, and remember words of wisdom from my visit on May 15, 1998 with His Holiness the Dalai Lama: "Non-judgemental compassion for the human predicament is the lesson we all must learn, and earth is our school."

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A graphic designer/yoga teacher from Athens, Georgia, who was diagnosed in 1995 with **Infiltrating Ductal Breast Cancer, Stage II-B**

In November 1994, at the age of thirty six, Debora Wright discovered a lump of approximately the size of an almond on the right side of her right breast during a routine self-exam. No symptoms, beyond unexplained tiredness, prepared her for this discovery.

A lacto-ovo vegetarian for nearly fifteen years, Debora was well-aware of the importance of diet and good health. Her immediate and first response was to examine her diet and consider additional ways to refine her eating choices to support healing. She'd read about the links between fibrous cystic breast conditions and diet. Debora believed the recommendations she'd studied might work for her. She made changes in her diet by eliminating caffeine, sugar, and all dairy products, monitoring her condition over the next two months to determine if fibroid cysts might explain the lump.

After two months and no change in the size or quality of the lump, she consulted her gynecologist. A biopsy and mammogram were suggested. The needle biopsy performed in the office revealed the presence of a-typical cells and the possibility of a pre-cancerous condition. However, several days later the lump was undetectable (although still palpable) from the mammogram studies.

She sought out two "second opinions" to determine what course of action would be appropriate. A surgical biopsy was performed in March 1995. This biopsy revealed Infiltrating Ductal Carcinoma. The lump has already developed small, satellite tumors which, until then, had been undetectable through examination or mammography. Staging was determined to be II-B, and a total mastectomy followed by high-dose chemotherapy and radiation was recommended. It was believed that such an aggressive approach to treatment could effect a cure.

The night after the surgical biopsy, Debora spent two hours with her surgeon reviewing every detail of diagnosis, treatments, and procedures he recommended for this type of cancer. She felt strongly that she needed time to make the right decisions. To move ahead with confidence, it was important to her that her next moves would be from a position of strength and knowledge – utilizing informed and educated choices. The support of family, friends, years of yoga practice, and meditation, aided her to steadfastly pursue the research and maintain balance of "well-being" while gathering information.

Her investigations revealed statistics demonstrating no difference in long-term outcome for patients waiting one-to-three months after biopsy before starting treatment. Feeling strongly that taking the time she needed to make decisions would benefit her final outcome, she postponed conventional treatments.

Grateful for early detection of her cancer, Debora took the time she needed to think and respond in a way that made sense to her.

During this time, a dear friend gave Debora a copy of Michio Kushi's book, *The Cancer Prevention Diet: Michio Kushi's Blueprint for the Prevention and Relief of Disease.* Immediately, the study of macrobiotic techniques became a part of her self-preservation, research, and healing program. She began practicing macrobiotic approaches to lifestyle and diet, using the book and applying the recommendations for breast cancer.

Inspired and encouraged by her reading, Debora decided to seed guidance on macrobiotics, and arranged a consultation with Michio Kushi in May 1995. The consultation further inspired and empowered her with the knowledge and conviction she needed to actively contribute to her own healing through the macrobiotic approach. The knowledge gained through Mr. Kushi's guidance enabled her to exert a new level of personal control over her condition, not offered through any other medical approach. His direct and specific recommendations allowed her to understand how to personally apply the diet and lifestyle changes necessary to facilitate her healing. Debora began to build her strong foundation in nutrition while better enabling any decisions of what the next treatment step would be.

The revealing news of the biopsy marked the beginning of many challenges. Facing the fears of a life-threatening disease and the issues of mortality that arise was more than enough to handle physically and emotionally. Debora, however, also faced this challenge without health insurance. As the burden of the financial impact increased, she was forced to file bankruptcy as her only alternative to stabilize her difficult financial situation. Her income level qualified her for financial support only if she chose to undergo chemotherapy and/or radiation treatments. No other alternative or complementary treatments were covered under this program. Debora was angered and frustrated at the limited, narrow support that was available. She was getting results through her dietary and lifestyle changes, but could receive no support or financial assistance to take advantage of these modalities to their fullest potential.

The Kushi Institute provided the greatest support for Debora. The educational programs empowered her with the knowledge and skills to reverse her health condition through the macrobiotic approach, improving her health condition in a matter of months. She was able to buffer the extreme costs incurred through this health crisis by being pro-active in her own healing and seeking out health approaches that she could take responsibility for (such as macrobiotics). She continued this pro-active stance and built a strong foundation in macrobiotics in a few months while deciding what steps would follow.

At the end of June 1995, Debora decided to undergo a complete mastectomy while going full steam ahead with macrobiotics. Having now followed macrobiotics for nearly four months, Debora experienced rapid recovery from the surgery, impressing her doctors with the speed of healing.

Following surgery, Debora visited with her oncologist to discuss chemotherapy and radiation treatments. After that meeting and with more information gathering, Debora once again carefully thought through the next steps. Feeling strong, energetic, and healthier than she had ever felt before, Debora believed the macrobiotic approach to lifestyle was creating this feeling of wellness. She took a full month away from doctors and research and chose to experience, full-force, the power and benefits of this lifestyle combined with yoga and meditation. She spent the month relaxing, renewing, and healing at a yoga center retreat.

After that month, she returned to the oncologist and informed him that she would not move forward with chemotherapy or radiation treatments. Confident that healing was taking place, and having blood work-ups and medical reports supporting that stance, Debora felt additional conventional treatment would jeopardize the progress she'd made.

The blend of alternative approaches and conventional treatment worked for Debora. In June 1999, exactly four years after the mastectomy, Debora continues to be healthy with strong blood-work and a strong commitment to the macrobiotic approach.

Mr. BURTON. Sounds like some people like you quite a bit. I don't even get that kind of applause when I go home. [Laughter.]

First of all, let me ask a few questions here.

Ms. Mack, when you had your breast cancer, did you have it in any of your lymph nodes?

Ms. MACK. No, I did not. It was diagnosed early enough. I had no lymph node involvement. Therefore, my prognosis was much better.

Mr. BURTON. Did you have any chemotherapy?

Ms. MACK. Yes, I did. I had 6 months of preventative chemotherapy. At the time I was diagnosed, the protocol for breast cancer without node, lymph node involvement, had gone to 6 months of preventive chemotherapy following a mastectomy. That wasn't done even a year before. Usually they didn't follow along with anything. And then the 5-years of Tamoxifen after that.

Mr. BURTON. Did you have radiation, too?

Ms. MACK. No, I did not.

Mr. BURTON. Did not have to have radiation?

Ms. MACK. No, I did not.

Mr. BURTON. I recall when my wife had her breast cancer and she did have it in five of her lymph nodes, and that's why the prognosis was not that good. One of the most tragic things that people go through is, when they start, women start to lose their hair after the chemotherapy. So I just wish everybody in America could have the opportunity to share the kinds of pain, mental pain, that women and their husbands go through when that sort of thing occurs, in addition to the other side effects of cancer that affect the family life.

You are to be commended for what you are doing. We really appreciate it. I am sure other Members will have questions for you.

I do want to ask Mr. Kushi a few questions. You have—apparently a lot of these people had diseases that would have been deemed terminal illnesses before they went on your program. Some of those people you mentioned had lymphatic cancer and they also had cancer that had spread into the stomach and into the pancreas. I heard one that said the liver, which I always thought was a terminal situation. How do you account for the reversal of their problems? Is it strictly because of the macrobiotic diet you talked about?

Mr. KUSHI. All cancers are heavily related to and caused by daily eating. For example, pancreatic cancer, as I mentioned, is caused by heavy poultry eating.

Mr. BURTON. Poultry?

Mr. KUSHI. Poultry and egg eating, and also shellfish eating, and hard-baked flour, et cetera; of course heavy fatty, oily foods. So now when we approach this cancer, we must reduce, eliminate or reduce those foods which we're eating, and we are recommending more grain, vegetables, and other healthy ones. We try to eliminate as soon as possible from her body or the patient's body the effects of accumulated fat and those accumulated bad influences.

Mr. BURTON. How do you eliminate that? Some people talk about these like chelation therapy. Do you just do it by diet?

Mr. KUSHI. Through the diet, a very simple way. I would like to present maybe one example.

Mr. BURTON. Sure. Go ahead.

Ms. AKBAR. Hi. My name is Chris Akbar. I am one of Michio's assistants in Boston. In 1985, I was diagnosed with inflammatory breast cancer at Yale-New Haven Hospital. I was a grad. student working on a Ph.D. in physics at the time. My diet consisted primarily of ice cream, chocolate, cheese omelets, and pizzas. I was very fat. I weighed 170 pounds. Primarily dairy food and sweets.

I discovered a red hot inflammation in my breast, very painful. I went and had penicillin for 2 weeks and nothing happened. Then I had a mammogram that showed nothing. I had ultrasound; it showed nothing. I finally had a surgical biopsy. They told me I had inflammatory breast cancer. This was in 1985. They told me I had 2 or 3 months to live. They said it was the most lethal; it was immediately in my lymphatic system.

I said "Why do I have cancer?" to my doctors. This was at Yale Medical School, and they had a lot of research there. They said, "It's genetic." But nobody ever had cancer in my whole family.

Then I said, "What can I eat? I am huge. I am obese. What can I eat?" They said, "Don't lose an ounce, because if you lose any weight, the cancer is going to be killing you even faster, if your body is starting to waste away. So have some Chocolate Ensure, which is made out of basically sugars and oils." They served us chocolate-covered donuts in the waiting lounge of the radiation laboratory where I was going. I thought something was a little bit strange.

Anyway, I started chemotherapy the next day. It was CAF. It was adriamycin, 5-FU, and cytoxan. Adriamycin made my hair fall out within 3 weeks, and I was devastated by that, plus nauseated. I went through menopause at the age of 33, basically, because of the drugs. Then I did radiation twice a day for 6 weeks. That was a very intense experience also.

Meanwhile, I had read a book about macrobiotics. It was by a physician from Philadelphia who had prostate cancer that had spread throughout his bones. He was basically a hopeless case. He was the chairman of Methodist Hospital. He picked up some hitchhikers who were hippies back in the late 1960's who said "Try a macrobiotic diet, it will save your life." Well, he did. After 1 year of macrobiotics, he was completely cancer-free, with no other medical treatment. He was on a gourmet French diet, with heavy fats, heavy meats, heavy sauces, wine, everything. He was from Philadelphia and he went to Le Bec Fin Restaurant, basically.

I was on a gourmet chocolate diet. I said this is the cause of my problem. I really think dairy food goes to the mammary part of my body and creates a problem. It just makes sense. I picked up a book, the Cancer Prevention Diet Book you have. It said, "Dairy food and sweets is the primary cause of breast cancer." That was the main thing I was doing. It said, "Stop those things and start taking some things to clean it out."

Well, I came to Michio for counseling. His wife had just done her cookbook. I said this is my bible. I am just going to follow this book. I did. Michio gave me very simple remedies. He gave me a plaster made out of barley and cabbage that I just put on my breast every night. In 5 days, I felt the tumor getting smaller and softer. He gave me something to reduce my weight, simple vegeta-

bles like daikon, which is a long white radish, and carrots. I just grated them and ate that every day. I lost 50 pounds within like 2 months. All this fat came off of me.

I had a really bad pancreas from so many eggs and cheese I had eaten. He gave me a simple drink made out of cabbage, carrots, onions, and squash, called Sweet Vegetable Drink. I took that and my pancreas cleaned out. I no longer had sweet cravings. I didn't want chocolate every afternoon at 4. I had chronic constipation. I think that is often associated with breast cancer, because the toxins sort of buildup in your body and you can't eliminate them. He gave me something to strengthen my intestines, a simple like oriental drink made out of a white powder, a root powder, like a starch that strengthened my intestines.

I just did his diet. I never have touched, in 14 years since, I haven't touched any ice cream or chocolate or dairy food or meat, and I don't miss it at all, or sugar. After 2 months, I got incredible diarrhea one night. I wondered what was happening. The next morning I had realized that my entire tumor that was hanging on here was completely discharged out of my body naturally.

What had happened was in your intestines, when you eat, the nutrients from the foods that you are eating are absorbed and it changes the quality of your blood. If you are taking these things like I mentioned, these macrobiotic-type things, it actually goes through like a solvent and goes in and through your body and cleans everything out. So as I was losing all of this fat, everything was literally, along with the tumor, was just absolutely discharged out of my body. It was very effective.

I am a scientist, so I kept very careful records of what I was doing and how my body was reacting. I found if I took any extra oils—he had told me oil is like throwing oil onto a flame, which was this inflammatory tumor—if I ate any oil, the redness would come back. In fact, it did, the inflammation. I could actually cause the inflammation to come back. I just literally eliminated all of that stuff that caused the cancer, took these things, these vegetables and grains and beans and seaweeds, and whatever, to clean out. Literally it flushed out of my body and saved my life.

So in 2 months, when I was supposed to be dead even with the medical treatments, it saved my life. It was so effective. It literally used the food as a cleaner to go through and clean out my body, very effective. I was really impressed. So I'm alive; 14 years later, here I am.

Mr. BURTON. I would guess you would be impressed.

[Applause.]

Mr. KUSHI. Those friends, besides many hundreds of other people, have been experiencing similar ways.

Mr. BURTON. Well thank you, Doctor.

My time has expired. Let me yield now to my colleague, Ms. Norton.

Ms. NORTON. Thank you very much. Both of these testimonies have been very, very impressive and very important.

I would like to know, Mr. Kushi, what is your training or your background that led you to the development of your approach?

Mr. KUSHI. Fortunately, I was not in medical school. I was a political science student, international law. After the end of the war,

the World War, I wanted to have world peace. So I became a world federalist. Mr. Norman Cousins and a friend sponsored me, and I came at the age of 23 years old to America, 50 years ago. Then while I was studying in Columbia University's graduate course, accumulating various kinds of documents, the drafts of world constitutions and other related documents, I started to wonder whether even if this world government, world federation is born, how about sickness, how about love, how about sharing of people, how about prejudice or discrimination, those mental problems. And then I wondered, unless those things were corrected, there is no world peace.

So I started to search for a solution, including visiting Dr. Einstein and Mr. Norman Cousins and various others, Thomas Mann, and so forth. But there were no active clear answers. But we have made religions, hoping to make people better. But between religions, then fights arise. Then we hoped education had high expectations, and also material prosperity; then again, unfortunately, sickness spread, crime spread.

So I started to—I gave up all political science studies and I started standing on a corner in New York's Times Square. Since I had been here, I started to watch people. What is humanity; what is humanity? It took 2½ months; then I understood. Everyone had been, mankind has been made by two factors: one, environment, and two, what we eat.

What we eat is entirely in our hands, freedom. Individual people are freely choosing, freely cooking and so forth. Now if proper diet is eaten, and the environment, certain clean environment is done, then happy conditions come. If not, then sickness arises, crime arises, violence arises. So then I found that in the American diet of the 19th century, 20th century, comparing 19th century and 20th century, tremendous change occurred. More increase in animal food. More increase in dairy food. More increase in refined sugar. More increase in mass production of food, agricultural products, et cetera, and so forth.

Exactly parallel with this change of diet, heart disease is increasing, cancer is increasing, and various kinds of so-called degenerative diseases are increasing, as well as so-called virus diseases and also mental problems have increased. So I wanted to change our current way we're eating. Then we began the so-called natural food movement and cooking classes. This is my background.

Ms. NORTON. It is certainly true, particularly when studying populations of different countries, research has begun to show the associations that you indicate. I also note that in your testimony you seem to have an integrative approach as well. You indicate the debt we owe to conventional medicine, and then you indicate that there are certain things that medical schools and others can do to integrate these approaches in order to get better results for people who have the disease or to prevent the disease.

May I ask if the people who are under your care, if you require that they not engage in conventional treatment or if some of them have also been engaged in conventional treatment while being involved with your diet?

Mr. KUSHI. Those things are up to the patient. The entirety of patients have entire freedom. However, because the cause is diet

and lifestyle, so basically the cure is, basically the diet, proper diet and proper lifestyle. Then in addition to that correction, patients, if they want chemotherapy or radiation or acupuncture or herbal medicine, that's fine. They can attach these. But I hope this treatment can be mild and not overdosed. Because in my opinion, and in other people's opinions, by overdose of chemotherapy, overdose of radiation, this often affects so much the suffering of the patients, not only suffering, I wonder maybe shortening their life also. A moderate approach, I hope, the medical treatment can take.

Ms. NORTON. I just want to say to Mr. Kushi, I think increasingly many people adopt the point of view you just expressed, that the treatment is worse than the cure, and many people forego such treatments.

I just want to say in closing to Ms. Mack, how important her leadership has been, that when you have come forward and others like you have come forward, you cannot imagine the effect you have had on people who would not otherwise come forward. By doing the race, there are women whose attention we could not possibly get except through the dramatic intervention of well-known women who are first, willing to indicate that they have had the disease, and then willing to show that the disease can be defeated. I certainly want to thank you for that.

I have a sister who is now president of a college, who has had breast cancer and feels herself entirely cured. Since I am her sister, not only do I want her to be cured for that reason, but because this thing may also run in families. I certainly appreciate the leadership you have given to this work.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Ms. Norton.

Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman.

Mrs. Mack, I just had a couple of questions. First of all, your leadership has been tremendous in the private sector in providing awareness and also raising funds. You cited in your testimony how much money had been raised privately just by the activities you have been involved in. Maybe you could comment to the committee on your suggestions for research and for funding, and what do you think would be an appropriate private-public mix of funds?

Ms. MACK. Well, I believe the Congress is doing an awful lot in the doubling of the moneys for NIH which Connie has been involved with. Getting the funding doubled for NIH will help all diseases. I believe that all that we do in research is where we are going to find the true answer to not just cancer, but all other diseases, and through research, through alternative medicines. Research in every way is going to make the difference. Public and private, we all have to work together. It is a large problem. The Government can't do it alone, and neither can the private sector. I think whenever we can partner and whenever we can work together, the cures and the research will come to make a difference.

Mr. MICA. One of the other things that I wanted to ask about was that you had talked about awareness and self examination. There seems to be somewhat of a lack of public awareness. How do you think we should best approach these campaigns from a private sector's standpoint or public or a combination? What do you

think is most effective in getting the message that you are trying to get out to women and others?

Ms. MACK. Well, I believe it is through hearings like this, through races, through advocacy, that all the women in this room, and all the people in the cancer communities do. We are blessed in this country with many generous, wonderful people who raise money in the private sector, but also our Congress and our administration, work diligently to find the answers to cancer, in particular, and diseases in particular. But I just think we have to continue. We can't sit, rest on our laurels. We have to continue to be out front and continue the fight, and to make more people aware.

I mean, as obvious or as outfront as I have been and Dr. Kushi and everyone else, there are many, many people out there who haven't heard a word we have said. We have to continue to get to the underserved. We have to continue to get the message out that early detection, until we find a cure, is the way to deal with most diseases if you find it, or prevention through ways that have been proven to make a difference. It takes a lot of money. It takes a lot of time, and it takes a lot of heart. Through public and private, we can do it together. We cannot do it alone.

Mr. MICA. Thank you.

Mr. Kushi, you spoke quite a bit about diet and changes in lifestyle and prevention. What do you see as the role of research today and how important do you think that is in finding a cure for cancer or addressing cancer treatment?

Mr. KUSHI. There are many approaches for cancer treatment and many ways we should also examine, and research should be done. However, as I pointed out, basic problems of cancer and other disease are what we are eating and daily life. Therefore, do research to associate diet and daily life with cancer, and if more research goes there and finds what kinds of results are coming, such as test in the clinical trials, in the hospital, this and that, et cetera; and data accumulation. For example, it's very easy to confirm that blood pressure comes down or cholesterol comes down, it is very easy by changing diet. Same thing, like for diabetes, it is very easy to offset, even though insulin has been consumed. Situations are also very easy by dietary control.

In a similar way, if you subject patients to a study about this type of cancer, or just study this type of sickness, how diet is related. I suppose I or someone else, we will be very happy to confirm that this kind of diet will offset or reduce or prevent that; while, if the current way of eating continues together with any medical treatment, how different outcomes will result. It is very clear, you can see that. Then after you have accumulated those data, then you can apply these clinical tests in the hospitals, you can apply it in other health clinics. Those data can be created easily in 6 months, 1 year, or at most 2 years' time, enough data which we can convince the people who are watching the healthcare field and educational field.

Mr. MICA. Thank you, Mr. Chairman. I yield back.

Mr. BURTON. Thank you, Mr. Mica.

Mrs. Mink.

Mrs. MINK. Thank you, Mr. Chairman. I want to compliment both of our witnesses. You have very inspirational messages, not

just to this committee and the Congress, but to the American people at large.

I detect the common theme of both of your testimonies, is a sense of personal responsibility. In your case, Mrs. Mack, your detection was by yourself through self examination. The message there is that notwithstanding all the medical instruments that are now available for detecting breast cancer, there is really no substitute for the once-a-month self-examination procedure.

In your case, Mr. Kushi, the knowledge that what you eat is what you are, I think, is an important message that we have to take very, very seriously. I do think that the points you make in your testimony, Mr. Kushi, have been well expressed by nutrition experts, by people in the medical profession who are constantly hammering on your diet, don't eat fats and stay away from this or that. So I think the general message is not that different in terms of the medical profession and what you are espousing.

The point, however, of getting the message earlier in life, particularly in places like the school lunch program in our schools and in our training programs. I have been told that medical doctors have less than one course subject on nutrition and the diet. They go out and they are treating patients with very serious illnesses, with very little perception about the importance of diet. So I think we have to carry the message to the professionals and convince them that the words they expound about diet truly have meaning. I think that that is what you have brought to this committee. I commend you for your work and for your leadership, and commend your book. I will get a copy and read it from cover to cover. Thank you very much.

Mr. KUSHI. Thank you.

Mr. BURTON. Thank you, Mrs. Mink.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. It is a pleasure to have heard both of you and to Mr. Kushi, to have had the women who have appeared here and gentleman to comment on the successes.

Priscilla Mack, you are so right. You know, over and over again, you said early diagnosis makes the difference. I am pleased that in my area with the American Cancer Society, with a number of hospitals involved, with Hadassa, we have been bringing a program called Check it Out to high schools, and inviting the 11th and 12th grade females to come together in an assembly and to learn self-examination. They ask very graphic questions. They learn it not only so they can get into the habit of doing it, but so that they can be the messenger, to bring the message to their older sisters, their mothers, their grandmothers, their friends. I guess that this is something from what you said, in terms of how you even discovered that you had a challenge, it is through the self detection.

So I want you to know how much I appreciate what you have done, and the fact that you have brought an enthusiasm and such strength to the whole concept of research and our own personal involvement, and certainly the Komen Race for the Cure. No wonder the money has doubled over the last year, because we have had inspirational people. So thank you.

I am interested, Mr. Kushi, whether or not first of all, these people who are such great testimonials to the concept of the dietary facet of it, do they come to you as a last resort? And how do they hear about you? Do you have any centers in Maryland?

Mr. KUSHI. Your home, I hope your house will become a center in the near future.

First of all, many people are coming to see me or my associates, or teachers. Many of them have already received medical treatment. They were declared—no way, terminal cases, or they themselves were dissatisfied with the results of the medical treatment. Those people come. Of those people who come, maybe 40 percent of people are this type.

Second is the people who got sickness and got diagnosed. Then they start before they receive conventional treatment, they start to search for alternative ways and come to us. That is the second approach. That may be about 30 percent or so.

Another number of people for the sake of keeping their health, for the sake of precaution, they also come. And people who have come to us because they found at that time maybe stage one, two, or three of cancer, different stages. But as I said, and as you know, many women are hesitant to go in for drastic treatment. So before receiving treatment, they search. Otherwise, after they receive some drastic treatment, then they still are told there is no hope. Then they start to search.

Mrs. MORELLA. Do they hear about you basically through your book?

Mr. KUSHI. Yes, through words, through books.

Mrs. MORELLA. Word of mouth, words spread.

Mr. KUSHI. Yes, that's right. We are not a commercial venture, so we never advertise. But through books, through education, and also our educational center, the Kushi Institute in Massachusetts. However, through that dedication for many years, many graduates have come. I develop those teachers. Throughout the world, several thousand teachers are out there. In this country, many States, many cities have also macrobiotic teachers. They are doing cooking classes, they are doing health advice or various social work.

Mrs. MORELLA. You would, it seems to me, suggest that doctors, that all doctors, all of the health practitioners include as part of their treatment that there be the recognition of how food as well as exercise and other moderate lifestyles, the role that food plays.

Now she mentioned some of the mixtures that you made. I mean do you have to have it in mixture form? Can you just have like good vegetables and have a list of dos and don'ts? Does it have to be mixed in a certain proportion?

Mr. KUSHI. It depends on the condition. For example, you know, like colon cancer, that more is caused by beef and pork and cheese, eggs. Eliminating that effect, then we need like grated daikon, grated carrots, green leafy vegetable juice, and so forth. More opposite factors we bring, and other factors to balance the condition. In the case of, like I would say intestinal problems, then there, traditionally the oriental countries have been using kuzu and also pickled plums, which are very good for digestion; and also, suppose, if you want to straighten out pancreatic cancer, then you better have sweet vegetables like cabbage, carrots, squash and onions: those

finely chopped in equal amounts, and with three or four times water, cooked 25 minutes. That's a sweet vegetable drink. Drink every day, one cup, two cups. That makes it easy to solve the cancer.

In the same way, our approach is, No. 1, the safest approach. No. 2, cost value is low. No. 3, at home they can practice and use foods, food which they can get very easy. Using them, they make home remedies.

Mrs. MORELLA. I guess I am going to have to buy the book. Thank you very much.

Thank you, Mr. Chairman.

Mr. BURTON. Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

To Ms. Mack, I want to thank you for being a leader in this area. So often what happens is, I think it was Martin Luther King, Sr., who said that you cannot lead where you do not go, and you cannot teach what you do not know. So often people go through difficulties. Once they get through their difficulties, they almost act like it never happened. But not only have you remembered, but you have acted on them to try to help other people. I think that there is no greater thing that we can do as human beings than to use our pains and our problems to turn them around and use them as a passport to help other people. So I thank you for your leadership.

As I was looking at the statement of our good friend Mr. Kushi, I just want to ask you a few questions because I am truly fascinated. Mr. Chairman, I am so glad you had this panel because I did not expect it to be so interesting. [Laughter.]

Mr. BURTON. Are you inferring that this committee is not interesting? [Laughter and applause.]

Mr. CUMMINGS. One of the things that you talk about is cost,* [see below] that so many people, they can't get healthcare because of the cost. I guess they may not have insurance or whatever. I am sure it must be very frustrating to you and probably I'm sure you too, Ms. Mack, when you are on this mission to help people and to know that cost of treatment is something that because people can't afford certain treatments, that people are literally not only suffering, but dying. I mean that must be a very frustrating thing for you all. I just would like for you all to comment on that.

Mr. KUSHI. I agree, and for example, more in conventional medicine, doctors learn in medical school training there is no single course for nutrition, and diet; but by eating we form blood, we form our limbs, we form all sides of our bodies. Without understanding that, there is no way to understand cause.* [It seems that Mr. Kuchi heard "cause" instead of "cost" in the question of Mr. Cummings. Therefore, he addresses the frustrations of symptomatic medicine where "cause" is not eliminated.] Therefore, all patients are frustrated. If treated with a symptomatical approach, symptoms maybe might be temporarily eliminated; but then the cause still continues, still taking heavy meat, et cetera. Then again, symptoms come back 2 years later, 3 years later, all very shortly. Again, in the hospitals, even in hospitals, what are patients fed in there? They are fed the cause of the sickness, that beef or ice cream or whatever. This is a very ironic situation!

While trying to help sickness, they are creating more sickness, and endless heavy treatment, more increasing chemotherapy; more radiation is needed; and doctors themselves, I know, many doctors are frustrated. Why should we not open our eyes to the cause. Without knowing the cause, there is no way of cure. That's the medicine of symptoms, but not cure. But cause is, day to day our own way of eating, our own way of lifestyle! There probably, our thinking, consciousness must change. We want to have the prosperity, we want to have that. Our thinking must need to change, but at the same time, we can begin from day to day life now.

We lost family cooking, with all outside fast food and this and that, et cetera; and together we are losing family cooking. Our family relations between father and mother and the children are becoming more and more troubled. Also in school, the concentration of students becomes troubled. The school lunch program is more fatty food, more heavy food, more sugary food. They can't concentrate in the school. Then unless we bring back to America and the entire world, which is influenced by America, good way of eating again, there is no way to solve this. America and other countries are all sinking down physically and economically.

Mr. CUMMINGS. I must tell you that you already had an impact on me. I have gone back there to the little room here to eat my potato chips, roast beef, and my Coke, and I could hardly get it down. [Laughter and applause.]

As a matter of fact, I left three-fourths of the bag of potato chips out there. I think I am going to throw them in the trash.

Mr. KUSHI. Let us think of our ancestors, your ancestors, all mankind's ancestors. Traditionally, we have been eating whole grains day to day. Right? Either bread form or rice form or whatever, and then vegetables, then beans. From beans, bean products we have been getting more vegetable quality proteins. Some countries may be getting seaweed, and so forth, a mineral source. Then we are doing home cooking. Animal food, like beef, our ancestors consumed much, much less. I have no objection to having that, animal food, but much less percentage, and not like currently, like antibiotics—or hormone-treated beef, and so forth. Then we didn't have cancer in the 19th century, 18th century. Why not? The tremendous change in the diet. Tremendous decline of what we are eating!

Mr. CUMMINGS. Thank you very much. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Cummings. I didn't know you were a standup comedian, but you are pretty good. [Laughter.]

Mrs. Biggert.

Mrs. BIGGERT. Thank you, Mr. Chairman.

Mr. Kushi, your diet seems to be quite the opposite of several diets that are popular right now in this country as far as losing weight.

Mr. KUSHI. For example?

Mrs. BIGGERT. Like the Zone diet or sugar busters, those high protein diets, which are high in fat, animal and dairy. But do you think that these type of diets then will contribute to greater cancer risks?

Mr. KUSHI. To certain period, for certain period, to certain symptoms they maybe contribute. But what macrobiotics recommends is very traditional, thousands of years or maybe a million years, mankind's experience, generations to generations, whole grain and vegetables, beans, et cetera. And that is the base. It then depends on climate, depends on where you live. Cooking methods change, and also combination of vegetables, combination of foods change. But the base is there, grains and vegetable base. Animal food you can add 5 percent, 10 percent, depends on your condition. Fruits also you can add, it depends on the seasons.

Suppose we didn't have in Washington, DC, our 20th century banana, because it simply didn't grow here. Now we are taking a banana every day. Or sugar, we didn't have sugar cane. We are not growing it here. All climates are different. Therefore, we need for those things to have moderation—tropical products, et cetera. That means environmental consideration is needed.

Mrs. BIGGERT. What about the role of exercise then?

Mr. KUSHI. Oh yes. The role of exercise is great. However, recently they are recommending that some special exercise is very popular now, certain types of exercises. I would say yes, you may do so. However, more important is day to day work, day to day active living. I am recommending to the sick people, the people who are sick and my associates, I am recommending every day with hot wet towel squeeze, scrubbing their whole bodies twice, morning and night, making blood circulation active, and so forth. Then take a walk at least a half hour, taking a walk if they can walk. Then if they can do any light exercise, fine. But not strenuous exercise. Then every day, singing a song, happy song—"You Are My Sunshine" or whatever, not a depressing song—every day. That opens the chest and makes the breath and circulation better, and the emotions up. Also I am recommending people wear cotton clothing, and more cotton bedsheets and pillow case, instead of synthetic ones; and more also putting green plants in the home, which emit oxygen and keep the house better. Also, this may be a problem now, not using a computer much if you are sick.

Mrs. BIGGERT. It sounds like a whole positive attitude.

Mr. KUSHI. Yes. Also microwave cooking is very questionable, microwave cooking. Now 75 percent of the American families are using microwave cooking. This is a big problem, question. Traditional cooking, like charcoal cooking, or the gas stove is much, much better. Furthermore, the like electromagnetic environment it is better to examine. Also, as home family cooking will be recovered, and I hope they have a chance, the whole family has a chance some evenings at dinner time, to talk to each other. They should sleep not at midnight, more like 10 or 11, and so forth. In other words, healthy, normal healthy life!

Mrs. BIGGERT. Thank you.

Mrs. Mack, I really appreciate your testimony and your presence here after the Race for the Cure last Saturday. It is amazing how across the country this type of activity is being conducted. I know in Illinois we had a big event there. I have to say that we didn't have quite the 66,000 people that were here in Washington, DC. But I think that does so much to raise the consciousness of the problem.

But in your work with breast cancer survivors, are there characteristics that you find that people have in common that are successfully overcoming their cancers?

Ms. MACK. Well, I will have to speak only for myself and the people I speak to, my impression of that. But I find like Mr. Kushi says, if you have a higher power and you do everything on your behalf that you can do to further your recovery, take care of yourself to find out what's out there to take care of it, and then what you can't do, let go and let God handle. Also, if you can do that and you have the serenity to do the right things for yourself and have that positive attitude, I find that through all of these things, we are changing the mindset that cancer is a deathnell. When we continue to do that, we also bring to that good mental health, which also affects your physical health.

Mrs. BIGGERT. Thank you. Thank you, Mr. Chairman.

Mr. BURTON. Well, thank you, Priscilla. You have been lovely as always, and we really appreciate your comments, especially the last ones you made. I think those are very important about having the higher power, the supreme being. A little prayer doesn't hurt. It doesn't hurt a bit. It kind of calms the soul and helps stabilize everything.

Mr. Kushi, I pledge to you, every morning I am going to start singing "You Ain't Nothing But a Hound Dog" so I can get myself off to the right start.

Let me thank you both. I think it has been very, very enlightening. We really appreciate it. Mr. Kushi, your book, I am going to recommend it to a number of my colleagues. I think they would like to read it as well. So thank you both very much.

Mr. KUSHI. May I just add one thing about diagnosis? Very simple. For the family, to know where diagnosis is about cancer conditions, in the beginning stage. At this place,* [Mr. Kushi points to the outside edge of his hand, below the little finger] if green color comes out, then we have to suspect in the near future cancer may begin.

Mr. BURTON. Here?

Mr. KUSHI. Yes. In the case of breast cancer, this center, green straight line* [Mr. Kushi points to an imaginary line running down the center of the underside of his arm, up through the center of the palm, to his middle finger] comes, in the case of risk. This begins 6 months before cancer, one of the symptoms. This is an acupuncture meridian, the so-called "heart governor" meridian. It goes across this breast. If that meridian is clogged from the breast, then down the arm, it then becomes a green color in the case of cancer.

In the case of the uterine cancer or ovarian cancer, here* [Mr. Kushi grasps his chin with his thumb and index finger] if we have a very fatty, large deposit, and especially a hard one, then uterine cancer, ovarian cancer or cervical cancer is very suspected. Prostate cancer too, is very suspected for men.

Mr. BURTON. Right here under the chin?

Mr. KUSHI. This. It's because low in the head reflects low in the body. It's very accurate. Various simple way of detection are available also, as information for home use.

Mr. BURTON. Thank you, Doctor, very much. Thank you both. We really appreciate it. Thank you all those who are applauding. I appreciate that as well.

We would like to now have Dr. Gardener, Ms. Zarycki, and Ms. Bedell-Logan come forward, please.

Dr. Gordon, since you have time constraints and you have to leave right away, you said you have a relatively brief statement you would like to make. So we will allow you to do that. Then we will go right to our ladies.

Dr. GORDON. Sure. I wanted to be able to stay around for questions though, if you would like to ask the questions too. I just was saying that I have to be back there by 3.

Mr. BURTON. In that case, if you wouldn't mind, Dr. Gordon, I think we will go ahead with this panel, and then we'll hold you, because I think we will be finished by 3.

Dr. GORDON. OK, great.

Mr. BURTON. Let's start with Ms. Zarycki. Did I pronounce that correctly?

Ms. ZARYCKI. It's Zarycki.

Mr. BURTON. Zarycki, I'm sorry.

STATEMENTS OF CAROL ZARYCKI, NEW YORK; N. LEE GARDENER, PH.D., RALEIGH, NC; AND LINDA BEDELL-LOGAN, SACO, ME

Ms. ZARYCKI. I was going to say good morning, but it's really good afternoon.

Mr. BURTON. Well, these hearings sometimes run a little ways into the afternoon, but they are very important.

Ms. ZARYCKI. Yes, they are. Thank you for the opportunity to testify regarding complementary and alternative practices, which I will call CAM, and the role of women's cancer treatment. I am Carol Zarycki, an advocate and breast cancer survivor of 2 years. In my written testimony, I have outlined issues and instances where we as patients have had to do most of our own research in seeking out CAM protocol. I will highlight some of these points and summarize my personal approach.

I am speaking for myself and other patients and advocates whom I'll call we, to request legislation for CAM medical research and funding rather than to continue regulation of standard allopathic treatments, the costs of which are ultimately borne by the taxpayer and the Government, and which do not show an increase in cancer survivor statistics. We are tired of hearing about measures such as time to recurrence, tumor regression rate, or time to disease progression, when the real issue is preventing cancer in the first place. We would like to see a shift of funding and research attention to the review of a standard cancer protocol that is less toxic, better targeted, and more effective, while at the same time, focusing on CAM therapies.

The role of insurance coverage is a primary factor in the CAM choice process, and needs to be addressed, not just for patented drugs or diseases with a name, thereby endorsing insurance coverage, but for natural alternative treatments, so that we don't have to invent new names for new types of cancers. We need to have access to treatments and clinical trials that will work with us as indi-

viduals rather than be limited in choices. Some toxic medical procedures given routinely can leave the immune system in deep disrepair, making one more susceptible to recurring disease for this very reason. Ironically then, one would have to seek alternative treatment not covered by insurance to alleviate or attempt to alleviate this previously non-existing damage.

Information needs to be made available so that individuals are fully informed of options and possible treatment outcomes, including quality of life and survival rates for the treatments they are choosing. Most women given Tamoxifen do not need the drug, and may even get the danger of side effects of blood clots in the legs or lungs, uterine cancer, strokes or heart attacks. A few of these women will have disease progression or recurrence anyway.

New legislation is required for alternative therapies in cases where old or even new drugs may not demonstrate an increased survival rate or even a better rate of progression-free survival.

There needs to be a recognition of chemicals in the environment and their effect on hormones from the fish we eat to our plastic-bottled drinking water. Our country regularly imports fruits, vegetables, and foods that have been treated by toxic methods, even when the imported food is labeled organic. Since it has been demonstrated that hormonal imbalances are an underlying factor in a growing number of breast and reproductive cancers, wouldn't it make sense to research natural hormones rather than add synthetic tamoxifen, raloxifine or premarin to an already overloaded hormonal system?

Evidence-based testing methods and not just scientific competition within the medical community, without regard for the population being studied, need to be employed. Trials which indicate life extension should additionally be able to demonstrate that this means for more than a few weeks, and should also discuss quality of life issues.

Non-toxic and non-invasive methods of cancer detection should be standardized, instead of encouraging mammograms which strongly increase a woman's chances of getting breast cancer in her lifetime. Also, for younger women with dense breasts and therefore, unidentifiable or undetectable cancer, mammograms can weaken the still growing tissues, thereby promoting future malignancies.

A focus on preventive measures which strengthen the immune system rather than early detection methods, which can also be too late detection, and with their own set of risks and hazards, can be incorporated into an individual's lifestyle. Allopathic medicine used on its own needs to clinically understand the traumas and debilities it is in itself creating, not curing. We want to be able to live in peace with the treatment decisions we are making, without fear that mammograms, therapies, toxic and synthetic drugs are doing a potential future harm to another part of our bodies. We do not want to hear about 5 or 10 year guidelines that we are being measured against, but rather experience peace by knowing about immune strengthening practices which will eliminate the need for these guidelines and also the topic of recurrence.

We are requesting a sharing of both conventional and alternative medicine, so that it can truly be called an integrative complementary medical practice. We must try a new approach because the old

ways are simply not effective in reducing mortality rates. We must try a new approach because the old ways are simply not saving our best friends' lives.

For my personal approach and upon initial diagnosis, I spoke to my herbalists, each of whom had started their practices due to family members' involvement with cancer. I contacted local and national organizations, including SHARE in New York City, becoming involved in support groups and informational workshops. I spoke with whomever I came in contact with who had gone through a similar experience. I started keeping a daily journal, prayed more, and learned about meditation. I made appointments with alternative naturopaths and noted visualization authors. I began juicing and nutritional therapy, checked out nutritional cleansing, enzyme and vitamin therapies, started ancient Eastern practices of Qi Gong and Jin Shin Jitsu, went to healing services and ceremonies of different cultures, bought more herbal books, and took classes to begin making my own combinations. I became a devout fan of acupuncture and studied homeopathy. I wouldn't say I did anything radically alternative, but then some consider meditation or acupuncture radical.

I began to teach others what I was learning about my favorite non-toxic personally tested alternative methods of healing. I have been blessed with a team of surgeons, oncologists, and alternative practitioners who have come into my life exactly when I needed them, and with whom I continue to discuss alternative information and ideas, even though they express doubt about the methods I am using.

There is, I found, a fine line between being cured and being healed. While we all want to think of ourselves as being cured or on the way to finding new cures, the only way this can happen is by allowing a healing to take place on all levels, mind, body, and spirit, and which standard allopathic medicine does not fully address. This is a highly individual process involving reflection and recognition of our relationship with surroundings, why we are here, and what we are called here to learn, and then working with this process rather than fighting it or attaching blame. When we approach this awareness, we have already begun to heal and our own energy, spirit, vital force, qi, and prana, are strengthened from within, turning the healing process into a curative journey. Thank you.

[The prepared statement of Ms. Zarycki follows:]

CONGRESS OF THE UNITED STATES
COMMITTEE ON GOVERNMENT REFORM
PERSONAL TESTIMONY ON ALTERNATIVE & COMPLEMENTARY
PRACTICES IN THE ROLE OF CANCER TREATMENT
June 10, 1999

Good morning. Thank you for the opportunity to testify regarding complementary and alternative practices in the role of cancer treatment. I am Carol Zarycki, an advocate and breast cancer survivor of two years.

I am here, speaking for myself and other advocates ("we"), to request legislation for alternative and complementary medical research and funding, rather than to continue regulation of standard allopathic treatments, the cost of which is ultimately borne by the taxpayer and the government, and which do not show an increase in cancer survival statistics. We are tired of hearing about measures such as time to recurrence, tumor regression rate, or time to disease progression, when the real issue should be preventing cancer in the first place. How many women do you know who rejoice when their cancer recurs in six years rather than five? Not surprisingly, death is more feared than any diagnosis.

We would like to see a shift of funding and research attention to the review of a standard cancer protocol that is less toxic, better targeted, and more effective, while at the same time focusing on alternative and complementary therapies, and addressing the following considerations.

I. We need to consider the role of insurance coverage as a primary factor in the alternative/complementary choice process. Not just for patented drugs or diseases with a name, but for treatments such as acupuncture and herbs, which cost the taxpayer a lot less and from which some toxic allopathic treatments were originally derived. If a disease is given a name, it has a chance of being covered by insurance. Why can't we offer coverage for natural, alternative treatments which can work sympathetically with an individual's vital force, so that we don't have to invent new names for new types of cancers?

II. We need to have access to treatments and clinical trials that will work with us as individuals, rather than be limited in choices due to insurance regulation and intervention. Interestingly, some toxic standard medical procedures given routinely, which can leave the immune system in deep disrepair, also make one more susceptible to recurring disease for this very reason. Ironically then, one must seek alternative treatment, not covered by insurance, to alleviate or attempt to correct this previously non-existent damage, thereby paying for treatment out of pocket, with insurance covering all or only part of the original standard treatment.

Therefore, treatment ends up being paid for twice. Once, for the cost of the standard treatment, when a patient is not informed of all side effects initially, because even the medical allopathic community is not certain of the outcomes of a lot of the treatments they offer.

Second, by having to pay out of pocket costs for alternative treatment, to relieve the physical and emotional pain, despair and suffering that the allopathic treatments supposedly "helped or cured", since it is a known fact that survival rates are not increasing from allopathic treatment. How can this effectively make sense when we say we are a progressive nation?

III. Means of information dissemination need to be made available, as they currently are lacking, so that individuals are fully informed of options and possible treatment outcomes, including quality of life and survival rates for the treatments they are choosing. Tamoxifen, while being a successful drug, will only help a few women out of 100. Therefore, most of these women do not need the drug, and may even get the dangerous "side effects" of blood clots in the legs or lungs, uterine cancer, strokes or heart attacks. A few of these women will have disease progression or recurrence anyway.

As another example, definitive evidence shows that estrogen does not protect against heart disease, and can promote an already existing but undiagnosed cancer, despite what drug companies have been saying for years. The potential to do harm must carry with it the obligation to inform.

IV. New legislation is required, so that not only drug companies with patents on new drugs or connections with institutions are receiving support, but alternative therapies begin to receive research and funding, as well. In general, drug firms will have no interest in an old drug for which no patent can be had. Old or new drugs may have never been able to show an increased survival rate or even a better rate of progression-free survival, so why are they still being used?

Why do some doctors in our country refuse radiation and chemotherapy when themselves faced with a cancer diagnosis, opting instead for alternative treatments in another country? A recent comment from such a doctor indicated that standard treatments weren't helping his patients all that much anyway.

Why is it that when one or two people in the entire world die from an herbal overdose or misuse, the herb is banned in this country, yet when patients die from side effects of chemotherapy and radiation, or more than 20,000 die a year from overdoses in the emergency room, or aspirin, tylenol or asthma fatalities occur, or more than 80,000 die prematurely from digitalis, nothing is done? This is highly unscientific research, and seems to be done merely because there is no lobby industry with vested funding to offer research and support to the smaller, alternative medical community.

V. There needs to be a recognition of the role of chemicals and the environment and their effect on hormones, from the fish we eat to our plastic bottled drinking water, finally seen as a possible link to a weakening and destruction of our immune systems. If foods and drinks, such as green teas, even from the health food stores, are not labeled as organic, a high pesticide residue content can be readily detected in the body. Our country regularly imports fruits, vegetables and foods that have been treated by toxic methods, even when the imported food is labeled "organic".

Additionally, since it has been demonstrated that hormonal imbalances are an underlying factor in a growing number of breast cancers, wouldn't it make sense to research natural hormones, rather than add synthetic tamoxifen, raloxifine, or premarin to an already overloaded hormonal system?

VI. Evidence-based testing methods and not just scientific competition within the medical community, without regard for the population being studied, need to be employed. If one is going to opt for standard treatment or complementary care, evidence-based clinical trials must be looked at as a primary measure of value. Trials which indicate life extension should additionally be able to demonstrate that the period is for more than a few weeks, and should also discuss quality of life issues, since this is usually a consideration.

Autologous bone marrow transplants have no data to offer as support, since they were mainly done outside of randomized clinical trials. This clearly illustrates the importance of conducting quality trials, while making certain that women have appropriate scientific evidence before making important treatment decisions.

VII. A focus on preventive measures which strengthen the immune system, rather than early detection methods, (which can also be "too late" detection, and with their own set of risks and hazards), should be incorporated into an individual's lifestyle. Preventive measures could be accomplished by doing daily breast massage, following a nutritionally supplemented program with chikung or tai chi, and incorporating acupuncture, herbs, homeopathy, visualization, prayer and meditation, among other practices.

VIII. Non-toxic and non-invasive radiation methods of cancer detection should be standardized, instead of encouraging mammograms, which, there is evidence from as far back as ten years ago, strongly increase a woman's chances of getting cancer in her lifetime. This can cause tissue and bone injury (which happened in my case) and then has to be attempted to be treated with alternative means. We recommend research of two new products, which are in the first phase of clinical trials.

Trans Scan, in Ramsey, New Jersey (201)934-9074, measures low level bioelectric impedence, similar to an ultrasound, and can differentiate benign from cancerous tissue from both cysts and axillary lymph nodes. Computerized Thermal Imaging in Utah (801)776-4700, being used at USC Norris Center in Los Angeles as an adjunct to regular treatment, more accurately identifies tissue while reducing the need for benign biopsies, which, according to alternative practice, can weaken the area and promote a future cancer.

I personally am not planning to have mammogram followups, which many of my colleagues are also refusing for the reasons stated above, along with the fact that mammograms are not always effective in detecting cancer for women of any age. Also for younger women with dense breasts and therefore, unidentifiable or undetectable cancers, mammograms can weaken the still growing tissues, thereby promoting future malignancies.

IX. We want to be able to live in peace with the treatment decisions we are making, without fear that mammograms, therapies and toxic and synthetic drugs are doing a potential, future harm to another part of our bodies. We do not want to hear about five or ten year guidelines as measures of our health, but rather experience peace by knowing that immune strengthening practices will eliminate the need for these guidelines and also the topic of recurrence.

X. From wisdom and insight gained through a personal breast cancer experience, and from an advocacy perspective of looking at ways to make treatments and options more accessible and specifically tailored to each individual, quality and length of life can both be optimized. We are requesting a sharing of both standard allopathic and alternative medicine, so that it can truly be called an integrative, complementary medical practice.

As a personal note, herbs have saved my life on two occasions in connection with cancer. The first time was when I started to take herbs to regulate hormones, which is how I found the cancer. The second time was after standard allopathic treatment, when the hormonal imbalance recurred and I started herbal treatment again, only to begin having pain in the initial tumor site. This alerted me to the fact that despite standard allopathic treatments, this had not "cured" the cancer. I realized that, for me, alternative treatment would offer the only real cure, of body, mind and spirit.

I was just beginning to research alternative medicine as I was diagnosed, but due to pressure from my team of surgeons and oncologists, I felt I had to rush to begin treatment, without being able to fully integrate alternative medicine at the beginning of my treatment. I was strictly told that to take any herbs, vitamins, or acupuncture treatments would interfere with the allopathic treatments, and most probably negate them.

The stress involved as my allopathic team attempted to battle with my alternative team was too much for me, and I simply chose to forego the alternative side, except for a total nutrition and juicing change, until after the surgery and chemotherapy. During the chemotherapy, I continued to deteriorate, and finally, when I felt my body was screaming that it had had enough, I quit the chemotherapy. At this exact moment, I felt a complete inner peace within and knew I had started a path to begin healing myself. It would have been wonderful if my allopathic team would have allowed a mix of both treatments, because this could have been another way to heal on all levels.

SHARE, a non-profit, self-help organization in New York City for women with breast and ovarian cancers, has been instrumental in the community by offering free access to resources, including a hotline, library and discussion groups, along with numerous, ongoing alternative workshops and wellness programs.

I am requesting health care reform, so that all cancer patients will have information regarding and available access to treatments, which does not currently exist in the allopathic community. Allopathic medicine, used on its own, needs to clinically understand the traumas and debilities it is itself creating, not curing. The only way this can happen is by legislation which reviews existing treatment options and allows for incorporation of alternative and complementary practices, with insurance considerations, thereby allowing choices for all involved.

We must try a new approach because the old ways are simply not effective in reducting mortality rates. We must try a new approach because the old ways are simply not saving our best friends' lives.

Those of us with testimonies as to the effectiveness of alternative and complementary practices will continue to use and endorse these practices, as we advocate in our communities and in the world, to continue to help all of humankind.

Yours in peace,

Carol A. Zarycki
Advocate & Survivor

Mr. BURTON. Thank you very much, Ms. Zarycki.

Ms. GARDENER. I wanted to say thank you, Mr. Dan Burton, and also committee members, for your role as David in confronting Goliath. I appreciate and admire you.

I had originally planned to sort of talk about my story and that's not what happened. But my story has led me to where I am now, the place I am now, and to what I have to share with you.

I also have an intimate knowledge as a result of my personal odyssey with breast cancer, of both conventional and non-conventional approaches. I probably would have just—I knew nothing about breast cancer or cancer really, but that people died from it, and was frightened by it. But ended up really very much using both of them in depth.

Up front, I want to say two things. I do not think any one approach, any one approach within either of those systems also, is right for anyone or for everyone. I have suffered no irreparable harm from any non-conventional approach, despite having had extensive exposure to many. I feel that every one of them has helped me in some way, some more than others. I say that because I know that's a concern that a lot of people have and a reservation they have about supporting the use of non-conventional therapies or making them available to people.

On the other hand, unfortunately, I have to say that—well, let me preface it by saying that I think that conventional physicians, most of them are very well-meaning and competent in what they do. I think they are often more fearful of cancer than the patients, and perhaps it's because they are being expected to cure something that they know they really don't understand. So that can be a very frightening thing, and maybe can lead them to be very rigid in the way they treat us as patients, feeling like we can't have any deviations and we can't waste any time because they are really so very frightened themselves.

But basically in contrast to my experience with non-conventional approaches, I do feel that I have suffered considerable and irreparable harm because of my treatment with conventional methods. I think most of us have. Some of us are more willing to acknowledge it than others because there's kind of a cognitive dissonance there that we want to believe that what we did was the best and that everything is OK, and we want to minimize I think, the price we have paid in many instances.

Of course some people have had less treatment than others. I guess part of my situation too is that I do not feel that if my point of view had been respected, I don't believe I would have ever ended up with the number of very invasive kinds of procedures that I did have to undergo, from which I continue to suffer the effects. One of them is lymphedema, which no one has mentioned so far, can be life threatening because if you have chronic swelling of the limb, there is a rare type of sarcoma which is a very lethal kind of cancer that can develop. It is rare, but all of these things are statistics.

So I guess every day there are people who conventional medicine has sent home to die that are finding their way back to life, even after they have had, been subjected to the often times brutal procedures of conventional medicine. I just wish I didn't have to say these things. I really do. I wish that my experience had been dif-

ferent, and I wish the experiences of many, many of my friends, some of whom I have lost and some of whom I have seen go through terrible suffering, who have sometimes made it through and survived. I wish I didn't have to say these things and have those perceptions.

I wanted to say a lot of things which I am not going to have time to say. I guess maybe I can say that—it's hard to, and I know everyone is wanting to go and I am too, because I have had a peach to eat today, that's it. I guess maybe let me say this. I think we have to find another way to approach cancer than conventional approaches, because conventional approaches are based on killing cancer. That does not guarantee in any way that it is going to heal us or keep us alive. There are no guarantees made of that. It is kind of like killing alligators instead of draining the swamp. We are not dealing with causation, and we are not dealing with healing. I had planned to give you some evidence to back up some of that, but we won't have time for that.

I'll just, in ending here, I will say that if anything that you hear today makes a difference to you or enough of a difference to you, then you will have to do something to make some changes. You will have to make some choices. I believe that when we choose, we are not choosing just for ourselves. We have to keep in mind that we are choosing really now for all because it is one world. We are starting to realize that, and see that vision I think more and more, that we are choosing for the human race and for the survival of Earth.

In one sense, both David and Goliath are within us, within each individual. So we have to decide whom we are going to serve, whom we are going to choose to serve. I do pray that each of us will choose well for the well-being of all of us.

[The prepared statement of Ms. Gardener follows:]

Testimony

Of

N. Lee Gardener, Ph.D.

Before the

Government Reform Committee
U.S. House of Representatives

On

"The Role of Early Detection and Complementary and Alternative Medicine in Women's Cancers – A Personal Story and Resulting Professional Observations"

Thursday, June 10, 1999

2154 Rayburn House Office Building
Washington, DC

My personal odyssey with breast cancer led me to an intimate knowledge of both conventional and non-conventional approaches. Up front, I want to say two things. I do not think any one approach is right for everyone. And I have suffered no irreparable harm from any non-conventional approach despite having had extensive exposure to many!

There is a growing body of research studies documenting the effectiveness of both complementary and alternative approaches to cancer detection, treatment, and even prevention. But cancer research seems to be a highly political process often with formidable barriers to the conduct of true scientific inquiry.

There are numerous cases of unexplained "spontaneous remissions" reported in the medical journals. When will we begin to study these exemplary cases as a group and identify any commonalities which may exist for future study? Unless funds are earmarked specifically for these novel types of studies it seems unlikely that they will be conducted.

Unsophisticated design of research is another problem. A study can be very tightly controlled and rigorous, yet lack the sophisticated design to look for such thing as interactions between variables. This is especially true when we begin to talk about designing transdisciplinary studies which cross the imaginary line between mind and body.

Recently I read that Dr. Linus Pauling, the only person in history to have won two unshared Nobel prizes, tried to interest conventional cancer specialists in studying a non-conventional approach - namely, the use of Vitamin C as an adjunct to cancer treatment.

Despite highly promising preliminary outcomes in actual usage with cancer patients, he found no interest or support from NCI. The two studies which were ultimately funded by NCI were both awarded to the Mayo Clinic which did not follow the protocol guidelines specified by Dr. Pauling. Yet NCI accepted Mayo's conclusions that vitamin C was ineffective in cancer treatment and stated that no further studies should be done to investigate it!

When I took courses on scientific research design, I was taught that science never closes the book of scientific inquiry. I was taught that science cannot prove anything, that it can only disprove hypotheses, and that the most well-established "facts" are merely hypotheses for which no one has yet found a competing, plausible explanation or a way to test it.

The Mayo Clinic researcher also refused to allow Dr. Pauling to examine the raw data. This brings up a critical point. If we are to have the best information available to us on issues as important as cancer, why is it that raw data is not shared once the original investigators have had a reasonable time to prepare a scientific report of their findings? Why is it that we fail to encourage or even allow the best minds to grapple with the data, analyze it from differing perspectives, and identify and defend alternate conclusions in the true spirit of scientific inquiry?

The problem of inaccessibility of data is a serious obstacle to the progress of true science. It also enables many abuses and the need for an Office of Scientific Integrity, and laws to protect people referred to as "whistle-blowers". Is it possible that researchers do not want true scientific inquiry to muddy their waters? Or perhaps they're afraid the waters will be cleared up and everyone will be able to see what is at the bottom.

Precedents exist for placement of what are sometimes referred to as "public use data sets" on the World Wide Web. Raw data which has been appropriately coded to protect confidentiality could contribute substantially to scientific dialog and progress.

One of the issues the Committee on Government Reform is addressing today is early detection. But early detection is too late! We desperately need research to identify precursors of cancer which are potentially reversible before cancer can get a foothold. Given our current track record for curing cancer, waiting until cancer occurs and detecting it early cannot be acceptable. A high priority for cancer research must be the investigation of methods which provide clues to biomarkers and other measurable features associated with cancer.

Another barrier to the use of complementary and alternative approaches appears to be a basic conceptual schism regarding whether the nature of cancer is essentially local or systemic. If one believes that cancer is localized than such things as mastectomy and prophylactic mastectomy are obviously treatment, and not barbaric anachronisms in our sophisticated, high tech age. (I know of at least one 19 year old who has had a double mastectomy.)

However, an increasing number of conventionally-trained cancer specialists now believe that cancer is systemic, not local, and that it is the biological terrain of an organism which must be addressed. Just as plants will flourish under certain environmental conditions and perish in others, the biological terrain is what provides an inhibiting environment or an enabling environment for the proliferation of cancer. Is it possible that someday we might say that cancer is the presence of a certain chemistry of the blood? Or that the world is not flat, and is not the center of the universe as it so obviously seems to be?

During chemotherapy my blood counts would hit rock bottom which meant the drugs were killing everything they touched. My oncologist was happy about this, and he was also happy about the fact that my counts would quickly come back up. But he could not explain it. Why did healing happen quickly for me but not for others?

Conventional cancer treatment has no way of knowing if a specific drug will work for a specific person. Every drug is essentially an experimental drug for any given individual. In fact, there are research facilities which can test a piece of a person's tumor, and determine which drugs will work best to kill that kind of cancer cell. Yet the actual survival rates are unchanged! In other words, if you take a drug that is tailored to killing the cells in your particular tumor, this does not impact your overall chances of survival! What is wrong with this picture?

Could it be that killing cancer cells is not the way to cure cancer? The conventional approach to cancer treatment is apparently straightforward, and seems to make common sense - detect cancer cells and kill them. And even when this approach is successful in killing tumor cells, the cancer too often "comes back with a vengeance". As one pathologist said to me recently, "You just don't know how breast cancer

is going to behave."

The bottom line is that there are no guarantees that simply killing cancer cells will keep you alive - even if you survive the treatment. You have to find ways to keep yourself alive.

If the role of conventional approach is to detect and kill cancer cells, what might be the role of complementary and alternative approaches? Over 50% of cancer patients include the use of complementary and alternative approaches in their treatment regime. I believe they have discovered that these are the approaches that will keep them alive.

Does complementary and alternative medicine offer false hope? Dr. David Bressler and Dr. Marty Rossman, founders of the International Academy for Guided Imagery, talk about the importance of giving patients neither false hope or false despair. They ask patients to consider what outcome they would like to have if they were in charge. They emphasize that although we do not know what the outcome will be, we can still cast our vote. And with imagery we can vote frequently by putting our attention on the desired outcome, instead of on potential undesired outcomes in the form of worry. There is increasing scientific support for the power of the mind-body connection.

In conclusion, the following brief quote gives us cause for optimism as well as guidance for future research directions. "I think it likely that many of our diseases work in (the following) way...We tear ourselves to pieces because of symbols and we are more vulnerable to this than to any host of predators. We are, in effect, at the mercy of our own Pentagons, most of the time." This was written not by a psychologist, but by an eminent biological scientist, Dr. Lewis Thomas, past-president of Sloan-Kettering Cancer Center.

N. Lee Gardener

Mr. BURTON. Thank you very much. Any information that you want to submit for the record, we can enter that into the record, even though you haven't had a chance. Maybe during questions and answers, we can cover some of that.

Ms. Bedell-Logan.

Ms. BEDELL-LOGAN. Thank you, Mr. Chair, for this opportunity. In 1987, my sister was diagnosed with a Ewing's Sarcoma in the calf of her right leg. The protocol for Ewing's is amputation, chemotherapy, and radiation. This was a very aggressive cancer. Thankfully, the physicians found it in time. I remember her fear of having her leg amputated at 25 years old.

We were in her room when an oncologist came in and said that there was a new experimental treatment for Ewing's Sarcoma where they would take a tube and slide it down through her vein, starting at the groin, and drop chemotherapy directly on her tumor. She was told that the likelihood of survival would not be changed, and that it very well may save her leg. On the strength of this, my sister opted for the new therapy.

At the beginning of the fourth treatment that she had, the technician couldn't get the tube down through her groin any longer, and they took her down to sonogram and found a grapefruit-sized tumor right where they had been going down with the tube. Because of the obstruction of the tumor, my sister developed massive bilateral lymphedema in both legs, which is a swelling of the limbs due to the inability for lymphatic fluid to move in and out of the limb appropriately. This is a very debilitating and very painful process, and because of that pain, the surgeons cut incisions into my sister's thighs and put permanent drains in them to continue to drain the lymphatic fluid. Both of these sites became extremely infected, and my sister was put on large doses of morphine and antibiotics and was dead in 4 months.

After her death, we found out that she had been a guinea pig. They had never done this procedure in this hospital before, and the physicians were not trained to perform the procedure appropriately. We have also found out that the worst thing you can do to a lymphedema patient is cut into them. This was never subjected to randomized control trials, and it's not used today as standard protocol.

A month after my sister's death, I started working for Medicare. My goal was to get into the trenches of the healthcare system to find out what makes it tick. I received an excellent education from the Federal Government, and went to work after that for a very large family practice and urgent care center. I have seen the system work from the perspective of the patient, the payer, and the provider.

I opened my company, Solutions in Integrative Medicine, 10 years ago. My company provides billing and practice management, consulting, and education services for patients, providers, and insurance companies. We have been at the forefront of a change, actively advocating for patients whose insurance companies denied payment for effective, but unconventional services. One of the things that I have heard here today was talk about the uninsured. For those people who are insured, there is a very big problem with

getting coverage for anything outside of opening a flower with a hammer.

We have been instrumental in developing the administrative and clinical basis for coverage of a host of integrative therapies, often at greatly reduced cost. But this effort has been very tedious, which makes it difficult to make a large enough impact for global change. One of the problems with research is that the researchers sit in their ivory towers and do research, and come up with sometimes very good outcomes for randomized control trials, but we can't implement them at the insurance level. Sometimes it takes 10 years to get a randomized control trial accessible to patients.

The U.S. Public Health Service estimates that 70 percent of the current healthcare budget is spent on the treatment of approximately 33 million chronically ill individuals. As the population ages, such conditions will consume an even larger portion of the national healthcare dollar. With this in mind, my company's vision is to change the perspective of the healthcare industry by providing professional education to insurance carriers, Medicare, physicians, and patient consumers.

An example of this education is lymphedema. Twenty percent of all women who have breast cancer, axillary lymph node dissection, mastectomy, will have lymphedema. Those numbers are even higher for men with prostate cancer. These survivors have now contracted lymphedema, the three consequences of lymphedema are swelling, recurrent infections, and tumor formations, called lymphangeosarcoma, which is untreatable. The lymphedema patients who do not receive early intervention may develop elephantiasis, which can lead to amputation of a limb.

Prompt treatment by specially trained lymphedema therapists who manually drain the engorged tissue has been shown to save limbs, save lives, and save healthcare dollars. The therapy is called combined decongestive therapy [CDT]. It has been a standard treatment in Europe for decades. But today, it is considered an experimental therapy in the United States, and is not a typically covered service. In the United States, our standard approach is to use expensive pumps that mechanically compress and decompress the affected limb, even though this therapy has been shown to have little benefit. In fact, it can press lymphatic fluid in the wrong direction and lead to a worsening of symptoms. For this reason, mechanical pumps for lymphedema have actually been banned in European countries.

In the past 2 years, we have been able to begin educating the insurance industry about CDT. We have been able to obtain coverage for Medicare patients in Maine, New Hampshire, Vermont, Massachusetts, and Florida, as well as many commercial insurance beneficiaries all over the country. This type of education and common sense is extremely important when it comes to medicine. Unfortunately, the rest of the public receives conventional treatment, costing insurance companies millions of dollars each year.

The treatment of lymphedema is just an example of the education and common sense needed in the insurance industry. The illusion is that the best medical practices are based on the result of randomized control trials. It was recently estimated that only 15 percent of medicine today has been subjected to randomized control

trials. It is a sad fact that since there is little to be gained by drugs or medical equipment companies from the lymphedema treatment regimen I described earlier, little attention or marketing is focused on such common sense therapies. This is why healthcare cannot simply be left to the private sector. Too often the perverse incentives of our system lead to short-term thinking and pharmaceutical band-aids, rather than comprehensive chronic disease management. The result, strangely, is poor quality healthcare at a higher cost. Those who can break out of the system can afford to pay out of pocket. Integrative medicine is becoming rich people's medicine.

We must put prevention of chronic illness in the hands of patients, treatment of chronic disease in the hands of integrative medicine teams, and acute and traumatic episodes in the hands of conventional medical providers.

I will say in closing that my brother died of AIDS in 1994. He was diagnosed in 1980. He was on the television show, 48 Hours, as one of the longest living AIDS patients in the country. They asked him how he did it. He said, "I stayed away from conventional medicine. I used my conventional medicine doctors to help me decide what were the best alternative treatments for me, and did nothing but alternative therapies," and he lived 14 years with a very high quality of life, and died of Karposi Sarcoma. Thank you.

[The prepared statement of Ms. Bedell-Logan follows:]

Solutions in Integrative Medicine

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Written Testimony for the House of Representatives
Committee on Government Reform
Oversight of the Department of Health and Human Services

The Role of Complementary and Alternative Medicine in the Detection and Treatment of Women's Cancers

A Perspective on Access to Integrative Medicine, Insurance Reimbursement and the Barriers in our Current Healthcare System

June 10, 1999

Washington, DC

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In 1987 my 25-year-old sister was diagnosed with a Ewing's Sarcoma in the calf of her right leg. The protocol for Ewing's is amputation, chemotherapy, and radiation in that order. This is a very aggressive cancer but thankfully it was caught early enough for treatment. I remember clearly my sister's fear of losing her leg, mortified at the prospect of disfigurement at such a young age.

I was with her at a hospital in Florida during her treatment and remember when the oncologist came into the room and told us there was a new experimental treatment for Ewing's that he would like to try. The doctor said the procedure involved inserting a tube into a vein near her groin and snaking the tube down her leg to drop chemotherapy directly on the tumor. He told my sister that this would not diminish her likelihood of survival but might well save her leg. On the strength of this hope, my sister opted for the new therapy.

At the beginning of the fourth treatment, the technician could not get the tube to slide into the same path they had been using previously. Somehow the vein seemed obstructed and my sister experienced intense pain. The technician gave up, and the next day they sent her to get a sonogram. The sonogram revealed a grapefruit sized tumor in the very spot they had been using to access her vein. Due to the size of the mass they could not operate. Then because of decreased lymphatic circulation, she developed massive bilateral lymphedema—a painful and debilitating swelling of the limbs. This caused her such intense pain the surgeons made incisions in her legs to "drain the lymphatic fluid". We now know that cutting into a patient with lymphedema is one of the worst things you can do. They put permanent drains in her thighs and both of the points of entry became severely infected. She became wheelchair bound and experienced excruciating pain 24 hours a day. They put her on high dose morphine and antibiotics to control the pain and infection, and we watched her die a slow, horrible death. She was diagnosed in June and died in late January.

After her death we found out my sister had been a guinea pig. The hospital had never performed this procedure before and the physicians hadn't been trained to use it. It had never been tested and is not standard treatment protocol even today. I came away from this experience determined to bring more humane approaches into our supposedly state-of-the-art health care system.

One month after my sister's death I started working for Medicare. My goal was to get down in the trenches and learn how the health care system in this country worked. I received an excellent education for three years at Medicare and then went to work for a large family medical practice. So I've seen the system work from all sides—patient, payer, and provider.

I opened **Solutions in Integrative Medicine** ten years ago. My company provides billing and practice management, consulting, and educational services for alternative and integrative medicine providers. Integrative medicine refers to a well-coordinated combination of traditional Western medicine and well-founded alternative therapies. At our company we have been in the forefront of change, actively advocating for patients whose insurance companies deny payment for effective but non-traditional services. We have been instrumental in developing the administrative and clinical basis for the coverage of a host of effective integrative therapies—often at greatly reduced cost. But this effort has been very tedious which makes it difficult to make a large enough impact for global change.

The US Public Health Service estimates that 70% of the current health care budget is spent on the treatment of approximately 33 million chronically ill individuals. As the population ages, such conditions will consume an even larger proportion of the national health care dollar. With this in mind my

company's vision is to change the perspective of the health care industry by providing professional education to insurance carriers, Medicare, physicians and patient consumers.

One of these chronic illnesses is lymphedema, something I witnessed during my sister's ordeal. The principal cause of lymphedema is axillary lymph node dissection—a procedure performed both diagnostically and as part of radical surgery for breast and prostate cancers. Roughly 20% of breast cancer survivors suffer from this malady. There are three major consequences of lymphedema: swelling, recurrent infections, and tumor formation. Lymphedema patients who do not receive early intervention may develop elephantiasis, which can lead to amputation of the limb. Prompt treatment by specially trained lymphedema therapists who manually drain the engorged tissue has been shown to save limbs, save lives, and save health care dollars. This therapy is called *combined decongestive therapy*. It has been standard treatment in Europe for decades. But today it is considered an "experimental therapy" and is not typically a covered benefit. In the United States, our standard approach is to use expensive pumps that mechanically compress and decompress the affected limb even though this therapy has been shown to have little benefit. In fact it can press lymphatic fluid in the wrong direction and lead to a worsening of symptoms. For this reason, mechanical pumps for lymphedema have actually been banned in some European countries.

In the past two years we have been able to begin educating the insurance industry about *combined decongestive therapy*. We have been able to obtain coverage for Medicare patients in Maine, New Hampshire, Vermont, Massachusetts and Florida as well as many commercial insurance beneficiaries all over the country. This type of education and subsequent coverage has saved Medicare alone tens of thousands of dollars in Durable Medical Equipment supplies and has lowered the hospitalization rate significantly. Due in part to this work, Senator Kennedy sponsored HR 4328, The Women's Health and Cancer Rights Act of 1998, which mandated coverage for lymphedema treatment. Even with this law in place, we are still struggling to obtain coverage for this treatment nationwide. Those patients who do receive this treatment are often those with the disposable income to afford it. The rest of the public receives conventional treatment, costing insurance companies millions of dollars each year.

The treatment of lymphedema is just an example of the education and common sense needed in the insurance industry. The illusion is that best medical practices are based on the results of randomized control trials. In fact it was recently estimated that only 15% of medicine today has been subjected to randomized controlled trials. It is a sad fact that since there is little to be gained by drug or medical equipment companies from the lymphedema treatment regimen I described, little attention or marketing money is focused on such common sense therapies. This is why health care cannot be simply left to the private sector. Too often the perverse incentives of our system lead to short-term thinking and pharmaceutical Band-Aids rather than comprehensive chronic disease management. The result, strangely, is poor quality care at higher cost. And those who can break out of this broken system are only those who can afford to pay out of pocket.

If we do not start moving back toward an outcomes-based, patient-centered, comprehensive care approach to chronic disease management, budgets will be busted, services will be slashed further, and the health, productivity, and competitiveness of our nation will suffer. It is time to heal the business of healing. We have an opportunity to meet patient demand and honor patient choice. Combining well-tested alternative therapies with the best of traditional Western medicine has been shown to improve health and reduce costs. We can have a system that works for patients, health care providers, and insurers. This is a tremendous win-win opportunity. But you cannot count on the private sector alone to take the lead. Health care is a highly regulated industry. We need leadership from government to allow

this humane and common sense approach to prosper. With your help we can evolve a health care system that improves the quality of life and death for our citizens without the artificial constraints that are compromising the integrity of our physicians, healers and citizens. We must put prevention of chronic illness in the hands of the patients, treatment of chronic disease in the hands of integrative medicine teams, and acute and traumatic episodes in the hands of conventional medical providers.

Evolving Integrative Medicine

The inability of conventional medicine to address chronic disease has created a shift in patient demand for medical services. Patients, on their own, have found that complementary and alternative medicine (CAM) addresses quality of life issues, provides means for long term care management, and more importantly, often allows for a decrease in pharmaceutical utilization. These fee-for-service modalities are usually paid for out of pocket by the patients. Even when faced with these additional costs, patients seek care outside of their conventional provider networks, thereby creating access to choices that tie into their own belief system(s). However, when patients pay out of pocket for CAM services they may or may not report receiving these services to their Primary Care Physician—thereby creating potentially dangerous disconnects in the continuum of their healthcare.

The concept of regarding the patient as the consumer is a relatively new concept in health care. Concurrently, the philosophy that patient choice may yield more positive outcomes is one that is becoming more widely embraced. Today's healthcare environment is one in which patients/consumers are choosing alternative branches of medicine that are not regulated by insurance guidelines. In the face of this reality, insurers are endeavoring to meet patient demand for alternatives by exploring means of expanding coverage to include these additional modalities.

In the past six years the rise in patient demand for CAM modalities has been repeatedly validated. Two surveys conducted by David Eisenberg, MD and colleagues from Harvard Medical School (1993: NEJM 328:246-252; 1998: JAMA 280:1569-1575) have thoroughly documented the prevalence and trends of use for CAM modalities amongst the American populace. In 1997 Eisenberg et al. found that "...extrapolations [from the survey sample] to the US population suggest a 47.3% increase in total visits to [CAM providers], from 427 million in 1990 to 629 million in 1997.. ." In both survey years the number of visits to CAM providers exceeded "the total visits to all US primary care physicians." Eisenberg et al. conservatively estimated that total expenditures on CAM modalities in 1990 was "approximately $13.7 billion." The 1997 data indicates that "estimated expenditures for alternative medicine *professional services* increased 45.2% between 1990 and 1997 and were conservatively estimated at $21.2 billion in 1997, with at least $12.2 billion paid out-of-pocket. This exceeds the 1997 out-of-pocket expenditures for all US hospitalizations." Moreover, upon further analysis, we see that "total 1997 *out-of-pocket* expenditures related to alternative therapies were conservatively estimated at $27.0 billion, which is comparable with the projected 1997 out-of-pocket expenditures for all US physician services.

Since 1998 more research dollars have been shifted toward CAM therapies with the establishment of the National Center for Complementary and Alternative Medicine (NCCAM). The Senate Appropriations Committee funded the NCCAM with $50 million to further the work begun under the auspices of the NIH Office of Alternative Medicine with its original budget of $2 million.

As more research results are published, it is affecting the way insurers are covering lives. As patient demand increases, insurers are creating ways to expand coverage to include some CAM therapies. The therapies insurers are attempting to include in benefits packages have little historical financial data (since

they are primarily paid for out-of-pocket and not processed through a billing service). Actuaries are finding that insuring CAM therapies is a difficult challenge. Without historical data as a foundation for an insurance plan, coverage of CAM therapies can appear to be too speculative. What is most difficult to determine in these actuarial attempts at coverage planning is the concept that by utilizing CAM therapies a patient will utilize fewer conventional therapies. This concept is most easily demonstrated when investigating conventional approaches to chronic illness such as arthritis, allergies, pain, hypertension, cancer, depression, cardiovascular disease and digestive disorders. Patients who fall within these categories of diseases are under obligation to move through the insurance system as outlined in Chart 1. These types of diseases are becoming easier to diagnose with more documentation available outlining classic symptoms. For example, less testing will be needed to properly diagnose migraine headaches, chronic fatigue syndrome, and myofascial pain syndrome. However, this gradual decrease in the need for diagnostic testing does not address the quality of life issues and long term treatment costs.

Chart 1

Chronic Migraine Headaches				
Provider		**Plan**		**Outcome**
PCP Evaluation	→	no treatment	→	Referral to Neurologist
	←		←	
Neurologist Evaluation	→	no treatment	→	Refer to radiology for CT scan and/or MRI
	←		←	
Radiology Testing	→	no significant findings/no treatment	→	Refer to pain management specialist
	←		←	
Pain Management	→	patient treated with pain medication	→	Refer back to PCP for medication management
	←		←	
Patients continued care		Patient utilizes pain medication and Emergency Room when in acute attacks.		Patients chronic pain is unresolved and could potentially create long term costs for insurer.

The plan of care referred to in Chart 1 does not entitle the patient to options that may cost less and more directly address the patients' chronic migraines. There are many CAM therapies available that have been found to relieve (without pharmaceuticals) and in some cases resolve migraine headaches. Hesitations preventing the use of CAM interventions at the onset of the complaint are concerns that life threatening problems will be overlooked due to lack of diagnostic testing.

The concept of integrating conventional and CAM therapies is one that embraces the diagnostic process at the primary care physician level to rule out serious illness. The U.S. Public Health Service estimates that nearly 33 million Americans suffer from chronic debilitating diseases. It is estimated that the

medical care of 9 million of these individuals, who are partially or completely disabled, accounts for 70% of the spending in current health care budget. Most of the spending associated with patients who fall into this category occurs in the final stage of the process outlined in Chart 1. These patient issues are unresolved—therefore creating a revolving door of over-utilization of health services—which becomes more costly as the patient grows older. Appropriate CAM therapies introduced after appropriate diagnostic testing may significantly improve the quality of life for the patient as well as control the cost of future medical care.

The patient, in the **Integrative** setting will be educated about their illness, instructed in ways of coping with pain that do not involve pharmaceuticals, and be treated with an appropriate CAM modality that ties in with the patient's belief system, thereby producing a more positive outcome. One of the less obvious benefits to this type of care plan is getting these types of patients off disability and back to work. Integrative medical approaches can also create a partnership based in prevention. CAM techniques encompass lifestyle changes that are significant to the course of prevention. This course is essential to building long term approaches to the prevention of the diseases that continue to drain health care dollars.

In an attempt to collect data many insurers have created rider policies or have become affiliated with pre-credentialed CAM provider networks. Rider policies usually cover an array of the CAM therapies most in demand. Many of these therapies carry strict utilization review guidelines that limit the number of visits or may have a monetary cap. Rider policies are purchased separately from a standard policy. Many employers are demanding policies that include CAM therapies due to a rise in absenteeism as well as employee complaints about lack of choices. Insurers, in an effort to comply with employer requests, will create a rider policy specific to that employer. CAM provider networks contract with some HMO plans. The plans will allow patient access to the providers at a discount to the patient. This option minimizes the risk to the insurer, and allows access to the CAM provider at a discount to the patient. The providers are usually credentialed and screened before entering the network.

Another issue that impairs the ability to implement comprehensive CAM coverage plans is credentialing. In an effort to reduce medical fraud and quackery, medical societies have developed strict licensure laws that govern the scope of practice of physicians and ancillary medical personnel within each state. Many CAM modalities, techniques and therapies are taught to a diverse group of medical providers. For example, craniosacral therapy classes are attended by nurses, doctors, massage therapists, physical therapists and others. Insurers are finding it difficult to credential a provider to perform craniosacral therapy when there is no licensure or certification in the delivery of this care. CAM provider networks across the United States are developing expertise in the credentialing of these providers. CAM provider networks provide credentialing criteria that parallel the teaching institutions most highly respected in their respective fields. The relationship between the insurer and the CAM network is essential to the quality of the care delivered in CAM medicine. Either of these interim coverage steps will allow and help to build a financial basis for the coverage of CAM. This in turn will create access for patients who cannot afford to pay out of pocket. However the CAM network is not a long term solution to patient access because of the lack of integration with conventional medicine.

Coding, Diagnosis and Procedures

Although the process of integration under one coding system has been a challenge, the American Medical Association has taken significant steps toward accepting CAM therapies such as physical therapy, osteopathy, chiropractic, acupuncture, manual therapies, and psychiatric services such as biofeedback and hypnosis. The AMA has adopted CPT codes for many CAM techniques, which in turn has opened doors to access and coverage for patients. The downfall of these conventional coding schemes, created

for CAM interventions but conceived from an allopathic perspective, occurs when CAM providers attempt to implement them. CAM providers tend to see patients from a holistic point of view, but the coding schemes assume that human ailments are best described as organ-specific pathologies. How does one "code" the treatment of an intestinal ailment that a CAM provider perceives as related to emotional stress, nutritional deficiencies, lack of exercise and other lifestyle factors? Evaluation and management codes, in fact, specifically prevent holistic care from being performed. If an osteopath, for example, sees a need to do nutritional counseling and some manual adjustment he would not be able to do so under current guidelines. Comprehensive treatment of complex chronic illness almost always demands some significant educational component, but the thoughtful physician simply cannot find in the conventional code book the support needed to do this different kind of medicine. Other branches of medicine outside of the conventional medical education system, view a patient and their illness as one, and do not separate the disease from the patient.

The coding description states that "Evaluation and Management services may be reported separately if, and only if, the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual preservice and postservice work associated with the procedure". Many holistically-trained healthcare providers feel that a large part of the philosophical and educational basis of the medicine they deliver has been compromised with coding that focuses solely on disease and the efficacy of a modality. Physicians who cannot spend quality time with their patients, due to coding restrictions, often refer troubled patients to potentially expensive psychiatric care. Many of these psychiatric claims are denied due to lack of substantial psychiatric diagnosis. Physical therapists as well as chiropractors experience similar challenges. Physical therapy and chiropractic care come from a root of education that includes empowering the patients to better care for themselves. With a reimbursement system based on diagnosis, it is becoming increasingly difficult for CAM providers to care for patients as a whole, while also offering education and options for lifestyle change. Systems are in place that will allow a certain number of visits per year, per patient for a given diagnosis. CAM providers believe that each patient is an individual and will respond differently to any given treatment. With this diagnosis-driven reimbursement system patients have few choices in regard to their health care delivery. CAM psychiatric providers experience a similar problem when a patient presents with chronic pain. These CAM psychiatric providers submit claims to an insurance intermediary in many cases that has expertise in the utilization review of psychiatric claims. If the diagnosis is low back pain, for example, the claim is denied due to lack of "psychiatric diagnosis". However, the provider may change the diagnosis to "adjustment disorder" (may tie in as an inability to tolerate pain) and the claim will be paid. Many of these CAM psychiatric interventions also include manual therapy and self care training which may be referred to as a mind-body program. When the provider submits the claim for the manual therapy part of the treatment to the psychiatric claims intermediary, the claim is denied for two reasons. The first reason is that the procedure codes used to describe the manual therapy cannot be paid for with a diagnosis of adjustment disorder. The second reason is that this intermediary only pays for psychiatric procedures. The provider then changes the diagnosis to read low back pain and sends the claim to the medical policy division. Many times these claims are also returned to the provider denied as the patient has exhausted their physical therapy benefit for the year. It is customary to use physical medicine codes to describe all types of manual therapy services, not just physical therapy. However, many insurance carriers do not take into consideration the fact that many other types of providers utilize these codes. When the insurer sets a protocol for the number of visits per year by a physical therapist, they attach the guidelines to the procedure codes and the diagnosis codes. Even though the care has a different root of medical origin, these two fields utilize the same procedure codes and are adversely affected by insurance company processing systems that are unable to process claims based on usage by profession. Usage by profession

would yield a quality of delivery that would permit integrative medicine to be incorporated into the existing reimbursement system.

In the absence of appropriate AMA approved CPT codes for some CAM therapies, more progressive insurers have created in-house procedure codes in an attempt to meet patient demands for coverage. Many CAM techniques can be described accurately with existing CPT codes, however many of these codes are used in the conventional setting with a different root of delivery. A dilemma that plagues this integration process occurs when existing CPT codes are used to describe CAM therapies, and the root of delivery is not housed in the same reimbursement assessment as conventional therapies. For example, a conventional reimbursement assessment may find it appropriate for a provider to spend 20 minutes with a chronic low back pain patient. Reimbursement for this service is calculated by the severity of the diagnosis. In naturopathic medicine a physician may spend 60 - 90 minutes with a chronic low back patient, which is appropriate based on the root of naturopathic medicine. The conflict occurs when the visit by the naturopath is reduced or denied because the guidelines for reimbursement are based in the root of conventional medicine, which is diagnosis-driven. The challenge for CAM providers is in educating the insurers in order to avoid fraud and abuse issues but also to protect the integrity of CAM approaches, given that the success of these therapies is intrinsic to how the care is delivered. The challenge for the insurer is to develop a reimbursement structure that will allow each profession to utilize the CPT codes currently available and create utilization review guidelines that are based on any given professions root of delivery. In the meantime, it is essential when coding CAM therapies using the CPT tool, that providers are in open dialogue with insurers in an effort to avoid fraud and abuse claims. For example, the appropriateness of utilizing evaluation and management codes to describe homeopathic assessments, even when performed by a MD, are seriously questioned at this time.

Many integrative centers have evolved across the United States. These centers usually include a medical director, usually a physician (MD, DO, or DC), with a staff comprised of such professionals as a naturopathic physician, an acupuncturist, a massage therapist, a nutritionist and a stress reduction program that incorporates lifestyle counseling such as the Jon Kabat-Zinn program, the Herbert Benson program, or the Dean Ornish program.

These professionals that are not easily credentialed by insurers are able to provide services under the direct supervision of the physician. The physician assumes responsibility for the therapists and bills "incident to" the physician. *Incident to Guidelines* for Medicare have very specific language addressing the employment relationship that is needed between the physician and other professional in order to deem incident to billing appropriate.

The education that is taking place in the insurance industry will continue to bring more and more players to the table to create an infrastructure that will introduce CAM to mainstream medicine. In a effort to reduce the cost of health care, more insurers will be allowing reimbursement for modalities that address chronic pain and illness. This in turn will reduce the over-utilization of services by patients who suffer from illnesses that conventional medicine cannot address in many cases without utilizing expensive and invasive interventions and/or pharmaceuticals.

With all of the many changes in medicine taking place, creating state by state variations, it is extremely important that we establish patient access laws at the Federal level. These laws are extremely important for patient safety as well as protecting the integrity of both CAM and allopathic medicine. Such legislation would support the many conventional physicians and CAM providers whom, banding together

across the country to provide whole medicine and education for our population, wish to especially focus on preventive disease management and overall cost reduction in today's healthcare system.

Mr. BURTON. Well, thank you very much. That last, not the last thing that you said, but the second-to-last thing that you talked about was very interesting. You are saying that in Europe, they have been using for lymphedema a different approach and it's been done for a good many years, and they have actually outlawed or done away with the pumps that are still being used as conventional medicine here in the United States?

Ms. BEDELL-LOGAN. That is correct.

Mr. BURTON. How do you account for that? You mentioned the pharmaceutical companies and some of the companies that produce these things. Do you think it is because of influences of these institutions?

Ms. BEDELL-LOGAN. I do. In 1997, which I have the report with me, Medicare spent on the East Coast alone, $13 million on pnuematic pumps. Most of those pumps are contraindicated. This is because when lymphatic fluid is simply pushed from the arm or the leg back into the body, it can create genital lymphedema in men and it can create lymphedema built up in the chest of women, which can create lymphangeosarcoma.

What these specially trained therapists do, who are trained by the Vodder method, which was really born in Germany, is they manually through a massage technique open up the passages for the lymphatic fluid to move out of the arm appropriately, and then they bandage the patient with a compression bandage to stop the arm or leg from filling back up.

Through this process, they are actually teaching the patients to take care of themselves at home. We don't want to have patients keep coming back and coming back for treatment because that is not cost-effective. But what we do want to do is make sure that these patients are completely self-sufficient in taking care of their own lymphedema. There is no cure for lymphedema, but we can certainly——

Mr. BURTON. Minimize it.

Ms. BEDELL-LOGAN. Minimize it, exactly.

Mr. BURTON. So through massage and through the bandaging?

Ms. BEDELL-LOGAN. Exactly. It is a very inexpensive treatment. They usually last anywhere between 2 to 4 weeks, depending on the severity of the case.

Mr. BURTON. Well, now some women are told by their doctors to wrap their arms or put a casing on their arm every day. Are you talking about that as well?

Ms. BEDELL-LOGAN. That can be helpful with minimal lymphedema. But when lymphedema becomes fibrotic and the limb gets very hard, the compression bandaging doesn't work unless those fibrosis are broken down through massage therapy.

Mr. BURTON. Through massage therapy.

Ms. BEDELL-LOGAN. Right.

Mr. BURTON. OK. Thank you.

Ms. Zarycki, you were very critical of a lot of the conventional thinking. I presume you have done a lot of study on this. How did you come to all these conclusions that you came to? It's very interesting to me.

Ms. ZARYCKI. I initially used conventional treatment. When I first started out, I wanted to take a chance and explore alternative

options. I was told by a myriad of conventional doctors that I went to that basically it was OK if I did alternative and it was OK if I did some herbs and this and that, but if I really wanted to make an impact and to live, I should really go with conventional treatment and I should not wait, and if I wanted to do alternative, I could always do that later. That was the comment that I got.

So instead of feeling like I had time to do more research, I felt like I really had to jump in and do the standard treatment. So in a sense, it would have been nice if both of those practices could have worked together as they do in other countries, as they do around the world, but not always in this country.

Mr. BURTON. From a personal standpoint, how do you account for those in Europe having more advanced treatments or optional treatments and the United States doesn't?

Ms. ZARYCKI. I think they are more open to research than we are, and I think that they are putting funding in other areas and concentrating it in other areas, rather on prevention more so than we are. We are using machines for detection when we should be using ourselves and our own inner energies to understand and work with our immune systems.

Mr. BURTON. You don't think that the companies that manufacture pharmaceuticals and products are exerting any influence here in the United States, or you haven't had that experience?

Ms. ZARYCKI. Well, I feel that is a large part of it, yes, in terms of the conventional side, sure. It is all tied together. But when they start getting the funding and when the smaller alternative organizations don't have a chance and they don't have the money to run any trials, clinical trials, randomized trials, that is what is happening in this country. So that is why we need more funding to go for those sorts of efforts.

Mr. BURTON. For alternative therapies?

Ms. ZARYCKI. Yes.

Mr. BURTON. Dr. Gardener, you mentioned that you suffered a great deal because you weren't exposed to or aware of alternative therapies and you continue to suffer because of those. Do you want to elaborate?

Can you pull the mic closer? I can't hear you.

Ms. GARDENER. No, that's not what I said.

Mr. BURTON. OK. I must have misunderstood.

Ms. GARDENER. Yes. I said it was not because I wasn't aware of them. I became aware of them. But it was because I was not—conventional medicine, first of all, did not respect my right to make choices about myself, about my own situation. It started out, for example, I wanted to have a needle biopsy of the lump, and they wanted to take it out right away.

Mr. BURTON. In the form of a mastectomy?

Ms. GARDENER. No. No, not before they did a biopsy, no. Not before they did a biopsy.

Mr. BURTON. They didn't want to do a needle biopsy?

Ms. GARDENER. They didn't want to do a needle biopsy. They wanted to just remove the lump. I wanted to just have a piece of it taken out, to see if it might be cancerous. At that point, we had no idea. I was in very excellent health. I had never felt better, in

a sense. I have heard other people say that too, just before they are diagnosed.

Mr. BURTON. OK. Thank you very much.

Mrs. Mink.

Mrs. MINK. Thank you very much. I certainly compliment all three of you for your very interesting and informative, provocative testimony. I know the time doesn't permit me to go into details of what you have to offer this committee and the Congress. I do have one or two points that I think need clarification.

Carol Zarycki, on your page 4 of your testimony, you said that you were personally not planning to have mammogram followups, and went on to discus the reasons for that conclusion. You heard earlier that there is still overwhelming dependence on mammograms, and that it is one of the major educational thrusts that the medical field is promoting and all the people that are into breast cancer are promoting. I would like to hear some amplification on the reasons you have come to, your own personal conclusion.

Ms. ZARYCKI. Well, I think mainly, using it as a personal experience, I suffered immense pain and suffering and that had continued on after a mammogram. That had nothing to do with just having a mammogram for having your breast analyzed. So the intense pain and the trauma and that sort of thing which can lead to a chronic condition, is something that women aren't really made aware of.

The other thing is that I think as we know, not all mammograms detect all cancers. So in other words, it can be a hit or miss situation. So why should I not subject myself to more immune-enhancing procedures, such as daily breast massage, which is much more immune enhancing when used with a castor oil and almond oil base and protects the person, and we can start our daughters and our children and our nieces on these. It will protect them. It will protect their endocrine, their reproductive systems. If anything is going to protect us, we need to strengthen our bodies. So why tear ourselves apart with machines and biopsies and synthetic drugs when we should be building up our systems.

Ms. GARDENER. Could I speak to that also?

Mrs. MINK. Yes, please.

Ms. GARDENER. Also we know that mammography is extremely ineffective for young women. Even for myself, I was not that young, but my lump which was very easy to feel, did not show up on a mammogram. Also, there is I know of one researcher at the University of North Carolina, who submitted a proposal, and this is an established researcher, well published, et cetera, who submitted a proposal to the Department of Defense to have funding to study sub-populations of women who were particularly susceptible to the radiation from mammograms. There is considerable evidence which was the support for this proposal, that there are these sub-populations in which breast cancer is increased when they are subjected to mammograms.

There are alternatives such as thermography, which are completely non-invasive and completely harmless.

Mrs. MINK. So what is your comment then on the lowering of the age to 40 years for suggested annual mammograms?

Ms. GARDENER. I don't plan to have any mammograms the rest of my life. I tell my daughter not to have them. I think they are dangerous and potentially very damaging. I think there are alternatives equally or more effective.

Mrs. MINK. I thank you for those personal comments. I want to add to the record that I was astonished to find that nurses in one particular hospital that I am familiar with, all indicated to me that they were not going to take any of the mammograms, for precisely the reasons that you have indicated. So it strikes me that we really need to open up the dialog on this issue and not put such tremendous reliance on this one technique as the way to make sure that we have early diagnosis and early detection of breast cancer.

Mrs. Mack certainly reemphasized your point, that notwithstanding the fact that she had had the mammogram and other clinical examinations, it was her own self examination that detected her cancer. So I think there is a great deal in your testimony that needs to set our thinking machines back on again in this very, very critical and vital area.

Ms. Bedell-Logan, one point that disturbs me which some of my constituents point out to me frequently, is that when they participate in trials or other types of research endeavors, that they are not covered by their insurance, not covered by Medicare, not covered by any health plan, and that they have to assume the costs of these trials individually and personally. Is that your personal understanding to what happens in these medical trials?

Ms. BEDELL-LOGAN. Absolutely. What we have been doing with insurance companies to try to bring randomized control trials that are very positive to a point of coverage and accessibility for patients much sooner than they are right now, is by creating relationships with insurance companies at the integrative medicine center level, where we treat that particular treatment as a petri dish at that one place. So the insurance company covers that particular service for a period of time, and we measure the outcome of a number of patients using that particular service. The patients get reimbursed for what they do, what they get out of those services, and we look to see what the long-term outcomes are.

But this is, as I said, one center at a time. It is tedious and very slow. But in the big picture, it can take up to 10 years to get a randomized control trial accessible to patients. That is extremely frustrating. It's frustrating for researchers. A lot of the healthcare dollars that are going toward research, by the time they actually get accessible to patients, there is something better that can be used. So it's really, to a degree, a waste.

Mrs. MINK. Mr. Chairman, that is really a very, very important point that we need to pursue why it is that our health policies established by Congress do not recognize the important contributions that these health trials, research trials are making to the ability of cures and other kinds of processes being developed. Unless they are covered by the medical insurance plans and health insurance plans, even our own Federal insurance plans, or Medicare, Medicaid, it is a real gap in our policy understanding.

Mr. BURTON. Why don't I work with you, and maybe we can draft some amendments to some of the healthcare legislation?

Mrs. MINK. I would be very happy to. I believe there is a bill pending somewhere, but it needs to really be focused.

Mr. BURTON. I will have Beth check on that. But let me just say before I yield to my colleague, Mrs. Morella, my wife had a tumor in her breast for the estimated 7 to 8 years that was not picked up by mammograms. She picked it up by accident through physical examination. When she told me about it, I said to her, you really ought to have the doctor check it. She thought it was a fibrous tumor. She went to the doctor and almost walked out of the office without having it checked because she didn't think it was anything, and of course it was. Not only had she had it, but it had spread to her lymph nodes. So they miss about 15 percent of them. That is why you cannot look at a mammogram as a panacea, as these ladies have mentioned.

Incidently, our next panel is going to talk about some alternative machines, I believe, that are being used in Europe through heat that will tell whether or not there's a cancer present. We ought to take a look at those too. So I hope you will stick around for the next panel.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. I want to thank the three of you for putting a personal face on it and giving us your experiences. As I try to pull this together, it seems to me we are saying first of all, self examination is probably the best way of diagnosing or noting that there is a problem with breast cancer. I also, and I'm going to let you all comment on these observations, second, that there is not enough research that is being done on alternative therapies. Third, is there a problem that researchers who are doing research on medicine, maybe the conventional medicine, don't want to share? I mean do we have a problem of territoriality and possessiveness? I mean should there be some sharing? And then how do people find out about alternative therapies? Should they just experiment, read a book?

Finally, do you see a role for diet, exercise, as we heard on the previous panel? What kind of a role does that play? I guess that gets you started, and then if I have more time, I will fire away with some more questions. I guess you could do it in any order that you want.

Ms. ZARYCKI. I will start out. I will just say that I think, as you mentioned, I think sharing is very important. I have come up with the same question between the two communities, because I in some instances had to be a go-between. I would ask my conventional doctor and tell him something that I was doing alternatively, that an alternative doctor would tell me, and they had worked at the same organization. I said well, why don't you two talk. He said, "No, no. Why don't you arrange a meeting for us. I don't have time to talk to him." So I would get comments like that.

So my question was, do they really each just want to stay in their own little area of expertise, or do they really not know about each other's expertise? That was my question throughout the whole process. I think it may be half and half. I am not sure. So I think that's real important in terms of sharing. I mean it would be wonderful to share all the information together and come up with some better protocol.

Mrs. MORELLA. It could also be difficult for a person to make a determination about what alternative therapy to use too.

Ms. ZARYCKI. Well, when you are first diagnosed, you are kind of hit with everything. My whole learning in this has been if you want to find something, you will. So you have to trust yourself and in a sense, just in the beginning it's very hard, which obviously a lot of us kind of go to whatever seems to be the appropriate thing, which it is at the time. But eventually, you learn about a lot of different things, and then you learn specifically what works. Then you learn that there is a lot out there in terms of the alternative field, but it's not necessarily for breast or women's reproductive cancers. So while I see a lot of my friends doing a lot of different things, a lot of those things may not be as specific as we can be. So I feel my personal responsibility, and I do that with colleagues and friends, and I do that on a personal basis now, is to inform them as to what they really need to do, not to add negative information into their system, be it in the way of a supplement that they may not need or a lot of different things that are just thrown out there on the market as a marketing tool.

Mrs. MORELLA. And diet? Do you want to comment?

Ms. ZARYCKI. Diet is very important. I initially started out looking at a few different programs that basically eliminated fat, eliminated meats, eliminated dairy, a lot of that. Then I integrated that. I spoke to a few different noted practitioners and noted people who had successfully gotten rid of cancers. They all have very positive programs. What I found worked best for me is not to take just one specific program and say I am only going to stick with this program and I am never going to eat this or that, but to really combine them and to use them all and come up with my own program. That is what I teach others today.

Mrs. MORELLA. I would like to give Dr. Gardener and Ms. Bedell-Logan an opportunity to quickly comment on it too.

Ms. GARDENER. You ask some great questions, and a lot of them very quickly. Self exam is best. OK, I have to really question that. First of all, early detection is too late. We need to get it way before that. Thermography actually, if we could start to use that, that would actually detect things much before you could even find your own tumor, find your own lump.

In the 1960's, they were doing trials—and thermography came out of the space satellite age, Sputnik and all that. They were using it to be able to sense. Anyway, sorry. I got off into a tangent. But basically, they were finding a lot of false positives. So they said well, this isn't working, we need to find something else. We are getting too many. False positives are when you say the person has a problem and they don't. OK?

What they did in a followup study of those that they had assessed was that they found that really those people did develop a significantly higher rate. They did develop breast cancer. So this was in effect a very early detector of cancer. Those are studies that were being done in conjunction with radiologists.

Also, the problem that you said about researchers, not enough research. I have to say we need not more research, necessarily, but better research. We need to look at interactions. Right now we have rigorous trials, but they are very simplistic. The answer is not

simplistic. I know about breast cancer, and we need to look at psychosocial factors, diet, environment, exposures, all of that sort of thing. So we need international sophisticated studies.

The third thing, researchers don't want to share. Many people are not aware that a publicly funded, Government-funded study, that data that is collected is not available to any other researchers unless those researchers choose to share it with them. There are precedents now, an increasing number of research centers who are putting their data on the web. It is called public use data bases. That is something that can help us to break down the real barriers to progress that exist now because of political turf issues and wanting results to come out the way you want them to come out, basically. It is research but it's not science. Then the role of diet and exercise—lifestyle is critical.

Ms. BEDELL-LOGAN. Let me take 30 seconds, if that's OK.

Mr. BURTON. Sure, go ahead.

Ms. BEDELL-LOGAN. Self-care and diet, in my opinion, only works for those people who really believe they are going to get cancer. Most people don't. So it takes a wake-up call to stop eating sugar and fat and all of that.

Second, the research needs to be more pointed and integrated with complementary and alternative medicines, so that we get all sides of the research instead of just one. I believe we have disease in this country called academic constipation. I think we need a legislative colonic to change that. [Laughter.]

Third, I think we need to heal the business of healing and really get information out to the public as to what is going on in this country.

Mr. BURTON. Legislative colonic? Well, you know, you hear everything up here after a while.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I, as I was sitting here, I was trying to listen very carefully to the last two responses. I guess when I sit here and I think about this being the most powerful country in the world, and we're able to do all kinds of things, and here you are here before this Congress of the United States and we can't solve all problems, but certainly we are here to solve problems and lift up the people of this great country.

I was just wondering, and sort of piggy back on what you just answered, but a little bit more specific. Sometimes I do believe that there is a disconnect between the public and the Congress. Sometimes I think we don't get it. I speak for all of us. At some point and on different issues, we don't get it. You all have been kind enough to come here and open your lives to us. Believe it or not, open your lives to America, because C–SPAN is covering this. So this is your moment.

What do you want us to do? What would you like to see us do as the folks who represent you, the 435 of us on this side and the 100 in the Senate? I mean what do you want to see us do? And do you think we get it? Ms. Bedell-Logan.

Ms. BEDELL-LOGAN. First, I would like to see the Access to Medical Treatment Act looked at a little more closely. I think it is an extremely important bill. I think it needs some attention. Raising

the Office of Alternative Medicine to NCCAM was an extremely smart move on the part of the legislation.

I think that you are right. There is definitely a disconnect between the people and Congress. So many people just don't know what happens here, but they do know what happens at home. What was very interesting in my personal experience is that my sister, who had a very treatable cancer, was dead in 6 months, and my brother who had a terminal illness, was dead in 14 years. We need to get that kind of information out to patients.

One of the worst things and one of the best things that has happened recently is the Internet. Unfortunately, it can be a very scary thing to surf the Internet about cancer treatments when a patient has no idea what of it is bunk and what of it is actually real. So I think that to a degree, people are getting scared to death, literally. In order to really change that, we have to start to take conventional medicine and move it into an area that allows patient access to the types of things that will soothe the soul as well as the physical body. We don't have those things available to us right now. In every single oncology center, there should be an acupuncturist who controls nausea, instead of giving people contraindicated medications. There should be a massage therapist in every emergency room, to be dealing with migraine headaches. All of these things, we tend to open flowers with a hammer, as I said earlier. Adverse drug reactions are a huge part of that.

What I believe that is going to start with is things like the Access to Medical Treatment Act, which I hope is very much supported in this room. Thank you.

Mr. BURTON. Would the gentleman yield, real briefly?

Mr. CUMMINGS. Certainly.

Mr. BURTON. Let me just say that I met with Congressman DeFazio this morning—yesterday. We are working to get the Access to Medical Treatment Act in proper form. We will be contacting all of you. If you are so inclined, we would love to have you as cosponsors. He will be the primary sponsor. He is the one who came up with the idea. It is a Democrat sponsor. I will be a cosponsor, and we will see if we can't get enough Members to move that thing through.

Mr. CUMMINGS. I am so inclined, Mr. Chairman. I think that, just to say to you, I think that's wonderful that we can move in a bipartisan manner.

That is what I want you all to understand, that you put a face on what we do here. I mean sometimes things happen, something happens over here, something happens in Iowa, something happens in Baltimore, something happens in Nevada, and all these things are happening and here we have an opportunity. You represent so many people who are in pain. That is why your testimony here is so very, very important. We just want you to understand that we hear you and we want to connect. We want to get it. So I want to thank you.

May I just ask one more question? I would like to have Ms. Zarycki, could you answer that same question? I think the doctor had pretty much answered the last time.

Ms. ZARYCKI. Sure.

Mr. CUMMINGS. What would you like to see us do as a Congress?

Ms. ZARYCKI. I think most importantly, since in this country, women faced with cancers initially go to conventional doctors and for conventional treatment, I would just like them to be aware of all the options and to let people, and let us know as patients what options are out there in terms of other things that they may not be promoting, but at least make us aware of them. I think that is all we're asking, so that we can each make our own choices, because it really is an individual process for each of us.

Mr. CUMMINGS. So I take it if you don't—somebody, I mean you hear this all the time, Mr. Chairman, the statement that the best patient is the well-informed patient, the one who goes out there and learns as much about his or her illness and whatever, so that they can ask the right questions and I guess do the right things. I guess that's another thing that the American people have to do. Would you all agree with that?

Ms. BEDELL-LOGAN. I don't really, because I have heard many physicians say to me that the informed patients are the ones who cause the most trouble, so to speak. What happens in many cases is that patients come in after reading off the Internet about acupuncture and herbs and all of this, and their doctors say, "We don't know anything about that. That's not efficacious." My sister had a bottle of garlic on her nightstand, and the oncologist walked in the room and threw it in the trash and said, "We don't want to give you false hopes. Garlic isn't going to help you."

What we need is a healing between the complementary, alternative medicine community and the conventional medicine community so that each one of those sectors of medicine come together and know what the other person is doing. There is nothing more frustrating than a physician getting caught with his shorts down by not knowing what acupuncture does. The physicians get very frustrated, and they say it doesn't work because they don't understand it. We need to change our medical education, which is a huge part of this process as well.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mr. Cummings.

The National Cancer Institute gets $2.7 billion, and less than about 1 percent of that is used on alternative therapy research. I think what we need to do is get them to realize that there is a strong sentiment in the hinterlands that we take a hard look at these alternative therapies, and maybe more money should be taken from that budget for alternative therapy research as well as conventional research.

So thank you, ladies, very, very much. We really appreciate your testimony.

We will now go to our last panel. I think this will be a very enlightening panel as well. We have Dr. Edward Trimble with the National Cancer Institute; Daniel Beilin, from Aptos, CA. I have never heard of that one before, Doctor; Susan Silver, from George Washington University Integrative Medicine Center; and James Gordon, M.D., Center for the Mind Body Medicine out of Washington, DC.

Thank you all for being so patient. Dr. Gordon has to leave very shortly, so Dr. Gordon, we'll start with you.

STATEMENTS OF JAMES GORDON, M.D., CENTER FOR MIND BODY MEDICINE, WASHINGTON, DC; SUSAN SILVER, GEORGE WASHINGTON UNIVERSITY INTEGRATIVE MEDICAL CENTER; DANIEL BEILIN, OMD, LAC, APTOS, CA; EDWARD TRIMBLE, M.D., HEAD, SURGERY SECTION, DIVISION OF CANCER TREATMENT AND DIAGNOSIS, NATIONAL CANCER INSTITUTE; AND JEFFREY WHITE, DIRECTOR, OFFICE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE, NATIONAL CANCER INSTITUTE

Dr. GORDON. Thank you very much, Mr. Chairman. I am really glad to be here. I appreciate the Members who are here. It has been wonderful listening to the presentations and listening to the dialog and seeing the composition of these panels, because what we have here is the kind of integration that we are talking about and that you are talking about. We have on this panel, we have conventional physicians, people who work with complementary and alternative therapies, we have patients, and patient advocates, and people who are using healing systems of other cultures. I think it is exactly this kind of integration that we need in our healthcare system.

I am a physician. I work here in Washington, DC. I have a private practice. I also for the last 9 years, I have founded and have led a non-profit called the Center for Mind Body Medicine. I was for 10 years before that, a research psychiatrist at the National Institute of Mental Health. I was the first chair of the Advisory Council to NIH's Office of Alternative Medicine.

I have been interested in therapies other than conventional therapies for 35 years. In fact, I was reminiscing with Michio Kushi that I met him some 35 years ago when I was a medical student at Harvard and his teacher, George Osawa, had come over to this country and was bringing macrobiotics here. So this is a movement with some history, and I have some history with this movement.

I want to focus today on what I hope is one specific answer to some of the questions that are being raised, which is the comprehensive cancer care conference integrating complementary and alternative therapies that you mentioned when you introduced me at the beginning, which is a conference that was created by the Center for Mind Body Medicine, but is now cosponsored by the National Cancer Institute and by the National Center for Complementary and Alternative Medicine, as well as the University of Texas.

This conference is particularly relevant here. Incidently, I would like to invite anybody who would like to come to please come to this conference. We are in pre-conference workshops now. The conference begins tomorrow morning at 9 at the Hyatt Regency in Crystal City. We welcome everybody, whether or not they can afford the full fee. We have generous scholarships and no one is ever turned away from any of our activities for lack of money. So I want to invite you to participate in this.

This conference was in a very real sense created to answer some of the questions that have been raised here, and questions that have been raised particularly by women. The questions are, are there any things other than conventional cancer care that I can use for my treatment, complementary or alternative? How do I know

if any of them work? How do I know if they are safe? How do I integrate them with complementary and alternative care? Who do I find who knows something about these things? How can I inform my oncologist about them? And how can I get them paid for?

So we created this conference last year and brought together about 120 presenters from all over the world. This year we have about 130 presenters. What we are doing is trying to answer these questions in a thoughtful way. We are having people like Michio Kushi. In fact, the study that you heard about on macrobiotic treatment of cancer, an early phase of that study was presented last year. We are having the people who are doing the most interesting work in complementary and alternative therapies present their work to the pillars of the American cancer establishment who are open-minded, who are interested in critiquing the work, interested in creating a dialog, and interested in developing the most effective kind of cancer care.

I particularly want to acknowledge the National Cancer Institute as well as the National Center for Complementary and Alternative Medicine, and Dr. Klausner, who at one of your hearings actually came up to me and said, "We love the conference you are doing. Is there anything we can do?" I said yes, you can cosponsor it and help support it. He said great. Dr. Wittis, his deputy director, who participated with us last year, and Dr. Jeffrey White, who is here, who has developed a whole series of panels for this year's conference. We hope we will continue to collaborate with them on this conference in the years ahead.

What we have done is both to have the material presented and critiqued at the conference. If you look through the program, you will see the whole variety of plenary sessions and panels that are presented. Then we have also put this information, the presentations together with the critiques, up on our website, which is www.cmbm.org, www.cmbm.org. So the information is there.

I think the kind of information that the last panelists were looking for, and that I think everybody with cancer is looking for, is let me see the best that is being done around the world, not only in the United States, but in Germany and China and Japan and South America. Let me see it presented, and let me see some people who really know their stuff scientifically, but who are open-minded, take a look at this literature and tell me what they think, and then let me make up my own mind.

I say this conference began with questions about these therapies for cancer, and that those questions were mostly asked by women. I am talking of course about cancers that women have, but I am also talking about cancers in other members of the family. The Office of Alternative Medicine, 60 to 70 percent of the calls the office receives were about questions about cancer. Most of those calls were from women. In my practice, at our center, it's women not only asking about themselves, but asking about their husbands and parents and children. So women are the ones who are doing much of the investigation. It is their questions we are trying to answer.

Let me just share with you three broad areas where I think it is very important to make advances and to make changes, and then I will be happy to answer some questions before I have to leave to go back and give a talk there. The first has to do with this issue

of sharing knowledge. We have knowledge available on our website. The National Cancer Institute is beginning to provide some of that knowledge as well. We need to make knowledge, the best possible information about these complementary and alternative therapies available, just as we need to make the best possible information about conventional therapies available.

Second or as part of that issue of sharing knowledge, I spoke with Dr. Klausner about a year ago and I want to continue speaking with him about training oncologists, physicians, nurses, oncology nurses to provide this kind of counseling, to provide enough time, enough emotional support, enough thoughtful guidance, and enough information about complementary and alternative therapies so that each person who comes who has cancer can have that kind of guidance. This is crucial. I think it is a missing element. People often feel pressured into doing one or another kind of therapy. I think there needs to be a time for reflection. We are very eager at the Center for Mind Body Medicine to create a training program for these counselors. We do it at our center. We believe it needs to be done at a national level so that every patient with cancer should have this kind of informed, sensitive counselor available for a significant period of time. When I work with people with cancer, I spend about an hour and a half to 2 hours with them, discussing their options, discussing their feelings about both conventional and alternative treatment. So that's No. 1, knowledge and how to share it.

No. 2 is the creation of healing partnerships. Again, this is a theme that I have heard this morning. This requires that we spend more time with patients, and especially that oncologists spend more time with patients. I know a number of oncologists in town. There are oncologists whom every one of my patients loves and loves to go see, and there are oncologists whom they dread seeing. The characteristics of the ones whom they love to see are that these are generally extremely kind people, they are people who take time, they are people who listen to questions, and they are people who if they tend to have preconceptions or areas of ignorance, they say "I don't know. I would really like to find out more." Or "I may be a little prejudiced. Maybe you could help me see this more clearly, or who should I talk to."

So I think this is crucial, that from the side of the practitioners, and of course not just oncologists, all of us who are physicians, I think that we need to share information. This needs to be encouraged, that all physicians should be sharing the best possible information about all the treatments they do, whether it is for cancer or any other condition, whether it's conventional, complementary, or alternative.

I also think that it is important that we encourage, and in this instance, women particularly. Women have been the leaders in the movement for self care and in the movement for creating healing partnerships with their physicians. They are the ones who first said, "What's going on down there, you tell me. I'm not ignorant. I want to know what's happening. I want to take part in my care." I think we need to encourage this, not only at the clinical level, but at the national level. I think it is very important, not only that people who are expert in complementary and alternative therapies,

but that women like the panelists who are on the last panel, be part of the advisory committees to the different institutes and centers at NIH.

Finally, or not finally, next to last, coming to the issue of research. Research is crucial, but there need to be new and more imaginative models of research. Coming out of last year's cancer conference, Nicholas Gonzales presented a very interesting, very promising therapy for the treatment of pancreatic cancer, a comprehensive therapy. NCI responded and agreed to fund, and is funding a clinical trial of this therapy, a very comprehensive alternative therapy which is being funded by NCI, and studied by Columbia University. This is the kind of partnership we need. We need to expand from studying single modalities to looking at comprehensive approaches, and we also need to understand that each person who has cancer is an individual, and that an approach that may work for one may not work for others. We need to design research to accommodate that individuality.

We also need to understand that there is a great deal, and this was brought out in the first panel, that all of us, and anyone who has cancer can do on her or his own behalf, and we need to study those therapies and put much more of an emphasis and much more of a financial emphasis on some of those mind body therapies, changes in attitude, meditation, relaxation, group support, nutrition, exercise, and to really see what is possible for people to do on their own behalf.

Finally, I would like to echo the suggestion, and I know your strong feeling, that it is time to pass the Access to Medical Treatment Act. It is time to open up the arena of treatment to all therapies that are offered by responsible people, and to understand that people can assume in partnership with a variety of healers, responsibility for their own care. Thank you very much.

Mr. BURTON. Thank you. We will push very hard to get that passed. We'll try to get as many cosponsors as possible.

We are going to have a vote. I would like to have one more of our witnesses speak. Ms. Silver, would you like to go ahead and speak? Then we will run and vote, and we will come right back and try to not have any more unnecessary demands on your time.

Dr. GORDON. I am going to have to go, though, when you break for the vote. I am sorry I do, but I have to speak at 3 in Virginia.

Mr. BURTON. That's OK, Dr. Gordon. I am going to try to see you tomorrow anyhow, so we'll talk further.

Dr. GORDON. Terrific. Thank you.

Mr. BURTON. Ms. Silver.

Ms. SILVER. Thank you for the opportunity to address the committee today. All of us who work in the field of complementary and alternative medicine are grateful for the visibility and the validation that you bring to the field by holding this hearing. The Center for Integrative Medicine is a division of the Medical Faculty Associates of the George Washington University Medical Center. Our program includes research, education, and clinical services. Patient care began in April 1998, and from the outset, we included a program for patients with cancer. That program is called the Quality of Life program, and it serves as an adjunct to conventional cancer treatment.

We share the committee's interest in research and the current level of knowledge about complementary and alternative medicine and its effectiveness in people with cancer. We have submitted two research proposals to NIH to investigate the use of reiki and guided imagery by patients with breast cancer and those undergoing radiation. As we all know, research is in its early stages. Thanks to the Center for Complementary and Alternative Medicine at NIH, the pace at which we receive documentation of complementary and alternative medicine's effectiveness will increase as researchers are supported in investigating these vital questions.

At the Center for Integrative Medicine, we are as anxious as anyone for those results. In the meantime though, we ask whether we can proceed with unproven, and note that I said unproven rather than disproven, modalities to assist cancer patients. Our answer is a resounding yes. We have asked ourselves this fundamental question: How can we enhance the quality of life of the person as patient?

Traditionally, on assuming the role of patient, a person has willingly surrendered quality of life, her sense of orientation and personal control in exchange for a cure. But we are beginning to suspect that surrender may be self defeating. We would suggest that successful medical outcomes are diminished when the patient lacks control, information, and support. Conversely, if these inputs are maximized, the patient may recover more quickly and completely, and have a higher quality of life, whatever the ultimate outcome.

Most cancer patients say that from the moment of their diagnosis, everything in life is changed. A life that was going on routinely is suddenly out of control. The entire focus on the what if's of cancer treatment and its outcome.

The Quality of Life program of the Center for Integrative Medicine can assist the patient throughout the course of her illness. At whatever stage of the illness the relationship with the center is initiated, we help determine and meet the patient's needs and goals in a comprehensive way. For patients newly diagnosed and awaiting treatment, we offer stress reduction with a focus on personal control and empowerment, immune system enhancement to help combat the disease, relief from symptoms caused by anxiety or depression as appetite loss, nausea, or sleeplessness.

For patients undergoing aggressive curative treatment, we offer relief from side effects of treatments, such as nausea or post-operative pain, immune system enhancement to help maximize the effectiveness of the treatment, relaxation and stress reduction to help restore the mind and body between enervating treatments.

For patients in remission, we offer stress reduction during periods of watchful waiting, rebuilding of stamina and flexibility following medical and surgical treatments, and resumption of healthful diet and nutrition, with added emphasis on cancer prevention.

For patients who experience a relapse, all of the services and objectives of the pre-treatment and treatment phase program can be resumed with even greater intensity. For patients with illnesses not responsive to curative treatment, we offer control of pain and symptoms of a progressive illness, mobilization of the powers of the mind to maximize quality of life, and reduction of stress to allow for end-of-life planning and resolution. Overall, the Center for Inte-

grative Medicine aims to restore a sense of control and well-being, and offer the patient the freedoms to heal physically, emotionally, and spiritually.

Let me offer just two examples of cases in which we are treating women with cancer. The first is a patient with recurrent endometrial cancer. Immediately following surgery, she was referred to our medical center for radiation. Thanks to an active partnership with the Division of Radiation Oncology, the Center for Integrative Medicine was called into the case as the patient came for her initial consultation. Along with vital information about her radiation treatment, the patient was given information about the center and the role of complementary medicine in easing her way through the course of illness. She was given a meditation tape focused on breathing and relaxation exercises that incorporate the details of the radiation experience.

In the following weeks, the patient participated in meditation and reiki and used both skills to reduce stress during treatment and to assist her in sleeping through the night. As the radiation progressed, side effects became extremely bothersome. Stomach and intestinal upset were frequent. But a combination of acupuncture and nutritional guidance got them under control.

As the radiation neared completion, the patient began focusing on the future. She requested further nutrition counseling, both to help restore her energy following treatment, and on a larger scale, sought advice on a diet that would do most to prevent a recurrence of her cancer. After 28 successive days of radiation therapy, the patient suddenly felt apprehensive about what to do without it. She had grown attached to her radiation team and to the routine of daily radiation appointments. But she found comfort and support in the relationships that she had formed with the providers in the Center for Integrative Medicine. She continues to practice the modalities that she learned and is looking forward to adding yoga to her routine to help build stamina and regain flexibility. She intends to check in with her complementary medicine team indefinitely for encouragement and renewal.

The second patient is a young woman with advanced breast cancer. At the time of diagnosis, she was offered several treatment options, and chose the most aggressive. She is currently undergoing high dose chemotherapy. Before her first treatment, the patient learned reiki and guided imagery. As she faced her initial dose of chemotherapy, she used both modalities actively to reduce her fear and the anticipatory side effects that she experienced. Today, as she continues in treatment, the center's reiki provider meets her at the oncology clinic and practices reiki with her as the medication is administered. Nausea and vomiting seemed inevitable side effects of her treatment, but the patient has found substantial relief with acupuncture.

This patient's prognosis is guarded. However, she has expressed confidence in the center's ability to maximize her wellness and comfort. She has learned skills for stress reduction and relaxation that she will utilize throughout her life. Whatever the outcome, feels empowered to maintain control of her life.

Let me say again that the Center for Integrative Medicine offers an adjunctive program of care for women with cancer. We are keen-

ly aware of the remarkable advances in oncology, through medicine, surgery, and radiation. We are in partnership with specialists who practice those techniques. But the goal and the value of our program is this. We change the experience of the cancer patient by placing her at the center of care and treating the whole person, mind, body and spirit.

Our patients convince us daily of the benefits that the center offers. But what of the patients we never see? The Center for Integrative Medicine operates on a fee-for-service basis, and our patients rarely have insurance coverage for our treatments. Consequently, our program is accessible only to those with the greatest financial wherewithal. Personally, I find it heart breaking to tell callers who are filled with hope, and sometimes desperation, that our services are out of their reach. That is an every day occurrence. I hasten to add that our providers offer a remarkable amount of pro bono care. But the reality remains that to be viable, the center must charge for its services.

The issue for payment for complementary and alternative medicine is inextricably linked to research and policy. Only when research demonstrates the efficacy and cost benefit of alternative medicine will it be incorporated into mainstream third party coverage. We need your leadership to harness the demand of millions of Americans to press for pure science, pilot programs, and demonstration projects that will assess the real value of complementary and alternative medicine. We need mandated benefits that will expand the scope of private and public insurance policies to even the most basic complementary modalities. We need Medicare to act as a model by including alternative medicine in its coverage. The Medical Nutrition Therapy Act of 1999, H.R. 1187, would mandate nutrition counseling as a core benefit of Medicare for the purpose of disease management.

Mr. BURTON. Pardon me, Ms. Silver. We have a vote on the floor. Would you mind——

Ms. SILVER. I have just about four more sentences.

Mr. BURTON. All right. Go ahead.

Ms. SILVER. That bill is languishing, pending major reform of Medicare.

Mr. BURTON. And the bill number on that again is?

Ms. SILVER. The House version is H.R. 1187. On the Senate side, it's S. 660.

Mr. BURTON. OK.

Ms. SILVER. As we meet here today, 60 million Americans are utilizing complementary and alternative medicine. A substantial number of them are women with cancer. As the Center for Integrative Medicine treats our small share, we are guided by the principle that wellness during illness is not a contradiction in terms.

Again, I would like to thank the committee for the opportunity to address you today. In a larger sense, I want to thank you on behalf of those who so urgently need our help.

[The prepared statement of Ms. Silver follows:]

Testimony

Of

Susan Silver
The Center for Integrative Medicine
George Washington University

Before the

Government Reform Committee
U.S. House of Representatives

On

"The Role of Early Detection and Complementary and Alternative Medicine in Women's Cancers"

Thursday, June 10, 1999

2154 Rayburn House Office Building
Washington, DC

Thank you for the opportunity to address the Committee today. All of us who work in the field of complementary and alternative medicine are grateful for the visibility and validation you bring to the field by holding these hearings.

The Center for Integrative Medicine is a division of the Medical Faculty Associates of the George Washington University Medical Center. Our program includes research, medical education and clinical services. Patient care began in April 1998 and, from the outset, we included a program for patients with cancer. That program is called the Quality of Life Program and serves as an adjunct to conventional cancer treatment.

We share the Committee's interest in research and the current level of knowledge about complementary and alternative medicine and its effectiveness in people with cancer. We have submitted two research proposals to NIH to investigate the use of reiki and guided imagery by patients with breast cancer and those undergoing radiation.

As we all know, research is in its earliest stages. Thanks to the Center for Complementary and Alternative Medicine at NIH, the pace at which we receive documentation of CAM's effectiveness will increase as researchers are supported in investigating these vital questions.

At the Center for Integrative Medicine, we are as anxious as anyone for those results. In the meantime, though, we ask whether we can proceed with unproven – note "unproven" rather than "disproven" – modalities to assist cancer patients. Our answer is a resounding "yes."

We have asked ourselves this fundamental question: "How can we enhance the quality of life of the person-as-patient?" Traditionally, on assuming the role of patient, a person has willingly surrendered quality of life – her sense of orientation and personal control – in exchange for a cure. But we are beginning to suspect that surrender may be self-defeating. We would suggest that successful medical outcomes are diminished when the patient lacks control, information and support. Conversely, if these inputs are maximized, the patient may recover more quickly and completely, and have a higher quality of life, whatever the ultimate outcome.

Most cancer patients say that from the moment of their diagnosis, everything in life is changed. A life that was going along routinely is suddenly out of control, the entire focus on the "what ifs" of cancer treatment and its outcome.

The Quality of Life Program of the Center for Integrative Medicine can assist the patient throughout the course of her illness. At whatever stage of illness the relationship with the Center is initiated, we help determine and meet the patient's needs and goals in a comprehensive way.

For patients newly diagnosed and awaiting treatment we offer:

Stress reduction with a focus on personal control and empowerment
Immune system enhancement to help combat disease
Relief from symptoms caused by anxiety or depression such as appetite loss, nausea, or sleeplessness

For patients undergoing aggressive curative treatment:

Relief from side effects of treatment such as nausea or post-operative pain
Immune system enhancement to help maximize the effectiveness of treatment
Relaxation and stress reduction to help restore the mind and body between enervating treatments

For patients in remission:

Stress reduction during periods of watchful waiting
Rebuilding of stamina and flexibility following medical and surgical treatments
Resumption of healthful diet and nutrition with added emphasis on cancer prevention

For patients who experience a relapse:

All of the services and objectives of the pre-treatment and treatment phase programs resumed with even greater intensity

For patients whose illness is not responsive to curative treatment:

Control of pain and symptoms of the progressive illness
Mobilization of the powers of the mind to maximize quality of life
Reduction of stress to allow for end of life planning and resolution.

Overall, the Center for Integrative Medicine aims to restore a sense of control and well being and offer the patient the freedom to heal physically, emotionally and spiritually.

Let me offer two examples of cases in which we are treating women with cancer:

The first is a patient with recurrent endometrial cancer. Immediately following surgery she was referred to our medical center for radiation. Thanks to an active partnership with the Division of Radiation Oncology, the Center for Integrative Medicine was called into the case as the patient came for her initial consultation. Along with vital information about her radiation treatment, the patient was given information about the Center and the role of complementary medicine in easing her way through the course of her illness. She was given a meditation tape focused on breathing and relaxation exercises that incorporate the details of the radiation experience.

In the following weeks the patient participated in meditation and reiki and used both skills to reduce stress during treatment and to assist her in sleeping through the night. As the radiation progressed, side effects became extremely bothersome. Stomach and intestinal upset were frequent, but a combination of acupuncture and nutritional guidance got them under control.

As the radiation neared completion, the patient began focusing on the future. She requested further nutrition counseling both to help restore her energy following treatment and, on a larger scale, sought advice on a diet that would do most to prevent a recurrence of her cancer.

And, after twenty-eight successive days of radiation therapy, the patient suddenly felt

apprehensive about what to do without it. She had grown attached to her radiation team and to the routine of daily radiation appointments. But, she found comfort and support in the relationships that she had formed with the providers in the Center for Integrative Medicine. She continues to practice the modalities she had learned and is looking forward to adding yoga to her routine to help build stamina and regain flexibility. She intends to "check in" with her complementary medicine team indefinitely for encouragement and renewal.

The second patient is a young woman with advanced breast cancer. At the time of diagnosis she was offered several treatment options and chose the most aggressive. She is currently undergoing high-dose chemotherapy. Before her first treatment, the patient learned reiki and guided imagery. As she faced her initial dose of chemotherapy she used both modalities actively to reduce her fear and the anticipatory side effects she experienced. Today, as she continues in treatment, the Center's reiki provider meets her at the oncology clinic and practices reiki with her as the medication is administered. Nausea and vomiting seemed inevitable side effects of her treatment, but the patient has found substantial relief with acupuncture.

This patient's prognosis is guarded. However, she has expressed confidence in the Center's ability to help maximize her wellness and comfort. She has learned skills for stress reduction and relaxation that she will utilize throughout her life, and whatever the outcome, feels empowered to maintain control of her life.

Let me say again that the Center for Integrative Medicine offers an adjunctive program of care for women with cancer. We are keenly aware of the remarkable advances in oncology - through medicine, surgery and radiation. We are in partnership with the specialists who practice those techniques. But the goal and the value of our program is this: we *change the experience* of the cancer patient by placing her at the center of care and treating the whole person, mind, body and spirit.

Our patients convince us daily of the benefits that the Center offers. But what of the patients we never see? The Center for Integrative Medicine operates on a fee for service basis, and our patients rarely have insurance coverage for our treatments. Consequently, our program is accessible only to those with the most financial wherewithal. Personally, I find it heartbreaking to tell callers who are filled with hope, and sometimes desperation, that our services are out of their reach. That is an everyday occurrence. I hasten to add that our providers offer a remarkable amount of *pro bono* care. But the reality remains that to be viable, the Center must charge for its services.

The issue of payment for complementary and alternative medicine is inextricably linked to research and policy. Only when research demonstrates the efficacy and cost-benefit of alternative medicine will it be incorporated into mainstream 3rd-party coverage. We need your leadership to harness the demand of millions of Americans to press for pure science, pilot programs, and demonstration projects that will assess the real value of complementary and alternative medicine. We need mandated benefits that will expand the scope of private and public insurance policies to even the most basic complementary modalities. We need Medicare to act as a model by including alternative medicine in its coverage. The Medical Nutrition Therapy Act of 1999 (H.R. 1187/S. 660) would mandate nutrition counseling as a core benefit of

Medicare for the purpose of disease management. That bill languishes today in Congress pending major Medicare reform.

As we meet here today, some 60 million Americans are utilizing complementary and alternative medicine. A substantial number of them are women with cancer. As the Center for Integrative Medicine treats our small share, we are guided by the principle that wellness during illness is not a contradiction in terms.

Again, I would like to thank the Committee for the opportunity to address you today. In a larger sense, I would like to thank you on behalf of those who so urgently need our help.

Mr. BURTON. Thank you, Ms. Silver.

Dr. Beilin and Dr. Trimble, we will be back in just a few minutes. We have one vote on the floor. I am anxious to hear from both of you, so we will be right back.

[Recess.]

Mr. BURTON. I want to first of all thank you for your patience. This has been a very, very long day. I am a little disappointed that what you are going to tell us is probably very, very significant and we didn't have you on earlier in the program. Nevertheless, I can assure you that what you tell us today will be taken to heart and used, and we will talk to the various agencies about it.

So let's start, I guess go down the list with you, Dr. Beilin.

Dr. BEILIN. OK. Thank you very much, Mr. Chairman, and members of the committee. Thank you for the opportunity to be here today. My name is Dr. Dan Beilin, OMD, LAc. I have a doctorate in herbal and oriental medicine, and hold a degree in physiology, as I was physiologist at the UCLA Department of Gastroenterology. I am in private practice in California in European complementary medicine and oriental medicine. I have been working in cooperation with a group of doctors and a radiologist, who have been measuring changes in the skin and the nervous system of patients who develop devastating diseases, such as cancer and autoimmune disorders. We have found a high correspondence between the nervous system's ability to control metabolism and circulation, also referred to as thermoregulation or heat regulation, and the growth of tumors and other degenerative disorders.

In complementary medicine, we try to step back one step and view the patient in terms of the interactions between the internal organs and tissues. Traditional orthodox medicine too often focuses on a single organ of the body, when in reality, many organs are involved in a subtle or not-so-subtle manner in the advancement of a particular disease state. Yet when we look at the body as a collection of systems, each interrelated with the others, we can actually begin to search for the cause of illness. Fortunately, I believe that we are approaching a technology which will provide a bird's eye view of the body as a whole, providing information about multiple organ expression and painting a picture of biological processes that may bring us closer to finding the cause of such diseases as breast cancer.

One technology is called regulation thermography, developed in Germany and legally marketed in the United States now. Regulation thermography offers a serious addition to the arsenal of physicians evaluating patients at risk of cancer or cancer recurrence. It works by taking temperature measurements of neurologically controlled points on the skin often above the organ in question, stressing the body with cool air, and then taking a second measurement of the same points. Computer software analyzes the response of the points and their adaptation to the rapid temperature change. More than 25 years of experience has demonstrated a relationship between such responses in organ pathology. The test is non-invasive, painless, and the machine is small enough to fit into a briefcase.

Regulation thermography is not intended to be a substitute for mammography or other methods of cancer detection. What it does do is provide information to the practitioner about the environment

in the body that could be contributing to the cancer growth, allowing the practitioner to design a treatment strategy utilizing the principles of alternative and complementary medicine, staying within the constraints of good science.

I prepared a few slides that better illustrate the theory behind regulation thermography and its contribution to cancer detection and treatment. So if you will check the monitors, the first slide is the idea of terrain versus tumor. Here, we see a large box, which represents healthy cells and fluids of the body. The small box represents a tumor which has grown for some reason and has now been diagnosed say by a mammogram. Medicine as of 1999, today, has given special attention to the destruction of the tumor, whether by surgery, chemotherapy, or radiation, but has neglected the internal environment that has contributed to the development of that tumor. Until recently, there have not been scientifically verifiable methods for measuring the factors in that tumor terrain. But this is critical if we are to develop therapeutic approaches aimed at treating the whole patient, not simply mounting a frontal attack on the tumor alone.

The second slide illustrates how we are internally wired, that the internal organs, such as the stomach, pancreas, liver or prostate, are capable of talking to the nervous system by taking precise measurements of skin temperature as we stress the body, similar to a stress ECG by the cardiologist, we can see how the organs and other tissues of the body behave around that stress. Changes in the way the body behaves to stress can indicate the possible presences of pathologies or pre-pathologies. German and Swiss researchers have gathered data over the last 20 years which have established normal values for stress reactivity in every skin region. Furthermore, many disease states have been documented for their patterns of skin dysfunction over the whole body.

Mr. Chairman, this is a method that is objective, reproducible, and very serious consideration for inclusion into every new complementary medicine hospital and program. It measures the pattern of response to stress which takes place in the terrain of the body. The information gathered can act as a marker test for lifestyle change prescription effect and preventive measures that have the potential to cut the increasing cost of cancer care.

In slide three, we see a thermogram above done with this new technology. Above, a normal thermogram, and below, a chaotic thermogram. You can see how there is a complete disruption of a certain pattern. The top one looking homogeneous, the next looks mixed up, showing a lack of regulation, of homeostasis or balance by the organs and nervous system. This is the whole body, with data taken from 80 points.

In the next slide, this is a study done by Professor Wagner in Germany. We see this, that 63 patients on the left bar with confirmed breast cancer by pathology, were sent to blind doctors doing clinical exams alone, with mammography added, and then with regulation thermography in conjunction with mammography. Interestingly, a higher percentage of tumors were identified using regulation thermography in conjunction with mammography than with mammography alone.

This and other studies conducted in Europe demonstrate that dynamic thermography can be a valuable tool in helping to diagnose the presence of occult disease. In fact, some studies suggest that in some cases, regulation thermography offers a viable alternative to mammography. If proven true, this would particularly be useful in geographic regions lacking mammography facilities or as a preliminary screening device for the family physician. In addition, studies suggest that regulation thermography may be able to detect the changes in the body that may preface the development of cancer. With regard to breast cancer and other types of tumors, research indicates that most tumors have taken at least 5 years from their inception to develop into a viewable size. What has occurred to the body's immune mechanisms during those years which creates the pre-tumor and then tumor? What do we know about the fertility of our inner soil, if you will, which nourishes or depletes the development of tumors? For these reasons, I strongly urge consideration for funding for studies in the United States.

On the last slide, of course breast cancer is not the only disease for which this technology may be utilized. Here is a statistical average of three patients with a progression of PSAs used as a prostate marker, and their corresponding thermogram of the prostate points taken by this method. Note the correspondence of a higher PSA, say on the left is 12.53, to the higher degree of rigidity of response seen in the thermogram are quite evident. When we see the lowering of the PSA, we see a better thermograph coming out as a result.

The point I make is that complementary medicine is not only comprised of non-scientifically based methods. It has in the past been shunned from the mainstream, but the effect has been to throw the baby out with the bath water. In recent years, Congress has taken important steps to address this issue, primarily through the creation of the Center for Alternative Medicine at the NIH, and the provision of increased funding for research in alternative medicine. Many leading teaching hospitals and other medical centers have established programs focused on researching and using alternative and complementary therapy. One of the roles for the Center of Alternative Medicine should be to act to bring these integrative centers together for advanced research on key technology, such as regulation thermography, and to provide additional funding for research so that the valuable alternative therapies will assume their proper place within the entire healthcare system.

Finally in closing, I also recognize that Congress this year will be dealing with the critical issue of patient rights with regard to Government funded and private healthcare plans. Unfortunately, alternative medicine has been neglected in the coverage decision-making of many healthcare programs. I ask you while considering this critical legislation, to keep in mind the proven benefits of alternative medicine, and the desires of a significant portion of the American public to have access to such treatment.

Thank you, Mr. Chairman, for inviting me here today. I appreciate this wonderful opportunity to share my opinions regarding present and future trends in medicine. I hope we can work together in the future.

[The prepared statement of Dr. Beilin follows:]

Statement of

Daniel Beilin, OMD

Before the

Committee on Government Reform

U.S. House of Representatives

On

Regulation Thermography and the Role Of Complementary and Alternative Medicine In Cancer Treatment and Prevention

June 10, 1999

Daniel Beilin, OMD,
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Mr. Chairman, members of the committee, thank you very much for the opportunity to be here today. My name is Daniel Beilin, OMD, L.Ac. I have a doctorate in Herbal and Oriental Medicine, and hold a degree in physiology, as I was chief physiologist at the UCLA Department of Gastroenterology. I am in private practice in Oriental and European Complementary Medicine. Recently I have been working in cooperation with a group of doctors and a radiologist who have been measuring changes in the skin and nervous system of patients who develop devastating diseases such as cancer and autoimmune disorders. We have found a high correspondence between the nervous system's ability to control metabolism and circulation, also referred to as thermoregulation (or heat regulation), and the growth of tumors and other degenerative disorders.

In complementary medicine, we try to step back one step and view the patient in terms of the interactions *between* his internal organs and tissues. Traditional, orthodox medicine too often focuses on a single organ of the body, when in reality many organs are involved in a subtle or not so subtle manner in the advancement of a particular disease state. Yet only when we look at the body as a collection of systems, each interrelated with the others, can we actually begin to search for the cause of the illness. Fortunately, I believe that we are approaching a technology which will provide a bird's eye view of the body as a whole, providing information about multiple organ expression and painting a picture of biological processes that may bring us closer to finding the cause of such diseases such as breast cancer.

This technology is called Regulation Thermography. Developed in Germany and legally marketed in the United States, Regulation Thermography offers a serious addition to the arsenal of physicians evaluating patients at risk of cancer or cancer recurrence. It works by taking temperature measurements of neurologically-controlled points on the skin, often above the organ in question, then stressing the body with cool air, and then taking a second measurement of the same points. Computer software analyzes the response of the points in their adaptation to a rapid temperature change. More than 25 years of research has demonstrated a relationship between such responses and organ pathology. The test is a non-invasive and painless, and the machine is small enough to fit into a briefcase.

Regulation Thermography is not intended to be a substitute for mammography or other methods of cancer detection. What it does do is provide information to the practitioner about the environment in the body that could be contributing to the cancer growth, allowing the practitioner to design a treatment strategy utilizing the principles of alternative and complementary medicine, staying within the constraints of good science.

I have prepared a few slides that better illustrate the theory behind Regulation Thermography, and its contribution to cancer detection and treatment.

SLIDE 1: Terrain vs. Tumor

Here we see the large box, which represents the healthy cells and fluids of the body. The small box represents a tumor, which has grown and now has been diagnosed by a mammogram. Medicine, as of 1999, has given special attention to the destruction of the tumor, whether by surgery, chemotherapy or radiation, but has neglected the inner ENVIRONMENT that has contributed to the development of that tumor. Until recently, there have not been scientifically verifiable methods for measuring the factors in that tumor-terrain. But this is critical if we are to develop therapeutic approaches aimed at treating the whole patient, not simply mounting a frontal attack on the tumor.

SLIDE 2:

This slide illustrates how we are internally wired - that the internal organs such as the stomach, pancreas, liver or prostate, are capable of "talking" to the nervous system. By taking precise measurements of skin temperature as we stress the body - similar to a stress ECG - we can see how the organs and other tissues of the body behave around that stress. Changes in the way the body behaves to stress can indicate the possible presence of pathologies including cancer.

German and Swiss researchers have gathered data over the last 20 years which has established normal values for stress reactivity in every skin region. Furthermore, many disease-states have been documented for their patterns of skin dysfunction over the whole body.

Mr. Chairman, this is a method that is objective, reproducible and bears serious consideration for inclusion into every new complementary medicine hospital and program. It measures the pattern of response to stress, which takes place in the "terrain" of the body. The information gathered can act as a "marker test" for lifestyle change, prescription effect, and preventive measures that have the potential to cut the increasing cost of cancer care.

SLIDE 3

Here we see a thermogram done with this new technology: Above, a normal thermogram, and below, a chaotic thermogram, typical of what you see in people with cancer. You see how one looks homogenous, and the next looks mixed-up, showing the lack of Regulation of Homeostasis by the organs and nervous system. This is the whole body, with data taken from 80 points.

SLIDE 4:

Here we see the research completed by Prof. G. Wagner in Germany.

63 patients with confirmed breast cancer by pathology, were sent to blinded doctors doing clinical exams alone, with mammography added, then with regulation thermography in conjunction with mammography. Interestingly, a higher percentage of tumors were identified using regulation thermography in conjunction with mammography, than with mammography alone. This and other studies conducted in Europe demonstrate that dynamic thermography can be a valuable tool in helping to diagnose the presence of occult disease. In fact, some studies even suggest that, in some cases, regulation thermography offer a viable alternative to mammography. If proven true, this would be particularly useful in geographic regions lacking mammography facilities, or as a preliminary screening device for the family physician. In addition, studies suggest that Regulation Thermography may be able to detect the changes in the body that may preface the development of cancer. With regard to breast cancer and also other types of tumors, research indicates that most tumors have taken at least 5 years from their inception to develop into a viewable size. What has occurred to the body's immune mechanisms during those years, which creates the pre-tumor and tumor? What do we know about the "fertility" of our inner soil if you will -which nourishes or depletes the development of a tumor?

For these reasons, I strongly urge consideration for funding for studies in the US.

SLIDE 5:

Of course, breast cancer is not the only disease for which this technology may be utilized. Here is a statistical average of 4 patients with progression of PSA's, and their corresponding thermogram of the prostate points. Note the correspondence is quite high. At this point, I don't think any urologist would turn down an additional prostate marking method, since the methods we have are insufficient or too aggressive.

The point I make is that complementary medicine is not only comprised of non-scientifically based methods. It has, in the past, been shunned from the mainstream, but the effect has been to throw the baby out with the bath water. In recent years, Congress has taken important steps to address this issue, primarily through the creation of the Center for Alternative Medicine at the NIH, and the provision of increased funding for research in alternative medicine. Many leading teaching hospitals and other medical centers have established programs focused on researching and using alternative and complementary therapies. One of the roles of the Center for Alternative Medicine should be to act to bring these Integrative Centers together for advanced research on key technologies, such Regulation Thermography, and to provide additional funding for research so that valuable alternative therapies will assume their proper place within the entire health care system.

Finally, in closing, I also recognize that Congress this year will be dealing with the critical issue of patient rights with regard to government funded and private health care plans. Unfortunately alternative medicine has often been neglected in the coverage decision making of many health care programs. I ask you while considering this critical legislation to keep in mind the proven benefits of alternative medicine and the desires of a significant portion of the American public to have access to such treatment.

Thank you, Mr. Chairman, for inviting me here today. I appreciate this wonderful opportunity to share my opinions regarding present future trends in medicine. I hope we can work together in the future.
-Dr. Beilin

Mr. BURTON. Dr. Beilin, before we go to Dr. Trimble, I hope when we get to the questions and the answers, that you will talk about, I think it was a proton device that can attack prostate cancer?

Dr. BEILIN. There is a type of hyperthermia that is a local hyperthermia device that is being reviewed right now.

Mr. BURTON. I want to ask you about that when we get to the questions and answers.

Dr. Trimble, thank you, sir, for being so patient with us today.

Dr. TRIMBLE. Chairman Burton, members of the Committee on Government Reform, thank you for inviting me to represent the National Cancer Institute at this hearing. I am head of the surgery section at the Division of Cancer Treatment and Diagnosis at the NCI. Sitting behind me today is Dr. Jeffrey White, who is Director of the NCI's Office of Complementary and Alternative Medicine.

By training, I am an obstetrician/gynecologist and gynecologic oncologist. My own patients include many women with cervical, uterine, ovarian, and breast cancer. My experiences in medicine as well as my own experiences caring for family members with cancer have made clear to me the importance of a holistic approach in cancer care.

The NCI is committed to fostering the integration of complementary and alternative medicine into modern cancer care. In 1989, we funded key research conducted by Dr. David Spiegel and his colleagues at Stanford and the University of California which demonstrated that psychosocial support prolonged long survival in women with metastatic brain cancer. Working with the National Center for Complementary and Alternative Medicine, we have established a cancer advisory panel for the National Cancer Institute. This panel, which meets three times a year, includes members from the conventional and the CAM cancer research community. This panel will help advise the NCI's Office of Complementary and Alternative Medicine run by Dr. White, on how best to evaluate CAM therapies, how to develop accurate CAM information for the public. We are also working with the National Center for Complementary and Alternative Medicine and other NIH institutes to establish centers for CAM research across the United States.

I would like to mention a few examples of the NCI's commitment to complementary and alternative approaches in cancer research. As Chairman Burton mentioned, for many years, the NCI has had a program evaluating natural products for anti-cancer activity. One of these products, Taxol, which is found in the bark of the Pacific yew tree, has been shown to improve survival significantly for women with breast, ovarian cancer. We have extended our study of natural products from plants to marine products. We are currently evaluating another natural product, shark cartilage, among patients with breast and lung cancer. We have evaluated chrono-biology, the delivery of chemotherapy timed to a person's circadian rhythms, in women with uterine cancer. We funded an important study conducted at the Harvard Medical School and published last week in the New England Journal of Medicine, which showed that new use of alternative medicine was a marker for greater psychosocial distress and worse quality of life in women with newly diagnosed breast cancer. We have started an unconventional innova-

tions program to spur the development of new technology in the diagnosis and treatment of cancer.

We have heard some discussion of the problems of lymphedema today. We have recently opened two phase III trials evaluating the safety of sentinel lymph node biopsy in women with breast cancer. If this is proved safe and efficacious, then we will be able to eliminate the need for axillary lymph node dissection, and spare these women the risk of lymphedema.

We are pleased to cosponsor the workshop described by Dr. Gordon, which opens tomorrow, on the integration of complementary and alternative therapy in cancer care. We look forward to continued interaction with the complementary and alternative medicine community in our efforts to improve prevention, screening, early diagnosis, treatment, and quality of life for women with cancer. I would be happy to answer any questions you might have.

[The prepared statement of Dr. Trimble follows:]

For Release Upon Delivery

THE ROLE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE DETECTION AND TREATMENT OF WOMEN'S CANCERS

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National Cancer Institute
National Institutes of Health
Department of Health and Human Services

Hearing before the House Committee on Government Reform
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2154 Rayburn House Office Building

Good morning. I am Ted Trimble, M.D Head of the Surgery Section, Division of Cancer Treatment and Diagnosis at the National Cancer Institute (NCI). I am pleased to be here today to talk with you about the NCI and the evaluation of complementary and alternative medicine in women's cancers. We at the National Cancer Institute recognize that this is an important and challenging issue, and we have taken steps to significantly alter our approaches to complementary and alternative medicine.

Our Nation is experiencing real progress against cancer. This is evident in our cancer incidence and death rates, which are declining. Between 1990 and 1996, these rates dropped for all cancers combined and for most of the top 10 cancer sites. After increasing 1.2 percent per year from 1973 to 1990, the incidence rates for all cancers combined declined an average of nearly 1 percent per year between 1990 and 1996. The peak year was 1992; from 1992 to 1996 the rate decreased 2.2 percent per year. This confirms the continued downward trend that was reported to the nation in 1998 for the period 1990 to 1995. The rates declined for most age groups, for both men and women. The overall death rate declined an average of 0.6 percent a year from 1990 to 1996, with the declines greater for men than for women.

Advances in Knowledge

While these declines are encouraging we continue to strive to accelerate and extend our progress so that all population groups may benefit. The National Cancer Institute is steadily building an environment that fosters the convergence of ideas from traditional and alternative approaches to the goal of eradicating cancer. The collective oncology research community has made exciting advances in understanding the biology of cancer and developing new ways to screen, diagnose, treat and prevent cancer.

Angiogenesis

Particularly compelling is new information about the development of blood vessels, or angiogenesis, and the cancer cell's ability to exploit this natural process. A number of angiogenesis inhibitors, which arrest tumor expansion by curtailing the formation of new blood vessels and, subsequently, the delivery of oxygen and nutrients to the tumor site, are undergoing testing in clinical trials. One of the agents set to be evaluated this year in a phase III trial co-sponsored by NCI and the National Center for Complementary and Alternative Medicine (NCCAM) is Neovastat, a preparation of shark cartilage. For many years other preparations of shark cartilage have been available as dietary supplements and have been used widely in the United States and abroad for treatment of cancer. Other anti-angiogenic drugs are under investigation for the treatment of breast and ovarian cancers and NCI continues to support a broad range of research projects addressing angiogenesis inhibition in breast and ovarian cancers, among others.

Cancer Genetics

The remarkable gains made in the area of cancer genetics have continued to direct progress in the screening and treatment of cancer and NCI has developed tools to maximize the benefit of this expanding collection of information. The Cancer Genetics Network is a group of family registries for breast and ovarian, as well as prostate cancers, enabling researchers to have access to information about inheritance patterns in these types of cancer. Researchers sponsored by NCI continue to study the tumor suppressor genes, BRCA1 and BRCA2. Mutations in these are sometimes present in inherited cancers, but not generally in spontaneous tumors or normal tissue. NCI has established the Genetic Annotation Index, a catalog of variations in cancer-related genes; and the Cancer Genome Anatomy Project, which has the goal of indexing all expressed genes in a given type of cancerous cell. To date, this database contains over 15,000 DNA sequences for breast cancer alone, of which more than 350 are novel genes. Also listed are around 600 unique genes in ovarian tissue, 3 of which have been linked to ovarian cancer. This type of information can be used to identify possible targets for molecular approaches to the diagnosis and treatment of cancer. In March, the NCI issued an invitation for applications for cooperative agreements to establish a national network that will have the responsibility for the development, evaluation, and validation of biomarkers: cellular, biochemical, molecular, or genetic alterations by which a normal or abnormal biological can be recognized or monitored. The NCI funds resources to make available breast cancer tissue specimens to researchers to study potential molecular markers.

Molecular Markers

Advances in the identification of molecules unique to or overexpressed in cancerous cells have led to sophisticated new treatments for many types of cancers suffered by women. The cell surface molecule, HER2/neu, was originally valued as a prognostic factor for breast cancer. NCI continues to support clinical trials gauging the usefulness of a new drug, Herceptin, a monoclonal antibody targeting HER2/neu for treatment of both breast and ovarian cancer in conjunction with chemotherapy. In addition HER2/neu is under consideration as a target for a cancer vaccine. Selective Estrogen Response Modulators (SERM) modify the effects of estrogen on breast tissue and have been prescribed as an alternative to hormone replacement therapy in women at high risk for breast cancer. The recent NCI-sponsored Breast Cancer Prevention Trial, which addressed the effectiveness of Tamoxifen in preventing breast cancer in high-risk patients, was stopped due to the obvious benefit to women who received the drug. This year the NCI expects to begin a highly anticipated comparison of Tamoxifen and another SERM, Raloxifene, which was approved for treatment of osteoporosis and has been shown preliminarily to reduce the risk of breast cancer.

CA125 is a molecule produced in normal uterine and ovarian tissue and is elevated in ovarian cancer cells. The NCI is sponsoring an important screening study, the Prostate, Lung, Colorectal, and Ovarian Cancer Trial (PLCO), that is, in part, an evaluation of a variety of techniques, including CA125 testing, for uncovering ovarian cancer.

Studies have revealed that approximately 90% of cervical malignancies are linked to infection with Human Papilloma Virus (HPV). NCI has a new study underway in which researchers are looking for ways to manage the mild cervical abnormalities that sometimes

progress to cervical cancer. The project is designed to evaluate the usefulness of testing for certain types of HPV as a means to differentiate between abnormalities and determine which treatment would be most appropriate. Another important study supported by NCI is currently being conducted in Costa Rica where investigators have screened about 10,000 women to obtain data on the incidence and prevalence of HPV infection and co-factors that increase the risk of cervical cancer. NCI is sponsoring a phase II trail to determine whether or not a carotenoid - rich diet can be effective in reversing mild cervical lesions. Changes in HPV status will be concurrently monitored. In addition, scientists at NCI are leading the development and testing of two promising HPV vaccines: one that could prevent new infection with HPV and another that would treat existing HPV. Vaccines against HPV could be instrumental in significantly decreasing cervical cancer incidence.

Tumor vaccines, which may encourage the immune system to recognize cancer cells, may help the body reject tumors and also help prevent cancer from recurring. Vaccine therapy in the treatment of women's cancers is an area of intense research activity. NCI is supporting clinical trials investigating the safety and effectiveness of several different types of vaccine-based approaches for the treatment of breast, ovarian, and endometrial cancers, as well as cervical cancer.

Natural Products Research

Since 1955, the NCI has screened samples of plant, marine and microbial origin for activity against cancer, and several clinically effective anticancer drugs, including vincristine, vinblastine, etoposide, topotecan, adriamycin, actinomycin, bleomycin and paclitaxel (taxol), have emerged from this program. Taxol's antitumor activity was discovered in the 1960s during a largescale plant-screening. Interest in developing the drug increased in 1979 after scientists found that Taxol has a unique mechanism for preventing the growth of cancer cells: it affects the fiber-like cell structures called microtubules, which play an important role in cell division and other important cell functions. Taxol has been proven, through intensive NCI-sponsored testing, to be effective in treating both ovarian and breast cancers and NCI is supporting continuing efforts to apply use of Taxol to other types of cancer including many types of pelvic malignancies. Another promising alternative is docetaxel (Taxotere, Registered Trademark), a compound that resembles Taxol in chemical structure. The drug's manufacturer is conducting independent clinical trials and is cooperating with NCI to test its efficacy in treating a variety of cancers including ovarian and cervical cancers.

Since 1986, the NCI's Developmental Therapeutics Branch has performed collections of plants and marine organisms in over 30 countries located in tropical and subtropical countries worldwide. Over 50,000 plant and over 10,000 marine organism samples have been collected through contracts with botanical and marine biological organizations, working in close collaboration with qualified organizations in the source countries. In addition to testing for activity in the NCI anticancer screens, over 110,000 extracts of these samples are available for testing by investigators at other NIH institutes and in the extramural community for activity against the whole spectrum of human diseases, including cancer, AIDS and opportunistic infections, and diseases of concern to the source countries, such as malaria and other parasitic diseases.

Other Treatment Advances

There has been real progress in successful management of cancers occurring in women. Chemotherapy or hormonal therapy administered prior to surgery has improved overall survival for many breast cancer patients. Women with invasive cervical cancer in five different randomized clinical trials benefited from the use of radiation therapy and chemotherapy given together; until now only one or the other was chosen.

NCI continues to support basic and applied research in many areas. We are moving ahead with a number of research efforts that involve the evaluation of CAM approaches to cancer-related problems. NCI, along with NCCAM, is supporting an evaluation of Dr. Nicholas Gonzalez's nutritional therapy at Columbia Presbyterian Medical Center, one of the NCI-designated Comprehensive Cancer Centers. At present, patients are being screened for the study. Another interesting area of potential research activity is the evaluation of green tea as a cancer prevention strategy.

By employing rigorous methodologies to studies in complementary and alternative medicine, NCI has awarded and continues to support many high quality CAM-related research projects. Among the many research efforts underway are projects examining the effects of dietary interventions in cancer treatment, projects examining the therapeutic value of vitamins and minerals in cancer treatment and prevention, studies in stress and pain management to enhance the quality of life for cancer patients, and studies examining the effect of natural inhibitors of carcinogenesis.

Complementary and Alternative Medicine

The NCI is moving very quickly in important directions to develop CAM information and expand research opportunities for CAM investigators. These activities are broad in scope and include strengthening our relationship with the NCCAM, the careful evaluation of CAM therapies, and the development of accurate CAM information for the public.

Recently, Requests for Applications (RFA) have been issued by NCI in conjunction with NCCAM and other Institutes. The intent is to establish Centers for CAM Research that would provide the resources necessary for the rigorous scientific study of CAM approaches, as well as Specialized Research Centers to investigate the biological effects of botanicals, including those that are available as dietary supplements.

We collaborated with NCCAM on the establishment of a Cancer Advisory Panel (CAP-CAM). The CAP-CAM meets 2 to 3 times a year and draws its 15 members from a broad range of experts from the conventional and CAM cancer research community. This group will review and evaluate summaries of evidence for CAM cancer claims submitted by practitioners, make recommendations on whether and how these evaluations should be followed up, and be available to observe and provide advice about studies supported by the NCCAM and NCI, and about communication of the results of those studies. There already are two submissions from the homeopathy community for review and consideration. Rather than have NCI conduct a best case series review independent of the CAM community, the

CAP-CAM will facilitate the joint review of data using this model. We are enthusiastic that this group can work collaboratively in a new partnership between the conventional and CAM cancer research community.

Imaging Research

Medical imaging has experienced astounding advances in the last twenty-five years. X-ray and other techniques allow for the diagnosis of abnormalities of the bones, organs, and other body structures, often before they have caused irreversible damage. Cancers that were once too small to be detected by physical examination can be pinpointed by imaging and treated before they can spread. The early detection of breast cancer by x-ray mammography is an example of the advances made which saves the lives of many women.

Current imaging techniques include more than just the standard x-ray. X-rays can be collected, recorded and analyzed to produce plain images on film or computed tomography (CT) scans. Radioactive materials called tracers, when introduced into the body, seek out a particular organ or structure (such as a tumor) and can yield an image of the organ or structure when special sensing devices detect the decay of the tracer. The responses of tissue exposed to a changing magnetic field can be recorded as magnetic resonance images (MRI). Ultrasound are sound waves of high frequency.which can pass through the body and produce images in real time of rapidly moving or stationary anatomical structures.

As a result of these developments, organs deep within the body can now be biopsied by long, thin needles guided safely to their targets by CT or ultrasound scanning, in many cases eliminating the need for general anesthesia and an open surgical procedure. Adaptations of MRI permit the refined visualization even of the arteries of major organs without the need for painful and potentially hazardous injection of contrast material into these vessels. The biggest impact that imaging research has had on women's health has been through the development of mammography.

Mammography

After skin cancer, breast cancer is the most frequently diagnosed cancer in women in the United States. It is second only to lung cancer in cancer-related deaths. It is projected that approximately 175,000 new cases of breast cancer will be diagnosed in 1999, and about 43,300 women are expected to die from the disease this year.[1] A woman's risk for breast cancer increases with age and continues to increase over her lifetime. It is important to understand that most women who get breast cancer have no known risk factors, such as family history of the disease.

Mammography is an imaging process that uses low-dose x-rays to take a picture of the breast. Regular screening mammograms, though not perfect, are the best method available today to detect breast cancer early. Early detection of the disease may allow more treatment

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[1]"Cancer Facts and Figures - 1999", American Cancer Society.

options. For most women, the National Cancer Institute recommends regular screening mammograms every one or two years starting in their forties.

The National Cancer Institute has developed information for doctors to help women who are between 40 and 50 years old decide when to begin having regular mammograms. There are six risk factors that doctors should be aware of that pose a high enough risk to warrant screening for a woman in her forties: previous breast cancer; specific alteration in a breast cancer susceptibility gene such as BRCA1 and BRCA2; a mother, sister, daughter with breast cancer; atypical hyperplasia (a condition where breast cells are both abnormal in appearance and increased in number) on previous breast biopsy; 75 percent dense tissue on mammogram at age 45-49; or, two or more breast biopsies, even if the results are benign. If none of these risk factors are present, three weaker factors still need to be considered: age of menarche; the number of previous biopsies (either zero or one): and, age at their first live birth (the risk for breast cancer for women with no live births is the same as for women who had a child at ages 25-29).

While mammography has had a major influence on women's health in the past twenty-five years, the NCI continues to work on ways to improve imaging methods for cancer detection and diagnosis.

Improving Imaging Methods for Cancer Detection and Diagnosis

The National Cancer Institute (NCI) funds numerous research projects to improve conventional mammography and develop alternative imaging technologies to detect and characterize tumors. For breast cancer screening, high-quality mammography, an X-ray technique to visualize the internal structure of the breast, is the most effective technology presently available. Efforts to improve conventional mammography center on refinements of the technology and quality assurance in the administration and interpretation of the X-ray films. To advance breast imaging, NCI is funding research to reduce the already low radiation dosage; enhance image quality; and develop and evaluate digital mammography as an improvement over the conventional, film-based technique; develop statistical techniques for computer-assisted interpretation of digitized images; and enable long-distance image transmission technology, or teleradiology, for clinical consultations. NCI also funds research on non-X-ray based technologies such as magnetic resonance imaging (MRI), and breast-specific positron emission tomography (PET) to detect the disease.

Digital Mammography

Digital mammography is a computerized technique that captures the image with electronic sensors rather than film, and displays images using an infinite scale of gray tone. This area of research is of great interest. Mammography X-ray films can contain subtle information not easily discernible to the radiologist. Preliminary data indicate that digital mammograms enhance the quality of the image and even magnify the view of specific areas of the breast. This technology is expected to improve the sensitivity of mammography, especially in radiographically "dense" breast tissue, which renders visualization of cancer problematic, and to decrease the radiation dose per mammogram. Digital mammography also will allow advances to occur in computer-aided diagnosis and teleradiology.

NCI funds many studies of this technology, including those of the National Digital Mammography Development Group. This multidisciplinary academic and industrial group is developing and evaluating digital mammography and related technologies such as image processing for improved lesion visualization, computer-aided diagnosis for enhanced image interpretation, and telemammography (electronic image transmission providing access to specialized clinical experts at remote sites). Currently, this group is testing the potential of digital mammography to serve as the next generation screening technology. NCI has also just released 2 new Program Announcements to alert the investigator community and the small business community to the need for and NCI interest in a concerted effort to overcome the problems of display for digital mammograms.

Novel Non-Ionizing Radiation (Non-X Ray) Imaging

Scientists are exploring novel non-ionizing imaging technologies including MRI, ultrasound, optical imaging, and other technologies. The NCI-funded studies encompass basic technology and instrumentation development through pre-clinical and clinical testing. There are currently 41 NCI-funded projects that aim to define the precise role of these technologies in detecting and characterizing breast tumors.

MRI, Ultrasound and Optical Technologies

Of novel non-ionizing technologies, MRI and ultrasound have been the most studied as ways to improve the sensitivity of breast cancer detection and staging. Both have shown potential for improving differentiation between benign and malignant lesions and in detecting tumors in dense breast tissue. Furthermore, MRI appears unique in its ability to define local anatomic tumor extent, or staging, critical for treatment planning. NCI funds a Cooperative Group of 14 medical centers that is evaluating the use of MRI to improve diagnosis of breast abnormalities. Preliminary results are encouraging, and the Cooperative Group has begun to study the value of MRI in screening for early breast cancer in women at high risk, such as those with a strong family history, or who carry the BRCA1 or BRCA2 genes. The Group is now in the process of expanding the study to include women who received radiation for treatment of Hodgkins disease. Such women are at high risk for developing breast cancer several years after their therapy for Hodgkins disease.

MRI and ultrasound have their limitations, too. One disadvantage of MRI is its requirement for the use of injected contrast material. NCI is funding some projects to study MRI techniques that will enhance the natural tissue contrast between normal and abnormal tissue. Advances in such techniques could lead to cancer detection without injecting contrast material. NCI funds a Cooperative Group of eight centers exploring the value of magnetic resonance spectroscopy (MRS) in four different cancers, one of which is breast cancer. Another property of tissue which physicians have used for centuries is the difference in hardness of normal and cancerous tissue, measured now by palpation. An equivalent method for "palpating" tumors deep in tissue is to measure the tissue elastography (compressibility). This can be done with either MRI or ultrasound, and NCI funds projects evaluating both approaches.

About half of cancers detected by mammography appear as a cluster of microcalcifications. Ultrasound does not consistently detect microcalcifications, nor can it detect very small tumors. Another limitation of ultrasound is that is not an automated, reproducible procedure. NCI is funding two research projects on two different techniques that detect calcifications by ultrasound. Several NCI-funded projects are improving the ability of ultrasound to detect very small cancers, and one project supports the development of an ultrasound device that produces images similar to a computed tomography scan, thus automating the procedure. Progress in all of these areas may come together to make ultrasound an alternative to mammography for breast cancer screening.

Recent technical advances in fiberoptic and laser technologies make optical imaging an exciting new area of potential for early cancer detection. NCI is funding eight projects exploring the use of optical techniques to improve breast cancer detection. Optical signals carry very specific information about the biochemical makeup of the tissue, but localization in space is not as good as with MRI or ultrasound. Therefore, some NCI-funded researchers are developing devices that combine optical techniques with ultrasound, for example, to combine the strengths of both approaches.

Optical technologies also show considerable potential for a variety of other tumors, most notably cancers of the cervix or ovary. Optical detection, diagnosis, and subsequent therapy of early cervical cancer are possible at a single visit, thus eliminating some of the problems associated with PAP smears. Optical technologies applied to the detection of ovarian cancer may bring some progress to this difficult medical problem which has eluded early detection despite advances in so many other areas.

Breast Biopsies

Imaging is also being tested as an aid in performing biopsies. The majority of women in the United States (80 percent) who undergo surgical breast biopsies do not have cancer. As an alternative to surgical tissue removal, image-guided, needle breast biopsy is being studied for women with non-palpable lesions. (Women who have large, palpable lesions usually undergo needle aspirations to determine if their lesions are fluid-filled benign cysts). Image-guided needle biopsy offers the potential advantages of minimized tissue damage, reduced waiting time until diagnosis, and cost savings. A multi-institutional research program is now testing the efficacy and cost-effectiveness of the large-core and fine-needle biopsies compared with more extensive surgical biopsies. (See attached list).

Other Areas of Study

In addition to research on imaging technologies, other research is developing methods to detect products of breast cancer (antigens) in blood, urine, or nipple aspirates, and to detect genetic alterations in women who are at increased risk for breast cancer. Once cancer is diagnosed, studies of these types contribute to characterization of breast tumors and can be useful in treatment planning. Still other NCI-funded projects seek to increase the utilization of mammography among women in age groups for which mammography has proven benefit. An emphasis is increasing utilization among minority and medically underserved women.

Unconventional Innovations Program

In addition to current imaging research being planned the NCI recently created an Unconventional Innovations Programs (UIP) to spur development of daring technologic improvements in cancer treatment and detection in the 21st century. The five year, $48 million program seeks to stimulate development of radically new technologies in cancer care that can transform what is now impossible into the realm of the possible for detecting, diagnosing and intervening in cancer at its earliest stages of development.

Envisioned are futuristic technologies that may sound like Star Wars medicine, but which are grounded in scientists' rapidly evolving grasp of how alterations in the molecules within our cells may lead to cancer. These technologies would enable physicians to scan the human body for molecular changes that foreshadow disease and, once detected, to intervene with minimally invasive procedures, including some that may seem like science fiction - such as injectable miniature robotic devices (nanorobots) capable of killing tumors or "smart" polymers that both detect cancer and deliver drugs.

To aid in identifying technology opportunities that could contribute to the stated goal and fundamentally change the way we detect, diagnose, and treat cancer, the NCI solicited input from the scientific community in the fall of 1998 in the form of white papers. Ideas and information submitted by investigators have contributed to the definition of scope for a Broad Agency Announcement (BAA) solicitation of contracts for the development of "Novel Technologies for Noninvasive Detection Diagnosis and Treatment of Cancer." Proposals were due April 15, 1999, and we are planning to make contract awards by September 1999.

The UIP will take a new management approach to the development of technology that will target quantum improvements in existing technologies or entirely new approaches, rather than incremental improvements to the state of the art. UIP management will actively recruit the interest and involvement of investigators from disciplines that have not traditionally received support from the NCI in taking on the defined technology challenge.

Survivorship

Although cancer remains among the worst fears of Americans, it is becoming increasingly clear that cancer is not the "death sentence" it once was. More than 8 million Americans alive today have a history of cancer. The past ten years have seen an explosion of new and effective treatments for cancer. The emergence of these treatments has enabled some researchers to turn their attention to developing treatments that are well-tolerated and effective, and to interventions that will help ameliorate the worst side effects of the treatment and the disease. Measurement of a patient's quality of life now is included routinely as a component of most NCI-supported clinical trials. Some of NCI's primary quality of life activities and research areas cover several areas.

Supportive Care

The side effects of cancer treatment can not only severely impair a patient's quality of life, but may also leave the patient unable or unwilling to continue with a recommended treatment regimen. NCI continues to pioneer studies on pain relief, fatigue intervention, and the alleviation of other problems that accompany a cancer's progression.

Access to Clinical Trials

NCI believes that clinical trials offer excellent, state-of-the-art treatments for cancer patients and should be accessible to any patient diagnosed with cancer.

Rehabilitation

Even when someone is successfully treated, effects of their disease may remain. Ongoing NCI-supported rehabilitation studies include research on a variety of interventions to aid in more normal functioning.

End of Life

Despite our advances, more than 1,500 Americans die each day from cancer. NCI is actively studying end-of-life issues. In addition to ongoing research in this area, NCI, in conjunction with several offices and other institutes at the NIH, is now currently soliciting proposals for research on ways to ease the final days of cancer patients who can no longer withstand treatment.

Long-Term Survivorship

As more people survive cancer longer, the needs of long-term survivors are gaining increased attention. Because recovering from cancer and living as a cancer survivor are new challenges, the National Cancer Institute (NCI) has established the Office of Cancer Survivorship (OCS) to explore the physical, psychological, and economic well-being of individuals who are cancer survivors. The OCS will support research covering the entire spectrum of issues facing cancer survivors. Areas in which there is opportunity for progress include:

long-term medical and psychosocial effects of cancer treatment;
factors that predispose survivors to second malignancies;
reproductive problems following cancer treatment;
insurance and employment issues unique to cancer survivors.

Information Resources

Communicating with cancer patients, individuals at high risk for cancer, the general public, and the health care community is a central component of NCI's mission and mandate.

Our programs are based upon needs identified through epidemiologic studies and market research among specific population groups, resulting in programs that are relevant and understandable to each group. Our patient education program, leadership initiatives for special populations, and minority research networks are all actively involved in spreading state-of-the-art information about cancer prevention, detection, diagnosis, treatment, and care.

Public Information about CAM

Of considerable importance to all of us is the public availability of accurate, up-to-date information about CAM therapies. NCI has taken steps to assure that this information receives the same consideration as conventional approaches in our evaluation and dissemination efforts.

Detailed CAM summaries are being prepared for cancer therapies identified by our Cancer Information Service and the NCCAM Clearinghouse as being of public interest. The development of these summaries will follow the same model as those for conventional therapies and include specific trial results and references to the published literature. They will be reviewed by the appropriate Physicians Data Query (PDQ) Editorial Board depending on whether the intervention is for the treatment or prevention of cancer or used as a supportive care intervention. In addition, these summaries will be sent to experts in the CAM community for review and comment before they are made available on the NCI web site. Reviews are in progress for shark cartilage and hydrazine sulfate; summaries for laetrile, Essaic, and antineoplastons will be drafted in the near future.

Several months ago, as a result of our own concerns and the constructive input from the CAM community, we removed from the NCI web site all previous CAM information and are creating new information that treats CAM dispassionately and fairly. We are in the process of completely rewriting all the NCI fact sheets that deal with CAM, with hydrazine sulfate and antineoplastons being the first therapies newly available on the web site.

We have established a lecture in CAM at the NCI as part of the medical grand rounds series in our Division of Clinical Sciences and open to all members of the NIH community interested in CAM approaches. The first CAM lecture will be presented by Dr. John Potter on July 20, 1999. The NCI has also initiated a Cancer Complementary and Alternative Medicine Research Interest Group. Dr. Eloy Rodriguez of Cornell University gave the first lecture in this series on April 2, 1999.

The primary avenues NCI uses to communicate with the public and the health care community are:

World Wide Web (http://www.nci.nih.gov): Currently NCI is redesigning its web site to increase its usefulness as a communication tool. The new web site will be organized so that clinicians, researchers, and the public can quickly and easily locate up-to-the-minute information that is relevant to their needs. A new addition to NCI's Web site is the CancerTrials site (http://www.cancertrials.nci.nih.gov). Through this site, patients, health care

professionals, and the public can learn about ongoing NCI-sponsored trials, read about the most recent advances in cancer therapy, and explore other information resources related to cancer treatment. This web site was used by many patients and others who wanted information about treatment advances publicized over the past several months.

Cancer Information Service: The CIS provides accurate, up to date cancer information to patients and their families, the public, and health care professionals in every state through 19 offices located at NCI-funded Cancer Centers and other health care institutions. By dialing 1-800-4-CANCER, callers are automatically connected, free of charge, to the office serving their region. Information on specific cancer types, state-of-the-art care, clinical trials, and resources such as support groups or screening and smoking cessation programs is provided in English or Spanish by specialists who respond to more than 600,000 inquiries annually. The CIS regional offices are NCI's focal point for state and local cancer education efforts that target underserved, high risk, and low literacy populations. Thousands of patients and others called the CIS to get more information about recent treatment advances that were in the news. The system is experiencing a higher busy signal rate that NCI wishes and efforts are being made to address that problem.

Physician Data Query (PDQ): Patients and health care professionals want and need access to accurate, up-to-date, comprehensive information about ongoing clinical trials. Through PDQ, NCI provides information about NCI-sponsored trials. We are in the process of expanding the database, with the cooperation of patient advocates, the Food and Drug Administration, and the pharmaceutical industry, to include all cancer clinical trials approved by the FDA and to revamp the way information is presented. This system has served as a model for other institutes at the National Institutes of Health, and we want to ensure that it continues to be responsive to the needs of the communities we serve.

Medical choices are increasingly made on an individual basis, requiring that physicians and their patients have access to the resources needed to make an informed decision about their treatment and care. Communicating the importance of research findings to physicians and patients in a clear and understandable manner is central to making critical decisions about a patient's treatment and care. NCI is committed to improving public understanding of emerging science and will continue to work with its public and private partners to raise public awareness of key issues in the treatment and prevention of cancer. NCI will work with its partners to provide the public with accurate, useful, and timely information for physicians, cancer patients and their families.

I will be happy to answer any questions.

Mr. BURTON. Thank you, Dr. Trimble. Let me start with you. I am not sure I understood exactly what you just said about the lymph nodes. Is there a non-invasive way to check the lymph nodes? Is that what you are saying? So you don't have to remove them? So that you would not run the risk of lymphedema?

Dr. TRIMBLE. What has been shown in smaller studies is that by the use of either a dye or a radioactive material, one can find the one or two lymph nodes to which the cancer drains. Those lymph nodes are removed and then examined microscopically. If those lymph nodes are not involved by cancer, then that person does not need a full axillary lymph node dissection. So that's the theory that supports our trial, in which half the people would get a full lymph node dissection, and the other——

Mr. BURTON. Let me just ask you, in some cases, they don't take out all the lymph nodes. They just take out some of them. If they take out some of the lymph nodes, don't people run the risk of getting lymphedema, even though they haven't taken them all?

Dr. TRIMBLE. Well, the risk of—you are correct. There is a risk of lymphedema with only removing some. But in, let's say when a full axillary lymphedectomy is performed, then 20 to 30 lymph nodes may be removed. Whereas in the new sentinel lymph node procedure, only one or two lymph nodes are removed. So the incidence of lymphedema following that sentinel node procedure is almost nothing.

Mr. BURTON. I see. OK. So instead of taking out 20 or 25 and then finding 5 that had cancer cells in them, you would just take out those that you were able to pinpoint through the radiation?

Dr. TRIMBLE. Right. Pinpoint that those are the ones that are closest to the cancer. That is where the lymph fluid would drain from that tumor.

Mr. BURTON. I see. OK. All right.

Dr. Beilin, you and I talked before the hearing. We were talking about other forms of cancer, such as prostate cancer. You told me that in Europe, they are using a new technology that would eliminate, in many cases, the need for, let's say, in prostate cancer, the prostate to be removed. You could just attack the cancer and part of the prostate. Is that correct?

Dr. BEILIN. Well, I hesitate to say eliminate the need for it, because every case is individual, and I think that we need a lot more research to be done. But currently there are a number of hyperthermia devices, one in particular is made in Spain, that is going through FDA review right now to be brought over. That involves a penetrating radio frequency hyperthermia that heats tissue beneath the surface of the skin that specifically could be directed toward tumor. There is fair science behind it. So there is a stack of literature that is available privately now, because it's being FDA reviewed by the company. That's just all I know about it.

Mr. BURTON. How long has that been used in Europe?

Dr. BEILIN. It's about 6-year-old technology that's now getting to be big in Europe.

Mr. BURTON. If it's 6 years in Europe, they must have records on this.

Dr. BEILIN. Yes, they do.

Mr. BURTON. Well, does the FDA here in the United States ever solicit those records, or do they just start all over from scratch?

Dr. BEILIN. That is a very interesting question. My impression with working with the FDA that I have done with the regulation thermography is that they look at most cases as new, and that they do not ask for studies that have been done in foreign countries such as Germany, Switzerland, countries that have the integrity of medicine that we do here. There are countries that are developed in the Western world just like ours, and I think that there should be some kind of movement to accept or at least be interested in the review of previous research that's been done abroad with such things as diagnostic early screening equipment.

Mrs. Mack, who spoke earlier, she said she did an early detection by palpation, by just feeling. Well, the tumor, when it is 1 centimeter in diameter is already multi-celled with thousands of cancer cells. That is not really early detection. We are talking about recognizing patterns of disarray and the control of tissue 5 years before it would be visable by other methods. So I think we need a little bit of creative expansion in our paradigm.

Mr. BURTON. Let me ask you about our paradigm. So there are two examples of where the FDA is looking at new technologies that have been used in Europe from anywhere from 6 to 10 years.

Dr. BEILIN. From 6 to 15 years.

Mr. BURTON. From 6 to 15 years.

Now you are here from the FDA, are you not? Do we have anybody here from the FDA today? You are from the FDA? Could you come up to the table, please? Are you prepared to answer any questions? You are only here to monitor the hearing?

Well, I will give you a question. We have been told in the last 24 hours of two cases, one involving the instrument involving hyperthermia, and the other instrument we're talking about as far as early detection is concerned, even before it's readily apparent through mammography or through physical testing, that these have been used in Europe for 15 years in one case, and 6 years in another, and they have not yet been approved by the FDA, and they could be a real adjunct to our therapies and research here in the United States and early detection. I would like for you to have the head of the FDA give me a written reason on why they are dragging their feet on these two things. OK? I would like to have that as quickly as possible.

Dr. BEILIN. Mr. Chairman, if I may add that recently, the FDA has made some changes that are actually positive in that they have granted new areas of possible registration of instruments, diagnostics and treatment that has allowed for marketing approvals more readily than they used to. So at the same time, they may seem slow to acknowledge technologies that have existed with good data, they are also moving in the right direction, from what I can tell.

Mr. BURTON. Well, I'm glad to hear that, but we still have technologies that could really, really help, at least from every appearance that I have seen, that they are still dragging their feet on. I just hate to see any bureaucracy get in the way of progress that is going to help save lives.

Ms. Silver, let me just ask you one question, and I'll yield to my colleague. In your statement, and I am trying to recall exactly how you put it, but you indicated that if there's new treatments or new things that people could take who have an illness that's very severe, they should be able to go ahead and take it even though there hasn't been approval yet if their life is at risk. Did I understand you correctly?

Ms. SILVER. I was referring to the complementary and alternative modalities that we practice in our center. In other words, those have not been proven, by and large. But they have not been disproven. That is to say that no one has suggested or proven that those modalities cause harm or are not efficacious. They have simply not been studied. So for that reason, we ask the question should we withhold those modalities, knowing as we do anecdotally that they can be effective with patients.

Mr. BURTON. And your answer is what?

Ms. SILVER. Our answer is we don't want to withhold those modalities.

Mr. BURTON. And you do go ahead and use them at the current time?

Ms. SILVER. We do use them.

Mr. BURTON. Are you having trouble with the FDA because you do that?

Ms. SILVER. No, no. These are non-invasive, apart from acupuncture, but the other modalities are non-invasive modalities. Many of them are mind body techniques that people can use routinely. So there is no oversight, as it were, because these are not drugs and they are not invasive procedures. But we also don't want to hold out false hope. We don't want to claim that any of these things is effective. We certainly don't claim that we cure cancer. We do say though that we can change the quality of life of a patient with some of these modalities, and our patients agree that their quality of life has been improved.

Mr. BURTON. Do you have some questions?

Ms. CHENOWETH. Mr. Chairman, I just want to thank you so much, for your continuing work in this area and your leadership nationally in this area. It is so very important to us in looking at American health and the role of Government in helping the American people stay healthy and to help them have access to the resources that help them stay ahead of the fight before the disease catches up with them.

I experienced a very difficult passing of my own mother through radical, as a result of radical surgery because of cancer. So I have strong feelings about this, and am very grateful to you, Mr. Chairman, and to your witnesses. I think that we in this committee need to focus, as you are doing, on helping Government get out of the way. You know, first do no harm is not only a good motto for physicians, but also for legislators. I am afraid that some of our policies that we have implemented have caused harm to the individual in not being able to take control of their life. I am concerned that whenever we try to help, we end up interfering and making the lives of our constituents harder. That is simply unacceptable.

Too often, access to public treatments is cutoff because the Federal Government is unsure of its safety. But to people with termi-

nal or potentially terminal illnesses, this seems to be a cruel joke, as it was in the case of my family. I think we need, as you have begun, to seriously question the role of Government in relating to certain institutions that may either help or prevent access to either new treatments or to education and information that will help us prevent disease. So thank you very, very much, Mr. Chairman for this hearing.

I want to ask Dr. Trimble, could you explain to me what circadian rhythms are?

Dr. TRIMBLE. Well, circadian rhythms——

Ms. CHENOWETH. In relation to a patient receiving chemotherapy.

Dr. TRIMBLE. Right. Circadian rhythms refer to any of the natural rhythms, whether that is day and night or the seasons and how they affect a person's physiology and the functions of their body.

In this case, we have some preliminary research suggesting that you could decrease the toxicity of chemotherapy if you gave one of the medicines, doxorubicin, at 6 a.m., and the other one, Cisplatin, at 6 p.m. So in a small study, it seemed as though there was less damage to the nerves and less damage to the bone marrow if you staggered the chemotherapy that way.

The NCI sponsored a large study in which half the women received their chemotherapy at any old time, whenever it was ready, prepared by the pharmacy. The other half got it at 6 a.m., and 6 p.m. Then they looked to see whether there was any difference in the toxicity and damage to nerves or to bone marrow. Unfortunately, in the larger study, there was no difference between the two. But we did think it was an important question and we are continuing to look and see how we can decease the toxicity of our therapies.

Ms. CHENOWETH. You know, Dr. Trimble, American women and probably women in most of the Western countries, subject themselves to some unpleasantries, mammograms, pap smears. We are careful about self-examination for breast cancer. With 14,500 deaths from ovarian cancer though in 1999, I am deeply concerned that there is no early detection program for this type of cancer. Seventy-five percent of ovarian cancers are not detected until the later stages of disease. So I wanted to ask you, what is the National Cancer Institute doing to help women be able to detect ovarian cancer before it reaches the critical stages?

Dr. TRIMBLE. Well this is obviously an extremely important area that we have been working on for some time. We are making a number of efforts to try to improve screening and early detection of ovarian cancer. We are funding a very large trial, the PLCO trial, involving 73,000 women and 73,000 men. The women are being, half of them are being screened with ultrasound and a blood test, CON–25 blood test, for ovarian cancer. So that is a test of the best available technology that we have, versus standard medical care.

We are also trying to develop some new tests. We have announced an initiative called the Early Detection Research Network, which is an opportunity for us to encourage laboratory research and clinical research into coming up with new tests, new screening tests for a variety of cancers. I know for this particular initiative,

there are seven laboratories in the United States which specialize in ovarian cancer that have put together an application just to focus on detecting earlier tests in ovarian cancer.

In addition, the NCI is committed to funding what is called a SPORE or potentially more than one SPORE in ovarian cancer. We have a SPORE, which stands for Special Program of Research Excellence, in breast cancer and colon cancer, prostate cancer. It has been a very successful program. It is designed to bring research from the bench to the bedside. Nine centers have applied for that program. Those applications will be reviewed at the end of this month.

So between these three initiatives, we think we are putting a lot of time and attention and money into trying to find a better screening. But you are absolutely right. We need a better screening.

Ms. CHENOWETH. Thank you, Dr. Trimble. I see that my time is up, but I had some questions for Dr. Beilin. So with the chairman's permission, I would like to submit them in writing.

Mr. BURTON. No, you can ask the questions. If you would just yield to me though, I have a question that I would like to add and then I will let you proceed. Will you yield to me?

Ms. CHENOWETH. We're on.

Mr. BURTON. Dr. Beilin, this device that they have used in Europe for 15 years that you demonstrated with your slides earlier, would it detect something like ovarian cancer?

Dr. BEILIN. In some cases. You know, there's no device that is going to be 100 percent or even maybe 80 percent, but there are cases that have been found when they haven't been found in any other way. We send them in. We refer them to radiology or to ultrasound, and do CA–125, the normal blood tests. So we are able to in a small percentage, reveal more than would have normally in other ways been revealed.

Mr. BURTON. I presume it is the same for prostate cancer or cervical cancer, or any other kind of cancer?

Dr. BEILIN. There are more cases found, but it's not a system that in any way could be used 100 percent of the time. That's just not the way to think about these things.

Mr. BURTON. But it would be a good adjunct?

Dr. BEILIN. It would be a great adjunct, and the cost is very little. The machines are costing less than $15,000, which is about a tenth of any of the other medical scanning or radiological devices.

Mr. BURTON. Dr. Trimble, I don't want to put you on the spot or the people over at NCI on the spot, but I can't understand why at FDA there's new technologies that have been used for 15 years with some modicum of success, a modicum of success in Europe, that have not been approved by FDA that could help you in detecting early cancer in places like my colleague was just talking about, cervical cancer and ovarian cancer. It seems to me that the bureaucracy isn't working together and there's no communication back and forth.

I mean if this has been going on for 15 years, even if it would only help one-tenth of 1 percent of the women who have ovarian cancer, it is something that should be looked at. Does your agency ever talk to FDA or look at these things that are going on in Europe and elsewhere?

Dr. TRIMBLE. Well, we have very close relations with the FDA, particularly in the areas of chemotherapeutic drugs. We have worked closely with them to design really international systems for monitoring toxicity of drugs and response to chemotherapy, in part so that as products are developed in Europe, we might be able to use that data to submit it to the FDA for approval, so we would not have delays waiting for data to come in on patients in the United States.

Mr. BURTON. Have you ever heard of this machine before that's been used in Europe?

Dr. TRIMBLE. I work in the division of cancer treatment, so we have been focused on treatment. We have opened several new initiatives in imaging, one for unconventional imaging. We have also recently funded the American College of Radiology to set up an imaging network to evaluate new imaging in the treatment of cancers. I met yesterday with Dr. Beilin to discuss how this particular technology could be integrated into our research portfolio.

Mr. BURTON. As well as the other technology he was talking about, the heat device? You talked to him about that as well?

Dr. TRIMBLE. No. I did not talk to him about that yesterday, but we would be happy to talk with him.

Mr. BURTON. I wish you would, because it sounds like it's very promising, and it's been used for 6 years in Europe and it's not moving very fast through FDA.

Can I make a request, and if you would write this down I would really appreciate it. I would like to request that the NCI provide a list to our committee of the cancer treatments, including drugs, devices, and other therapies that are available in Europe and Canada that are not available in the United States. The reason I am asking for that is because I have a feeling that you, and I'm sure you are very dedicated scientists as well as your colleague back there, but I have a feeling because there is so much on your plate right now, a lot of these things that are happening in other parts of the world that may have been going on for some time, may not have been really explored. As a result, some of those things, may be a good idea that might help us.

I can remember after World War II, we were bringing all the rocket scientists over here from Germany, many of whom should have been strung up, to help us with our rocket program because they were so far advanced and so far ahead of us. I would just like to know if you could give us a list of all these drugs, devices, and other therapies that are available in Canada and Europe that are not available here, because if we get that list, then we can start seeing what might be helpful. Then we can talk to you about those.

This is not in any way to denigrate the work you are doing. It is just to say that there might be some adjuncts out there that could be helpful to you.

Dr. BEILIN. Mr. Chairman, if I might ask the question of Dr. Trimble.

Mr. BURTON. Sure.

Dr. BEILIN. What is the status of mistletoe, because mistletoe therapy is being used in many oncology clinics in Europe? From what I understand, is that our drug companies here are trying to recreate a patentable mistletoe to be used as chemotherapy, but

without the original mistletoe therapy with the research results that they have gotten being acceptable by FDA.

Mr. BURTON. Before you answer that question, Dr. Trimble, this is one of the things that really bothers a number of people in Congress, because many people in Congress, including myself, suspect that some of the pharmaceutical companies have undue influence at the Food and Drug Administration and some of our National Health Institutions. I hope that's not the case, but we have that concern. When we hear things like what he just mentioned, that there is a therapy or a substance that is being used like mistletoe in Europe to help in areas like chemotherapy, and instead of using that or exploring what Europeans have done, which is very cost-effective and inexpensive, we have got the pharmaceutical companies trying to come up with something that is patentable from some synthetic property, some synthetic thing. The FDA then tests it, runs it through, they get a 6, 7, 8, or 9 year patent—I don't know how long the patents run on those things—so that they can make money. Who suffers? The patients do when there might be something much less expensive that's on the market over in Europe. Those are things that really bother people in this country.

Anyway, go ahead. I'll let you answer.

Dr. TRIMBLE. Well first, I'll take a pass on the mistletoe because I do not know anything about it. We will get back to you. But that is not an area that I have studied.

Mr. BURTON. OK. Well that would fall under the category of all the questions I just asked.

Dr. TRIMBLE. Yes. No, I can comment or I would like to comment on our interaction with our colleagues in Europe and elsewhere. The National Cancer Institute has made a sincere effort to exchange information with colleagues from around the world. We sponsor a meeting in conjunction with the European Organization for Research and Treatment of Cancer every 2 years, to discuss new drug development. We have regular meetings with colleagues in Japan. We also have been strengthening the ties between our clinical researchers in this country, those in Canada, and those in Europe.

Approximately 3 weeks ago, at the national meeting of the American Society for Clinical Oncology in Atlanta, I participated in a meeting to discuss trials in ovarian, cervical, and uterine cancers with representatives from Australia, Scotland, England, Norway, Sweden, Germany, Austria, and Italy. This is something that is happening in many other cancer sites as well. So we are definitely trying to find out what is going on elsewhere around the world, and make sure that people in the United States have access to the best ideas, wherever they are from.

Mr. BURTON. Dr. White, I understand that you may know something about the question that was asked about mistletoe?

Dr. WHITE. Yes. I can tell you a little bit about what we have done in this area. As you probably know, the National Center for Complementary and Alternative Medicine has 10 or I guess now 13 centers that it funds for various different diseases. It has a cancer center at the University of Texas, Houston, which we, NCI, co-funds with the NCCAM. That center is actually doing a phase I study of mistletoe in advanced esophageal cancer. They also have

done a variety of pre-clinical studies with other herbal approaches that are used outside the United States predominantly.

There are a variety of different preparations of mistletoe that are used in Europe and in Australia and various places. This is using one of those five or six that are available.

Mr. BURTON. How long has it been used in Europe, do you know?

Dr. WHITE. I don't know when it first started. The last randomized clinical trial that I am aware of that was done in Europe was published in 1988.

Mr. BURTON. 1988?

Dr. WHITE. Yes.

Mr. BURTON. That was 11 years ago. And we haven't gone through the studies yet on it here in the United States?

Dr. WHITE. Well, there has not been a study done in the United States, that I am aware of. But the review of that material, as I said, has been done at the University of Texas.

Mr. BURTON. You know, I have had cancer in my family. I have had people appear at this table here who have little children who are dying, and there's alternative therapies available to them, and we run into stonewalls with some of the agencies, FDA or others, and even doctors who have used some of these therapies they have tried to put out of business. When we hear of therapies, technologies, or simple products like mistletoe, that's being used in Europe with some effectiveness, and people are dying here, and I have to look at these kids and their parents, or some men that had Hodgkins disease that was going to be terminally ill, and he had to go outside the bounds of what's considered law and order to be treated, it really boggles your mind and bothers you. I just can't understand why we are having this kind of a problem.

If there is a technology or some substance that can be used in Europe and is being used for 10, and you said 11 years ago they were testing this and using it, why is it that the United States, the most advanced country in the history of civilization, is 11 years behind, 15 years behind in this other area, 6 years behind in another area, and when I ask these questions, they say of the FDA, this young lady that's sitting back there, she says, "Well we'll check on it and get back to you." But there really isn't any answer. I just don't understand it.

It seems to me that Dr. Trimble and you, Dr. White, and others, ought to be constantly looking at these alternative therapies along with the Food and Drug Administration, to try to make sure that we are giving the American consumer, the American patient, the very best opportunity to live a healthy life and to survive if they are in big trouble. I know you are trying to do that. But it seems to me that some place the golf club is missing the ball. That is why I asked that question of Dr. Trimble, that we get a list of all the cancer treatments they are using in Canada and Europe, and the devices and the other therapies, so that we can at least look at them and see what the heck is going on over there that we are not doing.

It is really frustrating to me when I hear this kind of stuff. Go ahead.

Dr. WHITE. Yes. I would just like to put a little bit of perspective on the mistletoe issue. I understand the broader scope of what it

is that you are saying, but specifically on mistletoe, the largest clinical trial that I am aware of was a randomized trial with three arms on it, one arm that patients did not receive any supplemental care after their surgery—this is for breast cancer. Another arm received standard chemotherapy, plus or minus radiation therapy for their breast cancer. This is all adjuvant therapy. The third arm received mistletoe.

The mistletoe arm did better than no therapy, but the chemotherapy arm did better than no therapy. The mistletoe arm did no better than chemotherapy. So I think it's not—so we're talking about first of all, adjuvant therapy. So this is not in advanced forms of cancer. Second, it is not something that represented in that study a step above what was already available to the patients.

Mr. BURTON. Dr. Beilin.

Dr. BEILIN. If I may comment that there are statistics being gathered an immunologist and oncologist colleague in Austria for the Germanic countries. They have discovered that statistics seem to be coming out that using chemo plus complementary therapy such as mistletoe together resulting, like in breast cancer, the number is 25 percent less recurrence rates when you use both together. So I think that those kind of statistics need to kind of leap over here so that we can begin to take the best and to integrate them and add them together to have an additive effect. That same statistic came out for prostate and melanoma.

Dr. WHITE. Is that published information?

Dr. BEILIN. I believe so. I can lead you to it.

Dr. WHITE. I would be happy to review that.

Mr. BURTON. Well see, this is the kind of communication that every American would like to see all the time, not just at the table here at a hearing.

So let me just ask two more questions, then I'll yield to my colleague. Then we'll wrap this up, because we have all been here a long, long time. The NCI gets $2.7 billion, $2.7 billion for cancer research. You are spending less than 1 percent of that on alternative therapies. We are hearing things here today that indicate that there are some alternative therapies with promise. I am sure you are going to give me a list of other things that have promise that we're going to get from Europe. Why is it that we only spend $20 million out of $2.7 billion on alternative therapies when half of the Americans who have problems are using and trying to find alternative therapies. It just doesn't make any sense to me. Can you give me an answer to that, Dr. Trimble? Why are we only spending $20 million?

Dr. TRIMBLE. Well, as I know that Mr. Chairman, that you have had some discussions with my director, Dr. Klausner, on this issue. We realize that we need to provide the American public with accurate information on complementary and alternative medicine, and we need to provide them with accurate appraisal of these techniques in terms of whether they work so that people in the United States can decide for themselves whether they wish to avail themselves of various complementary and alternative medicine techniques.

Mr. BURTON. But I think you are making my point. We need to spend more money than just less than 1 percent on that. Wouldn't you agree with that?

Dr. TRIMBLE. Well, I agree that we need to do more research. To that end, we have agreed to co-fund with the other institutes, centers for alternative medicine research across the United States. We are actively soliciting new ideas that we can test at these centers and through with their existing cancer centers. So we hope that we can make more information available and have more and better treatment which combine standard treatment, complementary medicine and alternative medicine for the people of the United States.

Mr. BURTON. Let me yield to my colleague. She has to leave.

Ms. CHENOWETH. Dr. Trimble, could you commit to us how much the National Cancer Institute will dedicate to alternative medicine studies and research?

Dr. TRIMBLE. No. That's above my pay level to make that kind of a commitment. I will commit that we are actively recruiting studies. We have committed to setting up centers to study complementary and alternative medicine. We will continue to forge a joint approach with our colleagues in other medical disciplines in this area.

Ms. CHENOWETH. Mr. Chairman, I wonder as a member of your committee, if I might ask that you would ask whoever is in the pay grade——

Mr. BURTON. Dr. Klausner.

Ms. CHENOWETH. Dr. Klausner, how much? I would like to know as a Congressman.

Mr. BURTON. I think what we ought to do is as the Congress take a look at the amount of money we are appropriating for NCI, and talk to the people on the Appropriations Committee. Maybe since NCI of their own volition isn't going to authorize more money for alternative therapies, maybe we should just specify in the appropriations bill how much you have to spend for that. If we did that, maybe that would break the log jam. But I will try to talk to Dr. Klausner. I want you to make a note that we do that.

I don't have any other questions. Do you have any other questions?

Ms. CHENOWETH. Mr. Chairman, I just wanted to share on the record with you an observation that I have made. You know, we broke all the barriers down when we passed NAFTA and GATT. Now we have the World Trade Organization. We are importing 22 percent of our beef that comes from foreign countries, and we don't know where. They have certainly different standards than we have. Yet we are consuming that beef not knowing that it's coming from foreign countries. Forty percent of our lamb sometimes comes from 7,000 miles away and we don't seem to ask a question about that. You know, we have toys that come from China, and we have hotwheels that come from Malaysia, and we have dog bones that come from Argentina. Nobody seems to worry about that in this whole global economy.

But what about getting information from Europe that we can use on a par the studies and benefit from them? It just seems absolutely incredible to me that we always have to reinvent the wheel when it comes to medicine. Yet in every other arena in this global

economy, but medicine, and freedom from medicine, and freedom from the institutions of the individuals sometimes when we make that choice, is what is sorely lacking.

I am afraid this Congress unfortunately is supporting the institutions and the patients have become a byproduct or just a necessary function for the institutions, instead of the institutions being a necessary function to better healthcare.

So, Mr. Chairman, I would love to work with you on perhaps requiring something in NAFTA or GATT that would mandate that these studies be accepted by FDA on a par.

Mr. BURTON. We'll take a look at it. I will get together with you and we will have Beth look into it, and see if we can't maybe do some of that.

Ms. CHENOWETH. Thank you.

Mr. BURTON. I think that at the very least, those technologies should not languish for 6, 7, 8, 10, 15 years before they are utilized here in the United States.

I was just informed that shark cartilage, for instance, I think Dr. Trimble said they are testing that, 7 years ago they started talking about it and we are just now doing it. So it seems like there is a lot of foot dragging.

Well, I don't have any other questions for you. Thank you, Mr. White. You weren't scheduled to speak, but we do appreciate your coming before us. Dr. Trimble, Dr. Beilin, thank you very much. Ms. Silver, thank you very much. I want to thank you once again for your patience.

We stand adjourned.

[Whereupon, at 3:45 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

ONCOLOGY NURSING SOCIETY

STATEMENT TO THE HOUSE COMMITTEE ON GOVERNMENT REFORM

HEARING ON WOMEN'S CANCERS

JUNE 10, 1999

10:30 AM

THE ONCOLOGY NURSING SOCIETY

Please direct questions to:
Eileen Meier, Health Policy Associate
The Oncology Nursing Society
(202) 408-6894

The Oncology Nursing Society (ONS) is the professional organization of 28,000 nurses dedicated to the care of oncology patients and to further the science of oncology care in the United States. The mission of ONS is to promote excellence in oncology nursing and quality cancer care. We applaud the House Committee on Government Reform for holding this hearing today to examine the role of early detection and treatments in the prevention of women's cancers.

We are gravely concerned about the seemingly lack of emphasis on women's health care and research in the past, and particularly the lack of progress in decreasing the incidence and mortality of certain cancers that affect women. Early detection and successful treatment is possible in a number of women's cancers. But for some women's cancers, there remains much to be done in the area of early detection.

LUNG CANCER

Greater public awareness, better treatment options and improved prevention efforts have assisted in the decline of overall cancer incidence and mortality in the United States. Unfortunately, women with lung cancer have not been included in this revolution. Lung cancer is not usually seen as a "woman's cancer" but it is the leading cancer killer of women in the United States.

The statistics surrounding lung cancer in women is staggering. Lung cancer claims more lives each year than breast and ovarian cancer combined. As early as 1997, lung cancer deaths rather than breast cancer claimed more women's lives, and by the year 2003, twice as many women will die of lung cancer than breast cancer. Between 1974 and 1994, there was a 20% increase in the incidence of lung cancer in men, but during that same time period, the percentage of women diagnosed with breast cancer increased by 147%.

Experts have also recently found that women are more susceptible to lung cancer than men. A 1996 study of tobacco-related lung cancer cases showed that despite the fact that men in the study started smoking earlier, inhaled more deeply and smoked more cigarettes per day than women, women were 1.2 to 1.7 times more likely to develop lung cancer.

There is also a wide gap between the federal government's funding of lung cancer research and its funding for other diseases. In a cost-per-death breakdown, $38,000 was spent per AIDS death, over $10,000 was spent on breast cancer, but only $768 was spent per lung cancer death. Increased research, detection programs and public education on the early warning signs of lung cancer could begin to bring down the alarming death toll of lung cancer in women.

The detection and thus the treatment of lung cancer has remained essentially unchanged for the past thirty years. Only 15% of lung cancer cases are found when the disease is restricted to the lungs, and nearly 80% of all lung cancer cases are detected in the late stages when effective treatment becomes difficult. Early detection is critical to increasing patients' chances for long-term survival and treating this cancer. If caught early, the disease can be curable in about half of all cases.

The earliest symptoms of lung cancer are easily missed. Women at risk for lung cancer need to be aware of early warning signs and alert their health care providers of these signs and symptoms. Early detection can bring a wider range of treatment options and possible better quality of life for these patients. If lung cancer is detected early, surgery, new chemotherapy regimens, monoclonal antibodies, photodynamic therapy, genetic manipulation and vaccines become available for more successful treatment.

EARLY DETECTION MUST BE COUPLED WITH ACCESS TO TREATMENT

Early detection is critical in the successful treatment of women's cancers, but detection must also be coupled with access to treatment. This becomes acutely evident in such programs as the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) administered by the Centers for Disease Control. This program works in partnership with state and local health agencies and with other community partners to provide education, outreach, screening services and follow-up care. The program serves older women, women with low incomes, the uninsured and underinsured and women of racial/ethnic minority groups who qualify.

As enacted by Congress, the NBCCEDP provides only funding for screening services. There is still no funding to provide the treatment services to the 2,342 women under age 65 who have been screened and diagnosed with breast and cervical cancer through this program. The current system for treatment through this program is an ad hoc patchwork of providers, volunteers and local programs who must stretch beyond meager means at times to find treatment dollars. This lack of funding for treatment must be remedied. The time and effort required to arrange for treatment services have begun to divert resources away from screening and detection. As a result, fewer women are being screened.

The Oncology Nursing Society supports and endorses the Breast and Cervical Cancer Treatment Act that would address these exact problems for treatment access. Treatment must be readily available for those who are screened and diagnosed, otherwise, early detection becomes almost meaningless for the unfortunate women who are diagnosed with either breast or cervical cancer in this program.

ADVANCED PRACTICE NURSES & EARLY DETECTION PROGRAMS

Finally, advanced practice nurses, such as nurse practitioners and clinical nurse specialists, manage the daily needs of oncology patients and educate patients. These nurses may be independent practitioners or work in collaboration with other health care providers to manage the ever-increasing number of oncology patients. They work in diverse settings throughout the country and often provide care in rural and medically under-served areas that lack other healthcare providers. Advance practice nurses have been shown to be cost-effective in cancer care, such as in early detection and screening programs.

Advanced practice nurses who specialize in oncology care must be actively utilized in the detection and screening of women for cancer. Oncology nurses have unique education

skills that they can offer women, including low-income and minority women. Programs that utilize advanced practice nurses who specialize in oncology care must be supported and encouraged.

We have touched on only a few issues here. As the Committee on Government Reform examines the issue of women's cancers, we hope that committee members will also carefully explore the issues of genetics and the detection of breast cancer, early detection of ovarian cancer and the specific needs of minority women who are at risk for particular cancers.

The Oncology Nursing Society thanks the House Committee on Government Reform for holding this important hearing. The Oncology Nursing Society looks forward to working with the members of the committee in the future to improve the detection and treatment of women's cancers. Our 28,000 members throughout the United States are available to the House Committee on Government Reform and its staff who have questions or need assistance with oncology-related issues.

Statement of the

American Society of Clinical Pathologists

to the

House Government Reform Committee

regarding
Early Detection of Women's Cancer

June 9, 1999

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The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

While ASCP members are involved in the diagnosis of all types of cancer affecting women, our statement today focuses on cervical cancer detection and prevention.

The Pap Smear Facts

The Pap smear is a proven screening method of detecting and preventing cervical cancer. It is the most effective cancer screening test in medical history as it is largely responsible for the 70% to 80% decline in death due to cervical cancer over the last 50 years in the United States.

Approximately 4,900 women die from cervical cancer annually in this country, making it the tenth leading cause of death from cancer in women. Approximately 14,000 new cases of cervical cancer are diagnosed each year.

The Pap smear is a safe, noninvasive, cost-effective medical procedure. Cells collected from a woman's uterine cervix are sent to a cytopathology laboratory where the cells are evaluated. The cytotechnologist prepares the slide and evaluates the specimen, which is composed of thousands of cells - usually between 30,000 to 200,000 cells in a single specimen. If the specimen is within normal limits, a report is sent to the woman's health care provider. If an abnormality is detected, then a pathologist examines the slide and issues a final diagnosis.

Barriers to Pap Smear Testing

While it is difficult to believe, more women (80%) die of cervical cancer because they have never had a Pap smear or they have not had a Pap smear in the last five years than those that die of a false negative Pap smear. We believe this is unconscionable.

There are many reasons why some women do not have Pap smears, or why Pap smears may be less available to women. Some of these reasons are explored below.

Trained Cytotechnologists Are Needed

The American Society of Clinical Pathologists' Board of Registry, in conjunction with MORPACE International, Detroit, conducts a biennial wage and vacancy survey of 2,500 medical laboratory managers. The survey measures the vacancy rates for 10 medical laboratory positions, and compares and contrasts these data with that from 1988, 1990, 1992, 1994, and 1996 studies. The 1998 data has just been made available, and the information regarding cytotechnologists, the professionals who interpret cellular material such as Pap smears, is of particular interest and concern.

The current vacancy rate for cytotechnologists (staff level) is 10.5%, an increase over the 1996 rate, which was 7.1%. This is the first increase in the

cytotechnologist (staff level) vacancy rate in eight years. It is also important to note that for rural areas, the cytotechnologist (staff level) vacancy rate is 17.6%, and totals 9.7% for small-medium size cities and 12.1% in large cities.

Also, while the vacancy rate for cytotechnologist (staff level) in large hospitals is 8.3%, the vacancy rate nearly doubles for hospitals with a 100-299 bed size - up to 15.8%. Hospitals with bed size of 300-499 reported vacancy rates for these professionals at 14.3%.

Laboratory managers were questioned about the difficulty they have in filling work shifts. 21% reported problems recruiting cytotechnologist (staff level) for day shifts, three times higher than the 8% reporting such difficulties in 1996.

While the overall vacancy rate for cytotechnologist (supervisor) has decreased over the past two years, 10% down from 12.5%, the vacancy rate in small-medium size cities for cytotechnologist (supervisor) is 20.0%. Vacancy rates for cytotechnologist (supervisor), while virtually non-existent in the east north central, west south central, and far west regions of the country, are explosive in the northeast (16.7%), south central atlantic (18.2%), and west north central (12.5%) parts of the nation.

These data show some cause for concern. Cytotechnologists are highly skilled and trained individuals, who must have at least a baccalaureate degree followed by a year of specialized training in cytology. Cytotechnologists must then take a rigorous national certifying examination, administered by the ASCP, in order to become certified. Laboratories rely on certified cytotechnologists to evaluate all Pap smears. With high vacancy rates, there is concern that some laboratories will not have the appropriate personnel available to evaluate Pap smears.

Medicare Reimbursement

Cytopathology smears are currently priced at $7.15 on the Medicare laboratory fee schedule. The actual cost of the conventional Pap smear (excluding new technology and the professional component for physicians) is in the range of $13 to $17. The cost of new liquid-based Pap testing is $28-$32. This price includes cytotechnologist salaries, overhead costs, quality control, laboratory supplies, and supplies given to healthcare providers who obtain the smear. The Medicare payment rate for Pap smears should increase significantly.

ASCP and other organizations are working with the Health Care Financing Administration to increase the Medicare payment rate for Pap smears. In addition, Representative Neil Abercrombie and Representative Mary Bono have recently sponsored legislation, HR 976, to increase the Medicare payment rate to $14.60. ASCP supports this effort to bring attention to the need for the Pap test and a more appropriate payment rate.

Liability

With annual screening, the chance of a woman developing cervical cancer can be reduced to less than 1%. Pap smears have an irreducible false negative rate (10%-40%) due to sampling errors on the part of health care providers and screening errors occurring in laboratories.

According to a March 1997 report in the *Archives of Pathology and Laboratory Medicine*, the continued availability of Pap cancer screening test is threatened by lawsuits because the legal system demands a zero error rate which is mathematically unachievable even in the most competent professional hands.

Socioeconomic Barriers

According to Healthy People 2000, the National Health Promotion and Disease Prevention Objectives, there are several key assumptions that may be used to help overcome barriers to cervical cancer screening. The objectives state, "low income, low education and advancing age are all associated with a decreased likelihood of receiving Pap tests." The report continues that "age influences both cervical cancer incidence and survival. While younger women are more frequently diagnosed with cervical cancer, older women are more often diagnosed at later stages of the disease and are more likely to die from it than younger women." We are also aware that certain populations of women - African American, Hispanic, Asian, and low-income rural women - often face cultural and economic barriers to Pap screening.

For example, it is not uncommon for low-income women of Hispanic descent to refuse Pap testing. Even if the Pap smear is free or of little cost, these women, whose families may rely on them for income and support, refuse the test because they do not want to know if they have cancer. A cancer diagnosis, in this instance, would mean extensive, and often prohibitive, medical costs to treat the cancer, and would tear the women away from their families for extended periods of time. Many women in this situation prefer not to know their potential cancer status. In addition, a lack of culturally appropriate materials or information communicated in Spanish is a barrier to Hispanic women being screened.

In a study compiled by the Centers for Disease and Prevention, it was determined that transportation and its costs were barriers to Pap testing for Native American women.

In speaking with public health officials, we are also aware of examples in certain Asian-American communities where it is considered shameful for women to have a Pap smear. In this culture, husbands may not want their wives to be examined "in that way" by a male physician.

Solutions

The Pap smear, named for its creator Dr. George N. Papanicolaou, is one of the most effective cancer screening tools available to women today. There are ways to lessen the barriers that exist to Pap testing, so that cervical cancer becomes a less formidable disease to women.

ASCP continues to work with the cytology community to provide continuing education and certification for these laboratory professionals. ASCP has also established a scholarship program for medical technology students, including cytotechnologists. The Society awards 100 student scholarships each year to assist with educational finances.

Title VII of the Public Health Service Act (Health Professions Education Partnerships Act of 1998, P.L. 105-392), includes a program for Allied Health Project Grants. This program has been effective in addressing the training and educational needs of allied health personnel, including cytotechnologists. However, further strides in funding are still needed to increase the number of cytotechnologists to an adequate level.

Increasing the Medicare reimbursement for Pap testing to an amount more in line with current costs would also help to attract and retain professionals in the field.

ASCP, along with many other organizations, are working to educate the general public and the priority populations mentioned above about the importance and effectiveness of the Pap smear. We are particularly proud of the efforts we have undertaken to help educate other health care providers about the Pap smear.

ASCP believes it is important to develop and disseminate educational materials to targetted populations and to the health care providers that serve them, and develop relationships with community organizations, such as schools, retailers, employers, social facilities, and churches, to assist in

reaching women that are not participating in cervical cancer screening programs.

We aim to continue these educational efforts, and look forward to working with you and others in the prevention of cervical cancer.

Statement of
Arnauld E. Nicogossian, M.D.
Associate Administrator
Office of Life and Microgravity Sciences and Applications
National Aeronautics and Space Administration

House Committee on Government Reform

June 17, 1999

As a partner in NASA's Human Exploration and Development of Space (HEDS) Enterprise, the Office of Life and Microgravity Sciences and Applications (OLMSA) seeks to increase commercial and scientific knowledge, to develop space for human enterprise, to effectively transfer knowledge and technologies to the private sector, and to improve the quality of life on Earth. As we move towards the utilization of the International Space Station (ISS), new opportunities for conducting research in space will become available to improve and expand knowledge, advance technology and research products in a wide range of disciplines. The experience gained in the past few years has helped us forge new domestic and international alliances both in academia and the commercial sector, as well as further develop our ground-based activities.

NASA's research and technology is not just about distant galaxies, astronauts and super-sonic aircraft. The science and engineering that make NASA's programs possible touch lives every day. This influence is most apparent in the field of medicine where innovative thinking has made it possible to adapt deep space technology to understanding, detecting and treating cancer. NASA's research is designed to learn how to fly higher and faster, and about how to live and work in space. Its application, however, often hits much closer to home.

The importance of innovative thinking is brilliantly demonstrated with NASA's application of Hubble Space Telescope technology in improving the first line of defense against breast cancer: regular mammograms. Who would have thought that the technology used to pinpoint specific stars among the millions in the galaxies could be used to find the tiniest abnormalities in breast tissue? This is not science fiction, but science fact, in your doctor's office today. NASA is reaching out to women and families to let them know how their space and aeronautics tax dollars are being applied right here on Earth-not only in cancer research but in many other areas of particular interest to women.

Much of NASA's research in health and medicine is especially important to women, because many of the troublesome symptoms experienced by astronauts in space flight are similar to conditions that affect many women on Earth, such as osteoporosis. We are very excited about this new initiative on technologies "twice used," once for NASA's principal mission in space and aeronautics, and again, for other purposes in the form of products and services, that directly affects us all. Indeed, NASA's less often stated mission is to improve the quality of life on Earth.

BIOMEDICAL RESEARCH AND COUNTERMEASURES PROGRAM: RESEARCH CONTRIBUTING TO KNOWLEDGE OF BREAST AND OVARIAN CANCER

NASA is providing this testimony to make the committee aware of NASA's ongoing contributions to biomedical research, and in particular, breast and ovarian cancer research. NASA's charter includes the conduct of research in support of protection of the health, safety and well-being of astronauts during spaceflight. Since the NASA astronaut corps includes both men and women, NASA-sponsored research is gender-neutral, addressing important health issues for both women and men related to spaceflight. In the context of that research and technology effort, NASA's Office of Life and Microgravity Sciences (OLMSA) makes significant contributions to the understanding of women's health issues, including breast and ovarian cancer. Some representative research tasks and an abbreviated description of each are listed below.

Special Tasks

- **Biocomputational Center Development of Virtual Surgery Techniques for Breast Surgery** Muriel Ross, Ph.D. The shape of a tumor is one clue to malignancy, with tumors having many tentacles usually being malignant and those that are more spherical in shape often being benign. Tumors larger than 3 cm. (more than an inch in diameter) can now be treated with chemotherapy to shrink the tumor. One of the applications of 3-D imaging technologies is to obtain images before and after chemotherapy to learn the degree of shrinkage of the tumor and to assess its extent. The remaining tumor has to be removed and the patient irradiated, but the patient may get by with a lumpectomy rather than with breast removal. This is called breast conserving therapy, and although the method is still controversial, women would support its use whenever possible since it prevents a more radical surgery, breast removal. Excellent 3D imaging is critical to this application.

- Another application of 3-D imaging is to provide reconstructive surgeons with a template of the breast to be reconstructed. A high fidelity 3-D image can be used, for example, to drive a computer to measure breast dimensions for more accurate matching of breast shape and size for reconstruction following surgery. Computer and imaging technology can then determine the best shape of the skin flap to be used in reconstruction.

- One of the more pressing needs in breast imaging is to be able to determine the precise location of the tumor in the breast, a soft, pliable tissue, no matter the position of the patient. Even during biopsy, the tumor shifts sufficiently due to pressure of the probe so that obtaining a tumor biopsy may require more than one attempt. In the Center for Bioinformatics, a goal is to use finite element analysis together with force-feedback computer devices to develop realistic simulations of tumor movement within the breast during biopsy and during surgery. These can then be applied to patients to improve success with biopsies and during surgery, particularly when the tumor is very small. If only a 10% increase in accuracy of tumor location during biopsy were possible, the savings in cost and in pain to the patient would be worthwhile.

- **Robotic Application for Breast Biopsy,** Ames Research Center, Robert Mah, Ph.D. A NASA-Stanford University team is in the preliminary stages of developing a smart probe that can be used for breast cancer detection and analysis. The probe is designed to "see" a lump; determine by its features if it is cancerous; and then quickly predict how the disease may progress. Researchers say surgeons may be able to insert the computerized tool's needle-like tip into breast lumps to make instant diagnoses and long-term cancer predictions. The instrument may allow health care providers to make expert, accurate diagnoses as well as to suggest proper, individualized treatment, even in remote areas.

Radiation Biology

- **Molecular Damage of Human Cells by X-rays and Neutrons**, Elizabeth K. Balcer-Kubiczek, Ph.D., Dept Radiation Oncology, U of Maryland School of Medicine Conversion of a normal into an abnormal cell is largely a result of change in gene expression patterns between the two cell types. Studies are designed to define cellular transformation in molecular terms by characterizing the altered genetic program induced by exposure to radiation. Antagonists or agonists of radiation-specific gene therapy could be applied in advanced molecular therapies or preventive strategies, such as those being developed for specific human populations at risk due to genetic hereditary factors (e.g., breast or colorectal cancers).

- **HZE and Proton-Induced Microenvironment Remodeling**, Mary H. Barcellos-Hoff, Ph.D., Life Sciences Div., Dept of Radiation Biology, Lawrence Berkeley Laboratory Identification of tissue-specific remodeling will provide fundamental knowledge of radiation effects on selected tissues, generate correlations between events in tissue remodeling, determine which events are tissue-specific or radiation quality dependent, and quantify these events for correlation with radiation fluence or dose.

- **Role of the Microenvironment in the Radiation Response of Epithelial Cells**, Mary H. Barcellos-Hoff, Ph.D., Life Sciences Div., Dept of Radiation Biology, Lawrence Berkeley Laboratory Determining the relationship between proliferation and apoptosis indices with two radiation-induced cytokines in mammary gland following whole body Fe-particle and gamma irradiation. Studies demonstrate rapid and global remodeling of the microenvironment in irradiated murine mammary gland and that characteristics of the HZE-irradiated remodeling are distinct from those following sparsely ionizing radiation. Data demonstrate that HZE particles can elicit specific microenvironment modifications as compared to reference gamma-radiation. They propose that understanding how HZE specifically alters the microenvironment may have ramifications for earth based cancer chemoprevention.

- **NSCORT: Radiation Health**, Administrator: Aloke Chatterjee, Ph.D., Lawrence Berkeley National Laboratory. Basic research efforts focus on several different but highly interactive approaches in order to provide critical information needed to assess the risks of carcinogenesis from exposure to protons and HZE particles during space travel. Theoretical studies will address track structure and quantitative estimation of initial DNA damage for all HZE particles of interest. Experimental studies of enzymatic DNA repair processes will extensively characterize repair by normal human cells as measured by four different end points and then

compare the repair responses of rodent and human cells in order to assist in the extrapolation of mutagenesis, transformation, and carcinogenesis data from rodent systems to humans.

- **Proton Radiation Studies**, Ann B. Cox, Ph.D., US Air Force Research Laboratory, Brooks AFB Ionizing radiations appear to increase significantly the incidence and severity of the disease endometriosis in female monkeys. Standard diagnostic radiation doses do not cause this disease, but relatively low doses of environmental radiations can do so in monkeys. Because of the publication of these results in 1991 by Fanton and Golden, other scientists examined female monkeys exposed to the environmental contaminant dioxin, and found that those monkeys also developed excess levels of endometriosis. It is important to emphasize that this result could not have been obtained from standard laboratory animals such as rodents because those animals exhibit a very different type of reproductive cycle from that of primates.

- **Radiation Effects: Core Project of the National Space Biomedical Research Institute**, John F. Dicello, Ph.D., Johns Hopkins Oncology Center, Johns Hopkins U Research is examining the novel use of pharmaceuticals to countermeasure the observed effects of radiation exposures. In one project Dr. Dicello and Dr. William Shearer, Baylor College of Medicine, Leader of the Immunology, Infection, and Hematology Team, are also considering the synergistic relationship between changes in immunological factors and the response of humans to protracted exposures to radiation.

- **Chemoprevention of Radiation-Induced Rat Mammary Neoplasms**, David L. Huso, DVM, Ph.D., School of Medicine, Johns Hopkins U The scientists are examining the effects of novel forms of radiation on mammary gland carcinogenesis in female Sprague Dawley rats. Firm links have been established between radiation exposure, hormonal factors, and the risk of developing breast cancer. The degree to which environmental sources of low level radiation contribute to the high incidence of breast cancer among the general population is still not known. However, recent studies suggest that women with defects in genes involved in the repair of radiation damage at the cellular level are at increased risk for developing breast cancer. In addition, women who have previously received radiation treatment for cancers such as lymphoma are at increased risk of developing secondary breast cancer.

- **Mechanisms of Genomic Instability from the Exposure of Mammalian Cells to High-LET Radiations (Cooperative Radiation Research with the National Cancer Insititute [NCI])**, Administrator: Robert Ullrich, Ph.D., University of Texas, Galveston, TX is investigating "Genomic Instability in High-LET Carcinogenesis". This project explores possible susceptibility of mouse-mammary precursor epithelial cells in vivo to high-energy (HZE) or alpha irradiation that results in radiation-induced genomic instability and its consequences on malignant transformation in order to explore the basis for tissue and cell-type sensitivities in the intact animal. He is testing the hypothesis that genomic instability is one of the first events expressed in irradiated cells in vivo, and is correlated with the subsequent occurrence of mutations in p53 and loss of cell-cycle regulation in clones that display cytogenetic instability. These effects will be related to the acquisition of a mutator phenotype, and the capacity for DNA double-strand-break (DSB) repair in vivo.

- "**High-resolution Digital Mammography/NCI**", James K. Walker, Ph.D., Nanoptics, Inc., Gainesville, FL The specific aims of this project are focused on the development, optimization, and pre-clinical evaluation of a scanning slot x-ray detector for digital mammography. The technical objective is to achieve increased capacity imaging characteristics of the scanning slot x-ray detector. This technology for digital radiology can be easily extended to general radiology for the chest and major organs. In this case, the typical x-ray energies are increased from about 20 keV to 80 keV. The real-time nature of image acquisition and display is particularly important for trauma or battlefield patients.

Full details of the above research may be obtained by examining the Life Sciences Program Tasks and Bibliography for FY 1995-1998 by accessing the "Research Opportunities" path at the OLMSA Life Sciences Division website: http://www.hq.nasa.gov/office/olmsa/. As part of infrastructure, NASA funds radiation facility beam time to the radiation research community for NASA research projects. In addition to the radiation biology tasks listed, Ames Research Center is working under a special grant on two projects, **Robotic Applications for Breast Biopsy**, Robert Mah, Ph.D., FY98 funding $50,000, and a second, **Biocomputation Center Development of Virtual Surgery Techniques for Breast Surgery**. Muriel Ross, Ph.D., FY98 funding $50,000.

Recognizing the importance of 21st Century technologies in women's health, NASA's Ames Research Center and the US Department of Health and Human Services' Office of Women's Health signed an historic agreement in October 1997 to work more closely on a number of technologies to benefit women's health. The two agencies are focusing their efforts on cancer, reproductive health, pregnancy, osteoporosis and education.

For more information, contact Dr. Joan Vernikos, Director of OLMSA's Life Science Division at 358-2530.

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