

**BREAST CANCER RESEARCH AND
DEVELOPMENT**

HEARING
BEFORE A
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BREAST CANCER RESEARCH AND DEVELOPMENT

WEDNESDAY, MAY 9, 2001

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Harkin, and Murray.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. It is precisely 9:30. The hearing of the Subcommittee on Labor, Health, Human Services and Education will commence.

We have one of our most important hearings of the year today. And that is the hearing on breast cancer. This subcommittee, as is generally known, has taken the lead on increasing the funding for the National Institutes of Health. I frequently say, because I think it to be true, that the NIH is the crown jewel of the Federal Government. And I sometimes add, to the displeasure of some, perhaps the only jewel in the Federal Government.

Senator Tom Harkin and I have taken the lead on funding for NIH crossing party lines. I learned a long time ago that if you want to get anything done in Washington, you have to be willing to cross party lines. The Senate passed a resolution 98 to nothing to double the funding of the NIH in 5 years. But the Senate is well known for druthers and not dollars.

Five years ago, Senator Harkin and I sought to increase the funding by \$1 billion as a step toward that goal. And we were defeated on the floor by a vote of 63 to 37. So we got out our sharp pencils and found the \$1 billion elsewhere establishing priorities.

Having lost on our budget resolution effort to increase funding \$1 billion the next year, we decided to try for \$2 billion. And again, we were defeated, this time by a narrower vote. But again we found money within the budget establishing priorities to give the money to NIH. And without giving the details on my vote on this budget resolution, we passed 96 to 4, an increase of \$3.4 billion, which would bring the funding for NIH to almost \$24 billion, right at \$24 billion, which would be just about a doubling.

This funding has produced really remarkable results in research advances, one of the notable ones being what has happened with stem cells. Right now we are in the midst of a battle to try to re-

move a prohibition which says Federal funding cannot be used on research on stem cells. Federal funding is permitted under a ruling by the general counsel for the Department of Health and Human Services for research on stem cells after they are removed. We have legislation pending which would remove the prohibition entirely.

I think mistakenly it gets caught up in the pro-choice/pro-life argument. We are not dealing with the issue of any of these embryos which would be used to produce life. They are to be discarded. There are extras which are created for in vitro fertilization. And these stem cells have remarkable capabilities already demonstrated on Parkinson's, spinal cord, diabetes and, perhaps, it is not determined yet, on Alzheimer's.

One of the issues we are going to discuss here today is what the impact is on cancers, whether it may reach there.

The issue of breast cancer is—well, I will just put it, there is no more important issue in medical research than breast cancer. It has competitors with ovarian cancer, prostate cancer, lymphoma, and heart ailments, and many other maladies. But it has claimed the lives of one woman out of nine. There has been an enormous increase in funding. I will put those statistics into the record, not to take too much time now.

[The information follows:]

BREAST CANCER STATISTICS

The National Cancer Institute (NCI) estimates that 1 in 8 women will develop breast cancer during her lifetime. This year approximately 238,600 women will be diagnosed with breast cancer and over 40,000 will die as a result of breast cancer. The risk of breast cancer increases with age. The risk is also higher in obese women and those who use oral contraceptives, ingest a high fat diet or fail to exercise. Detecting breast cancer in its early stages is difficult since the disease is often spread throughout the woman's body before the tumor is sufficient size to be detected during a monthly self-examination or by a physician on an annual examination. Mammography is more sensitive than physical examination at detecting small breast tumors but is still relatively insensitive since a tumor can exist for 6–10 years before growing large enough to be detected by a mammogram. Despite this relative insensitivity, early detection through mammography remains the best means of controlling breast cancer. For breast cancer that is contained within the breast, 5-year survival has increased from 72 percent in 1940 to 97 percent today. However for breast cancer that has spread outside of the breast, 5-year survival is as low as 21 percent.

Senator SPECTER. The schedule has a complicated Senate. And that is probably as true as the Senate has a complicated schedule.

Freudian slips are probably more accurate than the straight talk. But we have a vote set at 9:35 today.

STATEMENT OF RICHARD KLAUSNER, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. And we will now proceed with our very distinguished witnesses. Our lead witness is Dr. Richard Klausner, appointed director of the National Cancer Institute in August of 1995. He has been here on many, many occasions, and been on the circuit. And I thank him for the trip he made to Philadelphia, Pennsylvania, not too long ago.

Prior to that appointment, Dr. Klausner served as chief of the Cell Biology and Metabolism Branch of the NIH, Child Health and Human Development. He began his career at NIH in 1979 after

post-graduate work at Harvard, has his undergraduate degree from Yale and his medical degree from Duke University.

He is accompanied by Dr. James Marks, the director of the National Center for Chronic Disease Prevention and Health Promotion of the Centers of Disease Control, where he has held numerous positions over the past 25 years. An adjunct associate professor at Emory, he received his undergraduate degree in psychology from Williams, M.D. from the University of New York at Buffalo, and his MPH from Yale University.

Thank you for joining us today, gentleman. Dr. Klausner, we will turn to you. Our generalized rules are to set the lights for a 5-minute opening, leaving a maximum amount for questions and answers. We will have to see how we are going to do on time. We do have a fair-sized list of witnesses.

So Dr. Klausner, we look forward to your testimony.

Dr. KLAUSNER. Thank you, Mr. Chairman. And let me thank you on behalf of everyone for all the support. What I want to briefly do right now is to actually demonstrate some of the fruits of the support for research, beginning with one measure: What is happening to mortality rates from breast cancer.

Up until 1990, each year mortality rates were rising in this country. From 1991 to 1995 historically, for the first time, we saw mortality rates dropping by about 1.6 percent per year. And that is now accelerating to about 3.5 percent per year. We expect it to continue. We expect it to accelerate. Even if it stopped at this level but continued over the next 10 years, that would mean a 30- to 40-percent drop in the mortality from breast cancer.

We have achieved good dissemination of our best early detection tool, mammography, which you will hear about. But mammography is far from perfect. And to really effect early detection, we need new, really new, approaches. We have incrementally approved survival, but with relatively toxic and, with a few exceptions, not specific treatments.

It is likely that we can continue to make these incremental improvements. And we must make sure that all women have access to prompt and state-of-the-art treatment. But if we are going to do better, and we can and must, we must switch our treatment approach so that we know the different types of breast cancer, to treat each as a distinct disease. And we must now develop new treatments based upon the molecular machinery of each type of breast cancer.

So now we will do a 4-minute molecular biology lesson in breast cancer.

For 100 years we have diagnosed breast cancer by as you see on the left, looking under the microscope at abnormal cells. That is pretty much what we knew. That is not what cancer is. Cancer is a disease of molecular alterations. For the first time now, at the beginning of the 21st century, we can switch from looking under the microscope alone to reading genes.

And what you see there is a gene chip. To read the true molecular profile and discern the true molecular nature of breast cancer, there are about 30,000 genes on that little penny-sized chip. And so what we have done is challenged the community with an \$80 million program called the Director's Challenge to redefine breast

cancer. And you see the result in that chip, one experiment, 50,000 data points.

And as we suspected, breast cancer, while looking the same under the microscope, is at least—next slide—five different diseases. We could not know this before about 9 months ago. It is hard to read this. Take my word, it is five different molecular diseases. The most important thing is, all of these differences, when corrected for the exact same stage of disease, which today has been the best way of predicting outcome, you can discern the true molecular differences between totally different diseases that we are all lumping as breast cancer. The result is that we see entirely different outcomes for these different diseases, from one type having zero 3-year survival to another type having a 95-percent 3-year survival.

What will this mean? First of all, we need to switch to thinking about these as molecular diseases and as distinct diseases. As you have heard me talk about, we have gone in one generation from cancer being a black box to then, through research, drawing the circuitry of cancer.

But with that circuitry, we do not stop. It is this circuitry that provides the new and truly revolutionary targets for therapy against these different diseases. And now you will see what has happened.

From that circuitry, on the next slide we see all of the pieces of the circuitry that we know so far to be altered in different types of breast cancer. And in green is the list of all of the drugs that are already entering clinical trials, just in the last couple of years, that are now directed against each of those points of the circuitry.

I cannot over emphasize how much this is a complete change from the sledge hammer approach to the black box of cancer that we have lived with for too long.

We can see how quickly we have moved from identifying the targets, here classifying them in a new way. Fifteen classes of molecular targets in breast cancer, 68 individual targets identified specifically. And now already, 130 trials supported by the NCI and industry directed against all of these targets.

It is these therapies that you have heard me talking about for several years. The difference is, 5 years ago, if I would have drawn this, it basically would have been almost blank. One hundred thirty trials, 68 different targets, about 85 agents, this is the immediate effect of all of this research that you have supported.

PREPARED STATEMENT

And we now know that each of these targets are not present in breast cancer, per se, but in these different molecular forms. For the first time, these brand new technologies that have been now developed and disseminated to the research community, will allow us for the first time to think about the right treatment for the right disease.

And I will stop there and hopefully answer questions later.
[The statement follows:]

PREPARED STATEMENT OF RICHARD KLAUSNER

Good morning Senator Specter and Members of the Subcommittee. I am Richard Klausner, M.D., Director of the National Cancer Institute (NCI). I am pleased to have this opportunity to speak with you today about breast cancer research.

Over the past two decades, intensive research sponsored by the NCI into all aspects of breast cancer has led to many important discoveries. We understand more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, why some tumors are more aggressive than others, and why some women suffer more severely and are more likely to die of their disease. We are having increasing success in translating these discoveries into therapies that extend cancer-free survival and improve the quality of life for those continuing to live with the disease. Likewise, our discoveries are leading to more refined technologies for detecting and diagnosing breast cancer, better supportive care and improved outcomes for patients during and after treatment, and finally, we are getting closer to identifying effective strategies for preventing the disease altogether.

Though these advances have been significant and provide hope for the future, we still have far to go to remove the threat of breast cancer from women's lives. In 2001, it is estimated that 192,200 women will be diagnosed with breast cancer (another 1,500 cases will occur in men), and 40,600 will die from breast cancer. It is the most common cancer among women in each of five major population groups (white, black, Asian and Pacific Islanders, American Indians and Alaska Natives, and Hispanics), and the second leading cause of cancer mortality for women in all major population groups with the exception of Hispanics, for whom it is ranked first.

The breast cancer incidence rate in women has increased substantially, going from 83 (per 100,000 women) in 1973 to 118 (per 100,000 women) in 1998. Analysis of more recent trends (1992–1998), indicate that incidence is increasing by slightly over 1 percent per year among white women and is relatively flat among black women. In contrast to incidence, breast cancer death rates have decreased by 3.4 percent per year since 1995, including a significant decline in rates for white women and relatively stable rates for black women.

The increase in detection and diagnosis of breast cancer occurs for women of all ages but is greatest among those over 50 years of age, particularly women 50–64 years of age. Consistent with increasing utilization of mammography, the greatest increase in breast cancer incidence rates occurs in women diagnosed with early stage malignant disease as well as in women with premalignant tumors.

RISK AND PREVENTION

Approximately one out of every eight American women will develop breast cancer in her lifetime. About half of the incidence can be explained on the basis of identified risk factors, including heritable gene mutations associated with breast cancer, and investigators continue to search for the elements of breast cancer causation and understand how they influence each other. Undoubtedly, changing childbearing practices are important, since studies have repeatedly shown large increases in risk among women who have remained childless or who have delayed childbirth until their later reproductive years. Breastfeeding may reduce risk, although probably not for the durations practiced by most American women. It is widely accepted that risk is increased among women who are heavier consumers of alcoholic beverages and who are overweight (this latter relationship being true only for postmenopausal breast cancer). Since both of these factors are modifiable, they are viewed as important means by which disease incidence could potentially be reduced.

A great deal of attention has focused on the role of exogenous hormones, given the widespread exposure of women to both oral contraceptives and menopausal hormones. For oral contraceptives, there appears to be a slight increase in risk for current users of the preparations, although risk dissipates five years after discontinuation. More concern relates to menopausal estrogen use, since long-term use (10+ years) appears to increase risk to a moderate extent. This risk may be even further increased if progestins are added to the regimen.

Other factors are under investigation, but the relationship of risk to most of these factors remains controversial. There has been great emphasis on identifying dietary means of reducing disease risk, although there is little consensus as to which constituents of diet might be important (enthusiasm over a potential role of dietary fat has been tempered by recent studies that have failed to show much evidence for an effect). The role of physical activity is also not clearly understood. Extensive attention has focused on understanding the role of environmental agents, including ones to which women have been increasingly exposed, although studies to date have provided inconsistent results.

Cancer susceptibility is a critical piece of the puzzle. We know that disruption of fundamental cellular processes contributes to the development and progression of the more common, non-hereditary forms of cancer. Even among individuals who have inherited cancer-predisposing genes, the risk of developing cancer appears to be modified by other genetic and environmental factors. There is mounting evidence that a person's genetic make-up may influence susceptibility or even resistance to cancer-causing exposures. Opportunities now exist to determine how variations in these genes combine with environmental and other factors to induce cancer in the general population. There is great hope that controversies regarding many of the poorly understood risk factors may be resolved by assessing the interactions between genes and the environment.

Single mutations in major cancer-associated genes are thought to account for 5–10 percent of all breast cancer. Among the most important of these genes are BRCA 1 and BRCA 2 which are thought to account for nearly 80 percent of families with inherited predispositions to breast cancer. Women with these mutations are also at an increased risk for ovarian cancer. A variety of other much less common conditions caused by mutations in other genes contribute to an increased risk of breast and/or ovarian cancer in other families.

While these major breast cancer risk factor genes play an important role in determining who gets breast cancer in such families, not all who inherit such a mutation will get breast cancer. Though early studies suggested that the lifetime risk of breast cancer for those inheriting mutations in BRCA 1 and 2 might be as high as 80 percent, more recent studies suggest a much lower, though still quite elevated, risk in the range of 37–56 percent for breast cancer, and 16 percent for ovarian cancer. Whether these risks are the same for all of the more than 600 different identified mutations in BRCA 1 or more than 450 identified mutations in BRCA 2 is unknown. What is clear is that other modifier genes or environmental and lifestyle risk factors must play some important roles. In addition, current evidence suggests that the mechanisms that produce breast cancer linked to BRCA 1 & 2 mutations may differ in important ways from those that lead to other more common breast cancers. The evidence suggests that these genes have important roles in DNA repair and regulation of the cell cycle and therapeutic and preventive interventions should be tailored to these mechanisms in order to be effective.

The use of prophylactic surgery, such as mastectomy or oophorectomy, as a prevention method for high-risk mutation carriers has had extensive consideration and is sometimes offered to such women. However, the effectiveness of such treatment has been less clear. Recently, investigators sponsored by the NCI have produced significant evidence that such an approach can have real benefits. For instance, a 1999 study of women at high risk for breast cancer suggested a 90 percent reduction in risk of breast cancer after prophylactic mastectomy, and it has also been reported that BRCA 1 carriers who have bilateral prophylactic oophorectomy may have a reduction in breast cancer risk in the vicinity of 50 percent, even if they receive hormone replacement after surgery. Surgical approaches to prevention of cancer have significant adverse consequences and may not be acceptable to many women at-risk.

While tamoxifen has not been shown to reduce the risk of breast cancer specifically among high-risk mutation carriers, NCI's Breast Cancer Prevention Trial, including 13,000 women at increased risk for breast cancer, demonstrated that women taking the drug tamoxifen for an average of four years reduced their chance of developing breast cancer by 49 percent. Other health benefits were noted as well, but tamoxifen is not without potential harm, particularly for postmenopausal women, who had an increased risk of developing life-threatening health problems: endometrial cancer, pulmonary embolism, and deep vein thrombosis.

It is now vital to find effective preventive agents that cause fewer or no side effects. For example, raloxifene has action similar to that of tamoxifen, and was originally studied in the treatment and prevention of osteoporosis. Scientists noted then that woman who took raloxifene developed fewer invasive breast cancers than those who were given placebo. Raloxifene is believed to have fewer side effects than tamoxifen; to date, studies have not shown an increased risk of endometrial cancer from the drug. NCI began the Study of Tamoxifen and Raloxifene (STAR) in 1999 to compare the two drugs. As of April 1, 2001, 9,359 postmenopausal women at high risk for developing breast cancer have joined STAR, which is seeking 22,000 women. Lessons learned from BCPT have improved outreach to minorities, and 500 minority women have joined STAR. This is more than five percent of the total number of women on the trial.

Both tamoxifen and raloxifene block estrogen receptors in breast tissue, dramatically reducing the development of breast tumors that exhibit estrogen receptors (ER+). But neither drug seems to affect estrogen receptor-negative (ER-) tumors, which are more prevalent in women under age 50, in black women, and in women

at risk due to a mutation in their BRCA 1 gene. About 20 percent to 30 percent of breast cancers are ER-. NCI is sponsoring new research to discover strategies for preventing ER- breast cancer. Preclinical studies using animal models are critical for identifying new agents to prevent cancer: creation of animal models of ER- breast cancer (using the Mouse Models for Human Cancer Consortium) allows the development of protocols aimed at finding specific and potent agents to prevent ER- breast cancer. Agents to be studied in clinical trials to prevent ER- breast cancers include kinase inhibitors, nonsteroid anti-inflammatory drugs such as COX-2 inhibitors, and retinoids.

SCREENING AND EARLY DETECTION

Analysis of the data from the National Health Interview Surveys revealed that in the last decade, utilization trends for several cancer screening modalities, including mammography, Pap smears, fecal occult blood tests, sigmoidoscopy, and digital rectal examination, all increased. The most dramatic increase was seen in the use of mammography. Mammography was first monitored nationally in 1987, when less than thirty percent of all women 40 and older reported having a recent breast X-ray. Between 1987 and 1992, use of mammography almost doubled, and by 1998, 67 percent of women reported receiving mammography within the last two years. Utilization rates vary by age group. In 1998, 73 percent of women aged 50-64 reported recent mammography, while women in age groups 40-49 and those over age 65 received mammography at the rate of 63 percent.

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. Randomized trials in women screened for breast cancer with conventional mammography have shown reductions in mortality by 16 percent to 30 percent. We feel there is potential for improvement in the way screening is done. Problems with screen film conventional mammography include difficulty in detecting early lesions in women with dense breast tissue, false negatives with up to 10-20 percent of breast cancers detected by physical examination not being visible on screen-film, and false positives with only 5-40 percent of lesions detected by mammography being malignant on biopsy. The screen-film has limitations, based on the fact that film is the medium of imaging acquisition, storage, and display. Once the mammogram is obtained, the image cannot be altered or manipulated to obtain an improved view. These limitations pose a challenge for the technology developers to devise improved technologies for detection.

Digital mammography has potential advantages over conventional mammography, which include: improved detection and breast lesion characterization due to a more representative breast image; image acquisition and display are separated, and each component in this process can be optimized; image storage, transmission, and retrieval can be improved; and there is software to assist the radiologist in interpreting the images.

Over the past year, the NCI has been actively involved in facilitating the development of a rigorously designed trial with the American College of Radiology Imaging Network, four competing device manufacturers, the Center for Devices and Radiologic Health, Food and Drug Administration, and the Health Care Financing Administration (HCFA). The trial will start this summer, and will be conducted in women presenting for screening mammography at one of 20 participating sites. Approximately 49,500 women will be enrolled over 1.5 years and followed for an additional year. One fourth of the participants will be screened on each of the four digital mammography devices, and it is estimated that approximately 16 percent will be age 65 or older. Each woman will be screened with two mammograms—one will be a conventional screen-film, and the other will be a digital mammogram. Abnormalities on either screening test will be evaluated, and normal screens will be re-evaluated at one year with conventional mammograms.

The NCI continues to explore new ways to improve imaging methods for breast cancer screening. We are sponsoring research on non-X-ray based technologies such as magnetic resonance imaging (MRI), and breast-specific positron emission tomography (PET) to detect the disease. Scientists are also evaluating the use of several forms of non-ionizing radiation in the diagnosis of breast cancer. Promising areas of investigation include elastography, electrical impedance spectroscopy, and infrared spectroscopy. The possibility for the future of breast imaging is to use one or more of these technological approaches to enhance or even replace X-ray mammography as the screening study for breast cancer.

MOLECULAR APPROACHES TO EARLY DETECTION

As we understand more fully cancer's fundamental nature, our capacity to use a variety of tools to detect the molecular changes associated with a tumor cell promises to vastly improve our ability to detect and stage tumors, select treatments and monitor the effectiveness of a treatment, and determine progress. As the science advances, seeing how the processes and pathways inside a cell change as the cell transforms from normal to cancerous will allow us to detect changes in people earlier, and eventually we expect to be able to visualize the actual molecular signatures of a cancer. We will be able to tell which genes are being expressed in a patient's cells, and we will be able to translate this information directly into better management of the disease.

The NCI is furthering early cancer detection by establishing a new national effort toward discovery and development of novel markers for all cancers: the Early Detection Research Network (EDRN). The objective of the EDRN is to develop and test molecular tools capable of detecting early cancer and assessing cancer risk. To do this, the EDRN is unveiling cellular anomalies of early cancers, known as a cell's signature, which are signposts of a cell's progression towards cancer. By harnessing the uniqueness of these molecular signatures, the EDRN is turning these signatures into molecular tools—biological markers for screening and detection efforts.

The EDRN was specifically formed to address the unique testing strategies required for early cancer or risk assessment biomarkers. Because of low tumor burden in individuals with early stages of cancer or at risk for developing cancer, the testing strategy for these biomarkers is necessarily stringent. Not only does the biomarker need to be clinically adaptable, it must be highly sensitive and specific, be capable of identifying few abnormal cells among billions of normal cells, and be available for minimally-invasive testing if it is to be used for screening. To help address the specific testing requirements of early cancer and risk biomarkers, the EDRN distributes cancer researchers into separate, yet coordinated, development, validation, and clinical laboratories.

The EDRN's approach to biomarker research is also novel because it encourages leading cancer researchers to focus their research on highly prevalent cancers, like breast cancer. Of the 31 centers in the EDRN, nine are developing biomarkers to identify early breast cancer or an individual's risk of developing breast cancer. This comprehensive, collaborative approach to breast cancer research merges genetic pursuits with protein approaches, providing a systematic view of how the molecular signatures of breast cancer can be used as a unique, identifying mark.

Genetic approaches to breast cancer detection and risk assessment are currently underway in five EDRN developmental and clinical laboratories. Research encompasses biomarker discovery strategies, such as examining the patterns of active genes, known as gene expression, by comparing genes expressed in normal cells with cancerous or precancerous breast cells. Additionally, several laboratories are examining the gain, change, or loss of genetic material. Some studies involve genes whose levels are abnormally elevated in breast cancer, like BRCA-1 and Ki-ras oncogenes, and the p53 tumor suppressor gene. Others focus on genes that are inactivated by genetic changes, like the DNA repair gene XPD, and promising research of genetic loss on chromosome 4 in high-risk populations is underway. Hereditary studies are also proceeding to amass detailed information and biological samples from breast cancer prone families.

Complementary to gene-based research, protein-based efforts provide a view of how genetic gains, changes, and losses affect the proteins arising from such altered genes. State-of-the-art protein biomarker research for breast cancer is underway in four developmental and validation laboratories. Similar to gene expression pattern research, protein patterns are being explored in three developmental laboratories. In one laboratory, breast nipple fluid protein patterns are compared between normal and abnormal breast tissues.

Nipple aspirate fluid (NAF) is a substance that circulates in the breast ducts, the very structures where breast cancer originates. Because proteins associated with the biology of the breast are secreted into this fluid, examination of the fluid should provide a "snapshot" of the breast environment. The fluid can be extracted using a method similar to a breast milk pump, which is non-invasive and easily performed. The first goal of this research is to identify a protein signature in breast tumor tissue, then see if this signature can be reliably detected in NAF. Using the Surface-Enhanced Laser Diffraction Ionization (SELDI) Time-Of-Flight (TOF), with as little as one drop of NAF, investigators have demonstrated that different protein peaks could be identified in the samples from the cancerous breast compared to the normal breast in the same woman. Further studies are in progress to determine the validity of this approach with a large number of specimens.

A REVOLUTION IN DIAGNOSIS

Future attempts to advance our understanding of the etiology of breast cancer will undoubtedly require a better understanding of the natural history of this complex and multifactorial disease. It will be important to consider breast cancer not as one disease but as a collection of possibly heterogeneous diseases. A number of biomarkers should be useful in advancing thinking regarding breast cancer. Efforts are underway to distinctly classify tumors by a variety of parameters, including hormone receptor status, histologic patterns, and presence of oncogenes. This approach challenges conventional thinking, but it conveys the opportunity to target common precursor cells as well as divergent targets later in the developmental pathway.

The most pressing diagnostic challenges for breast cancer relate to directing therapeutic choices. Earlier detection of breast cancer is resulting in a shift to smaller tumors, and in over 50 percent of cases, there is no apparent spread to the axillary lymph nodes. Clinical practice guidelines suggest that all breast cancer patients be considered for some sort of adjuvant therapy, often involving toxic chemotherapy regimens. About 70 percent of lymph node-negative patients will actually be cured by definitive surgery plus local/regional radiotherapy. We do not know how to separate, with sufficient certainty, the patients with a high risk for recurrence from those in whom their cancer will not recur.

When patients have metastatic disease, either at the time of their initial diagnosis or at the time of recurrence, choices must be made about which therapeutic regimens will be most effective. As new, targeted therapies, such as Herceptin, are developed, it is important to be able to identify the patients most likely to benefit.

Both the decisions regarding which patients should be treated and the choice of treatment require greater understanding of the underlying biology of breast cancer and of the specific lesion present in the patient. New comprehensive molecular technologies are allowing researchers to look at the full spectrum of alterations that have taken place in the formation of a given tumor. The NCI initiative "Director's Challenge: Toward a Molecular Classification of Tumors" is funding investigators to develop profiles of molecular alterations in human tumors using DNA, RNA, or protein-based comprehensive analysis technologies. These "molecular signatures" are intended to redefine tumor classification, moving from morphology-based to molecular-based classification schemes. Tumor classification, based on morphology, or the tumor's structure, does not always accurately predict the patient's clinical behavior. Molecular profiles are expected to provide more informative molecular classification schemes for human cancers by identifying clinically important tumor subsets within morphological classes. The goal of the Director's Challenge projects is to have these new molecular classification schemes developed and ready for clinical validation by the end of the initial five-year funding period.

A group of Director's Challenge investigators has developed molecular profiles that identify subsets of node negative breast cancer patients. Tumors in one subset appear to arise from luminal cells in breast glands. Tumors in the second subset appear to arise from basal cells. Patients with basal cell tumors appear to have a significantly worse outcome and may represent those node negative breast cancer patients at greater risk for recurrence. Studies are underway to confirm and extend these initial findings. Another group that was just funded under the Director's Challenge initiative is attempting to use a different comprehensive analysis technique to characterize early breast cancer lesions.

Other research teams are working on development of robust techniques for analysis and detection of alterations in tumors. It is likely that patients who do not appear to have involvement of their regional lymph nodes but later have a recurrence of breast cancer have, in fact, released cells from the primary tumor site. A number of investigators are assessing methods for detecting residual disease and evaluating the clinical significance of their findings. The NCI will be holding a meeting in the autumn of 2001 to assess the state of the science of detecting minimal disease and to determine what the research agenda should be.

Development of tests to identify patients who will respond to particular therapies or classes of drugs requires considerable coordination and generally large numbers of patients or specimens from patients. The NCI has just launched a new effort, the Program for the Assessment of Clinical Cancer Tests (PACCT), to ensure the translation of new knowledge about cancer and new technologies to clinical practice. The initial focus of PACCT is on breast and colon cancer. As part of the effort to evaluate new markers and to validate the utility of some known markers/tests, the NCI is putting together reference sets of specimens. These specimens will be made available to academic and industry researchers to facilitate the development process. The PACCT is also developing criteria to help determine the data that are needed to move a marker test forward to clinical practice.

NCI is accelerating discovery and development of imaging methods that use new technologies to identify biological and molecular properties of precancerous and cancerous cells in order to predict clinical course and response to interventions. Scientists are studying women with estrogen receptor-positive (ER+) breast cancer before and just after initiation of tamoxifen therapy using PET, enhanced by the administration of a chemical agent that indicates estrogen receptor status, to evaluate whether this technique can be used to predict responsiveness to hormone therapy in this group of patients. Others are developing novel radiolabeled estrogen receptor binding molecules as potential tools for imaging and possible therapeutic applications. NCI-sponsored researchers are identifying a number of other molecules that can be conveniently labeled for imaging studies to target and characterize multidrug resistance factors in tumors as well as other tumor-specific features.

NEW STRATEGIES FOR TREATMENT

The convergence of scientific advances in the areas of cancer biology, synthetic and biosynthetic chemistry, and high throughput screening has resulted in the potential to exploit molecular targets for cancer treatment and the opportunity to revolutionize cancer drug discovery. We are developing a whole new generation of cancer treatments: "smart" drugs that target the molecular features characteristic of a particular type of cancer. Even within cancers, like breast cancer, that have been historically classified only on the basis of tumor site, we now know that significant heterogeneity exists in terms of molecular profile. For example, about 35 percent of breast cancers display higher than normal numbers of receptors for epidermal growth factor, whereas only 5 percent overexpress a protein called MDM-2. As many as 75 percent of breast cancers may have altered function of the p53 protein. Since in reality, multiple forms of breast cancer exist, the truly effective therapies of the future will be tailored to the molecular characteristics of the tumor being treated.

Every point of difference between premalignant or malignant cells and their normal counterparts is a potential target of opportunity for drug discovery. Targets may be revealed by understanding the consequences of fundamental molecular changes in cancer, such as those that spur blood vessel growth to nourish tumors or the means by which tumors spread by invading surrounding tissue and migrating from their site of origin. For breast cancer, more than 75 potential targets, representing over a dozen classes of targets, have already been identified. NCI is involved in testing over 50 new agents directed at these targets, and many others are being tested within the private sector. Scientists report new findings in cancer cell biology every day, giving us new targets to explore. The opportunities for discovery in this area are boundless.

As the most promising treatment strategies emerge from developmental testing, they progress to evaluation in clinical trials, the final crucial step in translating new discoveries into effective therapies for patients. In September 2000, the Early Breast Cancer Trialists' Collaborative Group, a world-wide collaboration of scientists studying breast cancer, reported that 5 years of tamoxifen therapy reduces the absolute death rate from breast cancer by 9 percent in women with hormone-sensitive cancers followed for as long as 15 years after the start of treatment. A majority of the patients that form the database for this international overview participated via NCI-sponsored tamoxifen studies. These long-term survival results prove the principle that targeting a specific biologic feature of the breast tumor cell, the estrogen receptor in the case of tamoxifen, can lead to improved outcomes. Furthermore, development of this targeted treatment demonstrates a prime example of the incremental manner in which successive clinical trials can result in important improvement in outcomes. The approach tests new agents initially in advanced disease and then moves the successful agents into earlier stage treatment aimed at improving survival.

An even more recent example of this targeted therapeutic approach is presented by the agent Herceptin. Recently approved by the FDA for treatment of advanced breast cancer, Herceptin is a recombinant antibody that targets a specific receptor on the breast cancer cell membrane. This agent has been shown to improve survival by an average of 5 months in women with advanced cancer whose tumors express this receptor. Two definitive studies sponsored by NCI are now underway to test whether this agent will improve survival even more markedly in women with earlier stage disease. It is plausible that Herceptin might follow the same path as tamoxifen and be useful for prevention of breast cancer, especially in the case of the hormone-insensitive variety that doesn't respond to tamoxifen. We still have much to learn about the optimal use of Herceptin and are actively studying ways to combine it with other active drugs without enhancing side effects. The NCI is spon-

soring ten trials currently with this agent, while Genentech, the maker of Herceptin, is sponsoring five trials, and there are 35 investigator-sponsored trials worldwide.

Based upon discoveries in the research lab, there is a plethora of breast cancer targets with active agents under development. Among the leading candidates that NCI is studying in clinical trials in advanced breast cancer at present is an agent that interferes with a prime growth pathway for breast cancer cells, the epidermal growth factor pathway. Phase II studies combining the agent with Herceptin and with chemotherapy will begin shortly. A humanized monoclonal antibody that interferes with the development of tumor blood supply (angiogenesis) by blocking vascular endothelial growth factor is also under investigation. A phase III study testing this agent in combination with standard chemotherapy has recently been approved by NCI. Another phase III trial is testing an inhibitor of an enzyme (matrix metalloproteinase) that destroys the supporting tissue around tumors, administered after conventional chemotherapy in patients with advanced disease. Still another example of a promising new therapy under evaluation is one of the first selective estrogen receptor degradation (SERDS) agents. Early work has shown activity in patients whose tumors are resistant to tamoxifen and a large trial is planned by NCI to test this agent in early stage disease.

Clinical trials for breast cancer treatment have demonstrated remarkable success and are a vital component of the NCI's research program. Currently our clinical trials database contains descriptions of over 165 treatment trials for breast cancer, including 103 NCI-sponsored trials. Of these, 81 are Phase I and/or Phase II studies in which novel approaches to treating breast cancer are tested for safety and efficacy, and 22 are Phase III trials representing interventions that are closest to general medical practice. The NCI Clinical Trials Cooperative Group program performs definitive, large-scale trials to determine whether new treatments actually improve upon results seen with current standard approaches. Presently, several new promising treatments are being evaluated in Phase II and III Cooperative Group trials. For breast cancer treatment, this effort is the largest single therapeutics development effort in the world.

While we are working steadily to find new and improved cancer therapies for breast cancer, we must be certain that the research results of our trials are communicated effectively to physicians and patients around the country. In November 2000, the NCI sponsored a Consensus Development Conference on Adjuvant Therapy For Breast Cancer that addressed major questions confronting physicians and their patients once a diagnosis of regionally advanced breast cancer has been made. An independent, non-governmental panel of breast cancer experts reviewed the results of clinical trials, and summarized what we have learned about breast cancer treatment and discussed promising research directions. Recommendations from this conference were widely disseminated in both the lay and professional media.

It is imperative that the questions we ask in breast cancer treatment studies reflect the needs of real people who are coping with breast cancer. The NCI has developed a new way to describe breast cancer as a series of clinical states that represent decision points confronted by patients and physicians. Each of the clinical states is characterized by tumor features and degree of disease progression, and lends itself to a tailored management plan based on its collection of defining traits. A woman who is faced with a diagnosis of breast cancer today has choices. As she consults with her physician she will learn about specific aspects of her own disease—the type of tumor she has, the number of affected lymph nodes, the presence or absence of estrogen receptors and tumor-specific antigens, and whether or not the disease has spread to other organs. She and her physician can make informed decisions about which treatments have potential benefits and which treatments have risks that outweigh their benefits in her particular case. And our clinical trials portfolio can be organized to correspond to the clinical states of breast cancer so we can ensure that our research is relevant and comprehensive.

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 7 million Americans alive today have a history of cancer. The past ten years have seen an explosion of effective, well-tolerated treatments for cancer. Researchers continue to develop interventions that will help ameliorate the worst side effects of the treatment, and measurement of a patient's quality of life now is included routinely as a component of most NCI-supported clinical trials.

In one of the largest follow-up studies conducted to date, NCI funded researchers surveyed the quality of life of almost two thousand breast cancer survivors, looking

at the woman's physical, social, emotional and sexual functioning post-cancer treatment. Results of this study confirmed earlier findings that while most breast cancer survivors continue to do well, women who receive adjuvant treatment experience poorer functioning long term. Fatigue, though not a significant problem for the majority of breast cancer survivors in this study, was closely linked with depression, bodily pain and sleep disturbance in those who did report fatigue. Lymphedema subsequent to surgery was found to be more of a problem than previously acknowledged clinically. Problems with arm swelling were reported by 46 percent of women undergoing mastectomy alone, 24 percent of women with lumpectomy and 26 percent of women with mastectomy plus reconstruction.

A descriptive profile of the demographic, clinical, and survival characteristics of breast cancer survivors diagnosed over a 24-year period in nine SEER areas in the United States was developed by NCI. An improvement in the relative survival by decade of diagnosis was confirmed, and additional analysis was done to compare married and unmarried survivors. Findings indicated improved survival rates for married survivors for each decade, reflecting the possible role of social support or economic advantage in better outcomes.

There are deficits in memory and concentration associated with breast cancer treatment. NCI funded a study to look at breast cancer survivor's intellectual ability, quality of life, and normal activities and roles following breast cancer treatment. Breast cancer survivors treated with systemic chemotherapy in addition to standard local treatment, were compared with age-matched breast cancer survivors who had received local treatment alone. Results of the study showed significant differences across a variety of neuropsychological tests between the two groups.

As more cancer patients are successfully treated, we must learn more from the experiences of long-term cancer survivors. The NCI will continue to support research covering the entire spectrum of challenges facing cancer survivors as this need continues to rise.

CONCLUSION

Last year, NCI invested \$439 million in breast cancer research, including \$3.5 million in proceeds from the sale of the breast cancer semi-postal stamp. We expect this to grow to \$464 million in 2001 and \$510 million in 2002 in accordance with the President's 2002 budget request for NCI as part of the National Institutes of Health. Illustrating our commitment to accelerate progress against breast cancer, the NCI convened a Progress Review Group (PRG) in 1998 to conduct an intensive review of our research portfolio in breast cancer. This initiative, the first of a highly beneficial series of PRG's fitting within NCI's new disease-specific planning framework, featured expert panels who provided a comprehensive view of the state of our current knowledge, and many of our research priorities reflect their recommendations. We have learned the value of including as broad a constituency as possible in our review, advisory, and planning activities, and we have forged new relationships with patients, practitioners, scientists in different fields of research and medicine, other government agencies, private sector companies, innovators in technology, and many other partners where such alliances were rare or non-existent only a few years ago.

We are making progress against breast cancer. The diligence of all the people of the breast cancer community is fulfilling the long awaited promise of science. We have reached an exciting point where we have a molecular window on cancer and our new strategy of looking at all aspects of breast cancer from a molecular point of view is bearing fruit. The pace of discovery is rapid. Our challenge is to translate this new knowledge into useful and effective screening, preventive, diagnostic, and treatment tools as quickly as possible to ease the suffering caused by breast cancer and relieve families of this terrible burden.

Thank you, Mr. Chairman, for inviting me to appear before the Committee today and to share with you the progress we have made against breast cancer. I will be pleased to answer any questions the Committee may have.

Senator SPECTER. Well, thank you very much, Dr. Klausner. There are quite a few questions, and we will come to that in just a few moments.

We turn now to Dr. Marks. Thank you very much for joining us, Dr. Marks, and providing the two-front war from NIH and CDC.

STATEMENT OF JAMES S. MARKS, M.D., M.P.H., DIRECTOR, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. MARKS. Thank you, Mr. Chairman. I am especially pleased to be here today to talk with you about CDC's national breast and cervical cancer early detection program. It is in its 11 year of providing free mammograms and pap smears to low income American women. The program has saved lives and raised the consciousness of Americans everywhere about the importance of screening.

And I especially want to put our program in context with what you have just heard from Rick. When the research is done, it needs to get out and get out quickly to the American public, to those in great need. As he described, we know how to save many of the deaths that now occur from breast cancer. Mammography is currently the single-most effective method for diagnosing breast cancer early. And the longer the breast cancer remains undetected and untreated, the greater the likelihood it will spread and eventually result in death.

We fund programs in all 50 States, the 6 U.S. territories, and in 12 Native-American, Alaskan-Native tribal organizations. In addition, we provide health education to the public, to health professionals, and a pay for variety of the medical procedures that are needed to confirm diagnosis.

Through September of 2000, we have provided over 3 million screenings. About 1.4 million of those were mammograms. And about 9,500 women have been diagnosed with breast cancer through the program and helped to find prompt treatment.

If this program did not exist, these women would still have cancer, but they would not be able to afford mammography, and the diagnosis would have been delayed for 1, 2, even 3 years until they could feel the cancer themselves. They would not have had someone working on their behalf to find treatment for them. And thus, for many of the women, their treatment also would have been substantially delayed.

The program's success is due in large part to a large network of professionals, coalitions and national organizations dedicated to the early detection and treatment of breast and cervical cancer. And you will hear from some of them today. But they include more than 7,000 individuals, who are members of this national network, that work with the State health departments in support of this program.

If we could, I would like to ask you to turn your attention to the maps on mammography use. As Rick described the declines in mortality, I want to show one of the predecessors to that decline. And that is the rapid change in mammography utilization. Here seen in the nineties, the darker States in 1999 are those where over 80 percent of women say that they have had a mammogram in the last 2 years.

And see where we were at the beginning of the nineties, where most States had less than 60 percent of women stating they had a mammogram in the previous 2 years. So there has been a substantial increase in the number of women getting mammography recently.

And we are especially pleased that, in fact, the racial and ethnic disparities that existed early in the nineties have now been reduced substantially.

What is our vision for the future of this? Quite simply, we want no woman to die because she lacked the knowledge, the access, or the finances for mammography screening or whatever test turns out to be more effective in the future. But we have far to go. We currently screen about 12 to 15 percent of the target population of 3.6 million eligible women; that is, women with no health insurance, ages 40 to 64, who are in need of mammography annually.

Identifying and educating and motivating these women, who have rarely or never been screened because of cost and geographic access, is challenging and labor intensive and often, in some communities, becomes a door-to-door, one-on-one campaign.

We know that mammography is not perfect. It misses some cancers. And it finds lumps that are benign that cause women to undergo further tests and needless anxiety. When research determines other methods to be more effective or accurate, we are prepared to move quickly to help women receive the benefits of the new proven screening or diagnostic technologies.

I will tell you one story as an example of what is happening in States around the country. A woman named Beth's husband lost his job after 28 years. Before he lost his job, it provided their health insurance, and she received a mammogram every year. This time she waited 5 years before she got another mammogram. She might never have had another one had she not found out about Vermont's Ladies First program, the screening program there.

She went in for her free mammogram, and it turned out to be none too soon. It showed a lesion that was cancer. The good news is that it was caught early and treated successfully.

Without that Lady's First program and the help to get treatment, though, she also would not have been able to afford treatment. As such, she got her treatment and was able to reduce that financial burden for her and her husband. She credits it with saving her life.

There are many stories like this out there. And while we like to hear them, we are also concerned about the ones we do not hear about, who did not get screening because they did not know about it. And we hope we can reach more of these women and catch their cancer early.

PREPARED STATEMENT

If more research from NIH or elsewhere provides us with something even better than mammography, we will use the CDC-supported programs and community networks to get that science to women as quickly as possible.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF JAMES S. MARKS

Mr. Chairman, members of the committee, I am especially pleased to be here today to talk with you about the Center for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program. Now in its 11th year of providing free mammograms and Pap smears to low-income American women, this program has saved lives, and contributed to the increased awareness of many

American women about the importance of screening and early detection in preventing deaths from cancer.

Today I will talk about why we are so committed to this program, why now is such an important time for this program, and what our vision for the future is.

Recognizing the value of appropriate cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) which enables CDC's National Breast and Cervical Cancer Early Detection Program to provide critical breast and cervical cancer screening services to underserved and uninsured women, including older women, women with low incomes, and women of racial and ethnic minorities. Breast health services are available for women aged 40-64. Appropriations have increased from \$5 million in fiscal year 1990 to approximately \$180 million in fiscal year 2001. There have been great successes and advances in detecting breast and cervical cancers with the help of this program, but challenges remain.

CDC supports early detection programs in all 50 states, six U.S. territories, the District of Columbia, and 12 American Indian and Alaska Native organizations. The program establishes, expands, and improves community-based screening services for women to reduce breast and cervical cancer mortality. The success of the breast and cervical cancer program depends on screening, education and outreach, partnership development, case management, and mechanisms to assure the quality of tests and procedures, all of which, are part of the program.

Through September 2000, more than 3 million screening tests have been provided to more than 1.8 million women. That number includes 1.6 million Pap tests and 1.4 million mammograms. Almost half of these screenings were to minority women, who have traditionally had less access to these services. More than 9,500 women have been diagnosed with breast cancer, more than 40,000 women were diagnosed with precancerous cervical lesions, and 715 women were found to have invasive cervical cancer.

CDC collects data from all funded programs to monitor and evaluate each clinical service program. For each woman enrolled in the program, information is collected on demographic characteristics, mammogram results, breast exams, Pap tests, diagnostic procedures and outcomes, cancer diagnoses, and, for women diagnosed with cancer, information on the onset of treatment.

The program's success is due in part to the dedication of a large network of professionals, coalitions and national organizations devoted to detecting breast and cervical cancer early.

- An estimated 27,000 health professionals are involved in providing breast and cervical cancer screening services to underserved and uninsured women.
- More than 18,000 health educators and outreach workers are educating women on the importance of early detection and helping them access critical screening and follow-up services. Many of these individuals are local employees and volunteers, most of whom are contracted with support from CDC.
- More than 7,000 individuals are now members of a national network of coalitions that have joined together with State health departments in support of this program.

The percentage of women ages 40 and older who reported ever having a mammogram increased from 64 percent in 1989 to 85 percent in 1997, and the percentage of women who reported receiving a mammogram within the previous two years increased from 54 percent in 1989 to 71 percent in 1997. Disparity rates for mammography utilization among most minority groups have either been eliminated or reduced, and overall, there has also been a recent decline in the rate of breast cancer mortality among all women. While much remains to be done, our most recent mortality data reflect that 19.4 women per 100,000 die of breast cancer, surpassing our Healthy People 2000 goal of reducing mortality from 23 to 20.6 women per 100,000.

Please refer to the maps that use CDC Behavioral Risk Factor Surveillance Survey data. These maps show trends in the states reporting women aged 50 years and older who had a recent mammogram in the years 1991, 1995, and 1999. The darker colors have the higher rates of recent mammography utilization. Although this is encouraging news, the maps show that we still have many more women to reach.

Breast and cervical cancers are very serious concerns for American women. During the past decade, almost one-half million women have died of breast and cervical cancer. In 2001, the American Cancer Society estimates that 192,200 women will be diagnosed with breast cancer and 40,600 will die of the disease.

Preventing or curing all cancers is our collective goal. But let me be clear. We know today how to prevent up to 30 percent of all deaths from breast cancer. It is not a new scientific breakthrough; it is mammography. This technology has been around since the late 1970s. Additionally, the Guide to Community Preventive Services has recommended routine mammography screening since the 1980s. Mammog-

raphy is currently the single most effective method for diagnosing breast cancer early. The longer breast cancer remains undetected and untreated, the greater the likelihood it will spread. The five-year survival rate drops from 97 percent when breast cancer is diagnosed at the local stage, to 21 percent when it is detected after having spread.

Mammography, however, is not perfect. According to the Institute of Medicine, routine screening in clinical trials resulted in a 25 to 30 percent decrease in breast cancer mortality among women between the ages of 50 and 70. When research determines other methods to be more effective or accurate, CDC is prepared to move quickly to help women receive the benefits of new proven screening or diagnostic technologies. Our goal is that all women should have access to existing and future detection methods and treatments so that breast cancer could eventually no longer kill so many.

To that end, we are working with the National Cancer Institute and an independent non-Federal Task Force on Community Preventive Services, to develop a *Guide to Community Preventive Services*. This Community Guide provides an in depth review of community health care interventions that are shown to be effective at promoting health and preventing disease. We are examining the community-wide interventions to increase the appropriate use of screening for breast, cervical, and colorectal cancer and the evaluation of the effectiveness of interventions to improve use of cancer screening. The review will be completed within the next 18 months and will be a useful resource to our screening programs in states to guide them on the most effective strategies to increase screening utilization. CDC will also be funding several research projects this year that will be designed to test the effectiveness of interventions to increase use for screening of breast and cervical cancer.

In October 2000, the Breast and Cervical Cancer Treatment Act of 2000 became law. This new law gives states the option of providing full Medicaid benefits to uninsured women who are diagnosed with breast or cervical cancer by the CDC screening program. We commend Congress, this committee, the National Breast Cancer Coalition, and the American Cancer Society for this unprecedented legislation.

Much progress has been made in making the Medicaid option a reality for many women in need of treatment. CDC and the Health Care Financing Administration (HCFA) have developed and distributed the necessary materials and instructions for states to implement this Medicaid optional benefit. On January 4, 2001 a guidance letter was sent to health officials in all 50 states to encourage their participation through the submission of a Medicaid plan amendment. Detailed questions and answers regarding the new benefit have also been provided. CDC and HCFA have hosted conference calls with national organizations, state breast and cervical cancer programs and state Medicaid agencies to encourage all states to consider this Medicaid option. To date, more than half of the States have taken action, including the introduction or enactment of legislation, revision or enactment of regulations, or the submission of revised Medicaid plans. Three States, Maryland, New Hampshire, and West Virginia, have U.S. Department of Health and Human Services (DHHS) approved amended Medicaid Plans; Rhode Island's plan is currently under review. Information about the Medicaid Treatment Act and its progress toward implementation can be located on CDC's Web site: <http://www.cdc.gov/cancer/nbccedp/law106-354.htm> and on the HCFA web site <http://www.hcfa.gov/medicaid/BCCPT/default.htm> and an electronic mailbox BCCPT@HCFA.gov.

What's our vision for the future of the breast and cervical cancer early detection program? Quite simply, we want no woman to die because she lacked knowledge, access or finances for mammography screening. Identifying, educating and motivating women who have rarely or never been screened for breast cancer is an enormous challenge. To be successful in these cases, the outreach efforts of CDC's program in communities often become a door-to-door, one-on-one campaign to reduce community and individual barriers that impede a woman's ability or decision to obtain the lifesaving benefits of early detection. Barriers such as fear, lack of transportation and child care, linguistic and cultural differences, and lack of physician referral are all common hurdles that must be overcome. Many outreach strategies are employed to overcome these barriers.

More and more women every year are reaching the age for regular screening—in fact, every eight seconds a baby-boomer reaches the age of 50—the age when the likelihood of developing breast cancer begins to increase rapidly—and a large number of these women are underserved or uninsured. To date, we have screened 12–15 percent of the target population representing 3.6 million women aged 40–64 in need of mammography services annually.

Let me end by telling you a story. It's Beth's story. Beth's husband David lost his job after 28 years. Before David lost his job, Beth made sure to get a mammogram every year. This time, Beth waited five years before she was checked. She might

never have had another one if she hadn't found out about Ladies First, the Vermont breast and cervical cancer screening program. When Beth went in for her free mammogram, it was none too soon. Beth's mammogram showed a lesion that turned out to be cancer. The good news is that doctors caught Beth's cancer early enough to treat it successfully. With other help from Ladies First, the cancer treatment was not a financial burden for Beth or her husband. Beth credits Ladies First with saving her life.

There are many Beths out there, and we love to hear their stories. But what concerns us most are the women we don't hear about, the women who are not getting regular screening. Awareness of the program isn't the issue; not being screened is. We hope that we can reach more of these women and catch their cancer early. And when research provides us something even better than mammography, we will use the CDC-funded programs to get that science to women as quickly as possible. Thank you.

PROGRESS AGAINST CANCER

Senator SPECTER. Thank you very much, Dr. Marks.

Dr. Klausner, starting with you, it is really very dramatic what you are testifying about today, with the total reevaluation as you analyze breast cancer with the molecular analysis and six different potential causative factors. We are looking for a very, very big increase in NIH funding this year. We are looking at \$3.4 billion.

And there is always a question raised, as to, is the money being wisely used. Are we putting too much money into NIH too fast to have it assimilated? And the other question, which is the corollary, how much progress is being made? And as you know, I make it a practice to ask you for a prognosis as to a cure date.

I realize that it is very difficult. I realize that it is perhaps impossible. But we finally got the researchers in Parkinson's to give us a five-year time interval. And to the extent that you can make a projection, it is very helpful to us on the subcommittee to carry the day for this very substantial increase in funding, if we are able to give some indication as to when there might be a cure.

Dr. KLAUSNER. Yes. I think we are going to have—

Senator SPECTER. This week in Philadelphia it is the Race for the Cure.

Dr. KLAUSNER. Right. I think—

Senator SPECTER. So what do you think?

Dr. KLAUSNER [continuing]. We are going to have cures, but I think there are going to be numerous cures. They are going to have to be aligned to the different types of diseases, as I have shown you. A date, as you know, is very hard to say. What I can say is that what is lined up at the starting gate, which is what I showed you, for the first time are the types of drugs and the types of targets that will give us the cure.

What is limiting the time, or knowing the time that we will have the answers about these is how many, how quickly, get out of the laboratory and into clinical trials. That is limited right now not by whether we have the targets, or whether we are beginning to have the drugs, but in fact by funding.

My feeling is—

Senator SPECTER. Are you saying that you could use even more funding—

Dr. KLAUSNER. Yes.

Senator SPECTER [continuing]. Wisely?

Dr. KLAUSNER. Yes. I mean—

Senator SPECTER. If you had your absolute druthers, what would the figure be?

Dr. KLAUSNER. In our strategic plan, where we know exactly what is coming in and exactly what our priorities say we want to fund, we have already produced a budget for NCI, as we are legally required to do, requiring a 20-percent increase over fiscal year 2001 in order to make sure that the pipeline I have shown you that is ready to be filled is filled.

Senator SPECTER. A 20-percent increase?

Dr. KLAUSNER. Yes.

Senator SPECTER. What do you project you would get if our figure of \$3.4 billion increase for NIH is finally approved?

Dr. KLAUSNER. An 11.8-percent increase.

Senator SPECTER. Can you give the subcommittee some specification as to where you would use that extra money?

Dr. KLAUSNER. Absolutely. Would you want me to do that in writing, or would you like that—

Senator SPECTER. Oh, I think you had better do it in writing because of the time limitation.

Dr. KLAUSNER. Yes. We are happy to do that.

Senator SPECTER. That would be very helpful. And if you could amplify in writing your projection as to the results that you would anticipate. This is a three-part writing. Number one, what have you been able to do with the existing increases? Two, what will you be able to do with an 11-percent increase? And three, what will you be able to do with a 20-percent increase?

Dr. KLAUSNER. Yes, sir.

Senator SPECTER. Dr. Marks, the Centers for Disease Control is an enormously important institution. But it has not gotten nearly the kind of attention that the National Institute of Health has. And I think something needs to be done to elevate the public perception there. I had heard about how bad the physical facilities were in Atlanta and finally decided to make a trip there last year and was shocked to see how bad they were.

And that picture had never been adequately presented to the subcommittee. We just had never known really how bad it was. So we added the \$170 million to your budget last year, looking for a long-range plan in excess of \$1 billion. While it is not directly on this point, I would be interested—well, it is directly on this point, because if you do not have an adequate physical plant, you cannot conduct your work on breast cancer.

What are your needs and how badly are you hurt by the current state of deterioration?

Dr. MARKS. The CDC's long-range plan for fixing its physical plant is, as you stated, about \$1 billion over a 5- to 10-year period of time. And with the monies that you supported and the Senate supported last year, that plan is well under way, especially in building on the Clifton Road complex, but also on the complex that is out in Chamblee. CDC currently has, in addition, 22 sites around Atlanta, mostly of rental space. And you saw specifically the situation in the laboratories, where, quite clearly, using World War II quonset huts as the labs is affecting the quality of that work.

Senator SPECTER. And that has impacted on your work on breast cancer, among others.

Dr. MARKS. It impacts all of our work. It impacts our work in several ways. One is that in some of the concerns that States have around potential environmental causes, those labs work on those. The other is that being spread out—in fact, much of the synergy that might occur between programs, in fact, is blocked—

Senator SPECTER. Let me interrupt you at that point—

Dr. MARKS. Sure.

Senator SPECTER [continuing]. And ask you to supplement it in writing.

Dr. MARKS. Sure.

Senator SPECTER. Let me ask you now about the mammography. We had a big controversy not too long ago as to whether there should be mammograms for women between 40 and 50. And this subcommittee took a very forceful position that those mammo-grams ought to continue. And we were accused of being political.

I had a hard time understanding that accusation. I do understand it sometimes. But I had a little trouble there. And I thought that if priorities were to be set, they ought to be set by the Congress as to where we wanted to spend the money.

Dr. Marks, what is your view of the importance of mammograms for women between 40 and 50?

Dr. MARKS. You know what the science has said, the consensus conference that came out of NIH. We believe that the data is becoming increasingly strong that mammography at those ages finds cancer early, that it can save lives. And in our program we support the States screening women in those ages.

That was not the case at the beginning of the decade, when the recommendations were for women 50 and older. But it is the case now. And we are seeing those screening rates go up.

Senator SPECTER. And one final question, on the issue of racial and ethnic differences, you say they are lesser now. How much differences are there on racial and ethnic lines?

Dr. MARKS. There still remains substantial differences in mortality rates by race. What we are seeing, though, is that the screening rates have narrowed substantially. And they appear to have been eliminated for African-Americans and for Asian-Americans. There are still some differences—

Senator SPECTER. I am going to have to go vote right now, because there is just a few minutes left on the vote. Actually no time, but we have a grace period of 5 minutes, which it will take me to get to the floor. But I would be interested to know what differentials are and what you would need to correct those.

Dr. MARKS. That would be fine.

Senator SPECTER. Okay. We will recess now, and I will be back just as soon as I can. Thank you.

Dr. MARKS. Thank you very much.

Senator SPECTER. The hearing of the Subcommittee on Labor, Health, Human Services and Education will continue. And after hearing from our distinguished ranking member, we will turn to panel number two.

Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

Senator SPECTER. Before you had arrived, I was excessively laudatory about you.

Senator HARKIN. Maybe I should not say anything.

Senator SPECTER. Well, it would be hard to improve your position over where it is now, but that never stops any of us from trying.

Senator HARKIN. We are in the Senate, are we not?

OPENING STATEMENT OF SENATOR TOM HARKIN

Thank you, Mr. Chairman, for calling this hearing and for your many years of dedication and leadership on this issue that means so much to all of us and some of us, perhaps, more poignantly than others.

As many of you know, both of my sisters, my only two sisters, both died of breast cancer at quite an early age. I often think that if they had had access to better screening and better care and earlier interventions, they would have lived much longer and still be alive today.

So I have often thought that we had to declare a war on breast cancer. We have come a long way, come a long way in the last 10 years or more. But we are still not there yet. We have to continue our efforts.

About a decade ago, when we first looked at this issue and how much money was going into research, I found that only about \$90 million was going into breast cancer. And so with the help of many of you in this room—and I see a lot of familiar faces from that battle of, well, it will be almost a decade ago now, when we offered the amendment to take \$210 million from the Defense Department budget and put it into breast cancer research, we did that.

I also want to publicly thank a member of our committee who is not here, but who was singularly also responsible for helping make that happen and to make sure that we have kept that in every year. We have maintained the funding at DOD every year. It doubled the funding for breast cancer research. And without the help of Senator Inouye from Hawaii, who serves both on this subcommittee and on the Defense Appropriations Subcommittee, I do not think that would have been possible. So I want to publicly thank Senator Inouye for his help in this effort.

This year I am proud to say that between DOD and NIH the Federal Government will invest about \$600 million on finding a cure or improving therapy for breast cancer. Again, this tremendous increase in a relatively short period of time is due in large part to the tremendous work of women across the country who have become activists and who have demanded actions.

As I said to a friend, it is not timidity that gets you anything around this joint. And I am glad that you are not timid.

But our investments are beginning to pay off through the National Cancer Institute. And I am sorry I missed Dr. Klausner's presentation earlier, but I am delighted that he is here, because he also has been in the forefront of ensuring that we get funds and the focus on breast cancer research.

Researchers are making exciting discoveries about prevention, detection, diagnosis, treatment and control. We know better than ever before how a healthy cell becomes cancerous, how it spreads, why some breast cancer tumors are more aggressive than others, why some women suffer more severely than others.

The discovery of the BRCA1 gene has led us to better identify women who are risk of breast cancer so the disease can be caught early and treated. Of course, the development of cancer-fighting drugs, like Tamoxifen, owe a great deal to our Federal research investment.

But again, building our research enterprise would be pointless if breakthroughs in diagnosis, treatment and cures are not available to patients. And hopefully, we are making progress on that front. About a decade ago, we added mammography screening as a Medicare benefit. And this subcommittee began funding a nationwide breast and cervical cancer screening effort for younger women who do not have insurance coverage. This initiative, which is run by the Centers for Disease Control and Prevention, has been a great success.

To date, in just a decade, more than 1 million low income American women have been screened, 9,000 in my own State of Iowa. So we are making progress. But as I said, this is an ongoing war, and we cannot let up now. We have to dedicate our resources, both on the research end and the outreach end, to make sure that we win this war.

Mr. Chairman, I am pleased that we have such a distinguished panel of guests with us this morning. I especially want to extend a special welcome to Christine Carpenter, who is visiting here from Peter Falls, Iowa. Her courage as a breast cancer survivor is matched only by the courage she shows as a breast cancer activist.

I am glad you are that. So I welcome you, Christine, and I welcome all of you to this hearing.

And again, Mr. Chairman, thank you for your leadership and your steadfastness in making sure we have the funds to continue our research and our outreach prevention programs, detection programs, at the Centers for Disease Control and Prevention.

Senator SPECTER. Thank you very much, Senator Harkin.

We have a very distinguished panel. Senator Harkin called special attention to Ms. Carpenter, an Iowan. And I similarly call special attention to Ms. Fran Visco, a Pennsylvanian.

It is always hard with a panel of this quality to know what the order of sequence should be. So that is solved by Bettilou Taylor, the clerk of this subcommittee, who alphabetizes.

So we have not shown any undue preference for Pennsylvania or Iowa. So you know what we are thinking about.

We turn now to Ms. Nancy Brinker, who is founder of the Susan Komen Breast Cancer Foundation, which she started 20 years ago in memory of her sister Susie, who died of the disease. To date, this foundation has raised over \$300 million to further research, education and treatment of breast cancer. She has served on numerous boards and advisory panels and is the recipient of numerous awards, including the Champions of Excellence Award presented by the CDC, Ladies Home Journal's 100 Most Powerful Women of the 20th Century, and Biography Magazine's 10 Most Powerful Women in America.

And although it is not on her introduction, I am sure the next group will classify her in the 10 most prominent women of some other group, if not the most powerful.

Nancy, the floor is yours.

STATEMENT OF NANCY G. BRINKER, FOUNDING CHAIRMAN, SUSAN G. KOMEN BREAST CANCER FOUNDATION

Ms. BRINKER. Thank you, Mr. Chairman, very much for that kind introduction.

And thank you, Senator Harkin and distinguished members of the subcommittee, for your enduring commitment to our cause. We do so appreciate it.

Many of you have been long-time supporters of the Komen Foundation and Race for the Cure. And I am here to thank you. And I am also pleased to be joined today by the chair elect of the Komen Foundation, Dr. Lasalle Leffall, who will also have a few brief remarks.

But I am here today neither as a physician nor researcher, but as a patient advocate and a breast cancer survivor myself. I began the Komen Foundation, as you pointed out, Mr. Chairman, when my older sister, Susie, died of the disease in 1980 at the age of 36. We did not start with much, a few hundred dollars, some friends, and a lot of will. But we had something more important. We had a mission. And it was to eradicate breast cancer as a life-threatening disease.

And to achieve that goal, we had to change both the clinical and the cultural environment in this country. And we have. The Komen Foundation has become the largest private funder of breast cancer research in America, expanded knowledge of biology, new treatment regimes, better screening and diagnostics techniques and public education and outreach, they have all improved the outlook for many women and are responsible for declining breast cancer rates.

Among women in the United States, the death rate from breast cancers have been decreasing by about 2 percent annually, suggesting that the awareness, early detection, and improved therapy are indeed having an impact.

When the Komen Foundation was first established, the Federal Government, as you pointed out, Mr. Chairman, was only beginning to recognize the importance of funding research. And as Federal funding has increased, strong public-private partnerships have produced real clinical results and a better quality of life for thousands of women and men. And the Komen Foundation and my colleagues, I am proud of them all, have forged many of these public-private partnerships. We have awarded more than \$68 million in grants for innovative research.

These grants often leverage Federal research dollars and enable world-class scientists in some of the Nation's most prestigious research organizations to investigate new ideas and advance research. But until a cure is found, the Komen Foundation believes that we must do everything within our power to promote the life-saving message of early detection and appropriate high-quality treatment.

Our public awareness efforts are crucial to our mission. And our grassroots approach has achieved extraordinary results. There are 118 affiliates across the country and abroad. We identify local community needs and fund non-duplicative education screening and treatment programs to meet these needs.

And thanks to innovative research, what we now know about breast cancer is at an all-time high. And the push for research and development of new technologies and therapies continues. However, while our knowledge base is rapidly increasing, the gap between what the scientific community knows and what women and men in their own communities receive is widening. The Komen Foundation is committed to closing this gap. We believe that to eradicate this disease we must not only invest in research and a cure for future generations, but we must meet the immediate needs of women and their families facing the disease today.

Whether it is cutting-edge research, grassroots education, screening or treatment, our progress at Komen and as a society is simply not possible without significant government support. We have dedicated millions of our own volunteer hours and privately raised dollars. But I assure you that we will continue our mission. But I must also emphasize that we know that we are not in this alone, and we need your help, your continued help.

I urge Congress and the President to increase funding for the National Cancer Institute for fiscal year 2002 to \$5 billion and expand funding for the NIH by 16.7 percent over the fiscal year 2001 level. The NIH increase is necessary to keep on track with the commitment of Congress to double the NIH budget between fiscal year 1999 and fiscal year 2003. I assure you that we will continue to add value to your investment.

And we need continued strong Federal support for the National Breast and Cervical Cancer Early Detection Program. This program provides screening, outreach and case management services to high-risk, low income women in all 50 States. To date, over 1 million women have been screened and thousands have been diagnosed. Yet because of current funding limitations, the program only reaches approximately 15 percent of all eligible women.

To ensure that many of this Nation's low income women are served, we urge an increase in Federal funding to a level of at least \$210 million.

PREPARED STATEMENT

And finally, we urge you to work with us as we explore and conquer the economic, cultural and knowledge barriers to bringing the fruits of scientific progress to the patients who desperately need them. We have made significant strides. I believe we are on the edge of real breakthrough that can save more and more lives. But we must have the funding to go the last mile in this race for the cure. We must close the gap between what we know about breast cancer and the care that we deliver. I assure you that the Komen Foundation will continue its commitment to closing this gap.

Thank you for this opportunity.

[The statement follows:]

PREPARED STATEMENT OF NANCY G. BRINKER

Chairman Specter, Senator Harkin and distinguished Members of the Subcommittee, thank you for the opportunity to testify on the state of breast cancer today and for bringing attention to this very important issue.

I am here today neither as a doctor nor a researcher, but as a patient advocate of more than twenty years. I began the Susan G. Komen Breast Cancer Foundation in 1982 after my older sister, Suzy Komen, died of breast cancer at the age of 36.

We didn't start with much—a few hundred dollars, an office in my home, and a few friends. But we had something more important—a mission—to eradicate breast cancer as a life-threatening disease. To achieve that goal, we had to change both the clinical and cultural landscape of breast cancer, and we have.

Today, the Komen Foundation has become the largest private funder of breast cancer research in America. Expanded knowledge of biology, new treatment regimens, better screening and diagnostic techniques and public education and outreach have improved the outlook for many women and are responsible for declining breast cancer rates. Among women in the United States, the death rate from breast cancer has been decreasing by about 2 percent annually over the past decade, suggesting that public awareness, early detection and improved therapy are having an impact on the disease.

When the Komen Foundation was established, the federal government was only beginning to recognize the importance of funding research. As federal funding for breast cancer research has increased, strong public-private partnerships have produced real clinical results and a better quality of life for thousands of women and men living with breast cancer.

The Komen Foundation has forged many of these public-private partnerships. We have awarded over \$68 million in grants for innovative research. These grants often leverage federal research dollars and enable world-class scientists in some of the nation's most prestigious research institutions to investigate exciting new ideas that advance breast cancer research.

Until a cure for breast cancer is found, the Komen Foundation believes that we must do everything within our power to promote the life-saving message of early detection and treatment. Our public awareness efforts are crucial to our mission, and our grassroots approach has achieved extraordinary results. Through 118 Affiliates across this country and abroad, we identify local community needs and fund non-duplicative education, screening and treatment programs to meet those needs.

Thanks to innovative research, what we now know about breast cancer is at an all time high; and the push for research and development of new technologies and therapies continues. However, while our knowledge base is rapidly increasing, the gap between what the scientific community knows, and what women and men in their own communities receive, is widening. The Komen Foundation is committed to closing this gap. We believe that to eradicate breast cancer as a life-threatening disease, we must not only invest in research for a cure for future generations, but we must meet the immediate needs of women and their families facing the disease today.

Meeting those needs will require greater access to current technologies and innovative therapies, particularly in medically underserved communities. Quality care can only be assured if all cancer patients are guaranteed medically appropriate and timely access to specialists and specialized treatment.

And we must also ensure adequate levels of reimbursement of new and existing technologies and therapies by private and public third party payers, so that the delivery of quality care and the dissemination of the results of our cutting edge research and development are not compromised.

The Komen Foundation's commitment to the delivery of quality care is steadfast. Through a landmark research study, the Komen Foundation has joined the American Society of Clinical Oncology (ASCO), Harvard School of Public Health and the Rand Corporation to address the serious lack of information about the quality of care cancer patients receive.

We want to know if patients are getting appropriate screenings and timely diagnoses; if physicians are accessible; if we are effectively managing pain; if patients are getting the full recommended dose of chemotherapy or radiation therapy; and how long it takes to get referred to a specialist. We also want to know if patients are given the option to participate in a clinical trial, a key to advancing new cancer therapies. And we want to know what is there for all patients, or only some.

Whether it's cutting-edge research, grassroots education, screening, or treatment programs, our progress at the Komen Foundation and as a society is simply not possible without significant government support. The Komen Foundation has dedicated millions of our own volunteer hours and privately raised dollars towards eradicating breast cancer as a life-threatening disease. I assure you that we will continue our mission, but I must also emphasize that we know we are not in this alone. We need your help.

I urge Congress and the President to increase funding for the National Cancer Institute (NCI) for fiscal year 2002 to five (5) billion dollars and expand funding for the National Institutes of Health (NIH) by 16.7 percent over the fiscal year 2001 level. The NIH increase is necessary to keep on track with the commitment of Congress to double the NIH budget between fiscal year 1999 and fiscal year 2003. I as-

sure you that the Komen Foundation will continue to look to add value to your investment.

And we need continued strong federal support for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). I was very disappointed to learn of the Administration's proposed budget cuts to this life-saving program. This program provides screening, outreach and case-management services to assist high-risk, low-income women in all fifty states, who otherwise do not have access to health care. To date, over one million women have been screened, and thousands of breast and cervical cancers have been diagnosed. Yet, because of current funding limitations, the program only reaches approximately 15 percent of all eligible women. To ensure that many more of this nation's low-income, medically-under-served women have access to this life-saving program, the Komen Foundation urges an increase in federal funding to a level of at least \$210 million. Komen is fighting hard for this increase in funding, and I hope you will join with us.

And finally, we urge you to work with us as we explore and conquer the economic, cultural, and knowledge barriers to bringing the fruits of scientific progress to the patients who so desperately need them.

We have made significant strides in the war against breast cancer. I believe we are on the edge of real breakthroughs that could save thousands of lives, but we must have the funding to go the last mile, and we must close the gap between what we know about breast cancer and what care we deliver. I assure you that the Komen Foundation will continue its commitment to closing this gap.

Thank you very much.

Senator SPECTER. Thank you very much, Ms. Brinker.

STATEMENT OF CHRISTINE CARPENTER, MEMBER, NATIONAL BREAST CANCER COALITION

Senator SPECTER. We turn now to Ms. Christine Carpenter, a school psychologist from Cedar Falls, Iowa, diagnosed with breast cancer in 1993 at the age of 45. She is the founder and president of an Iowa breast cancer education and advocacy group. She received her master's degree in education with administration from Illinois State University, a master's degree in human psychological services from Bradley, and a bachelor's degree in special education from the University of Northern Iowa.

Welcome, Ms. Carpenter, and we look forward to your testimony.

Ms. CARPENTER. Thank you. Good morning. My name is Christine Carpenter, and I am from Cedar Falls.

I am a 7-year breast cancer survivor, and I am also a mother, a wife, a school psychologist, and a member of the National Breast Cancer Coalition.

Thank you, Chairman Specter, members of the committee, and especially Senator Harkin, for your leadership and work on the issue of breast cancer. It is an honor to have the opportunity to testify today.

When I was diagnosed with breast cancer in 1993 at the age of 45, I did not think I would live to see my daughter, who was 14 at the time, graduate from high school. I am thrilled that I have lived long enough to attend her college graduation this month.

Although 7½ years have passed since my breast cancer diagnosis, there is not a day that goes by that I do not fear for the future. I am haunted by studies showing that more than half of the women diagnosed with invasive breast cancer die within 20 years.

Breast cancer came as a shock. I had always been healthy, ate right, exercised regularly, never smoked, rarely drank alcohol. I was vigilant about doing monthly breast self-exams and had yearly mammograms. I had even breast-fed my daughter for several years. And I had no significant family history of breast cancer. So how could this happen to me?

After doing a self-breast exam and feeling a lump, I was relieved when a mammogram showed nothing. But then a later biopsy confirmed breast cancer. I had been diagnosed with a disease for which there is no known cause, no prevention, no foolproof way of detecting, and no cure.

In the fall of 1993, I began my breast cancer treatment. I had a modified radical mastectomy and 6 months of chemotherapy. I got intravenous injections that made me feel tired and agitated. My whole body hurt. I lost my hair.

I had to take pills to counter the side effects of the side effects of medication. I felt shock, grief, and depression about what was happening to me. There were moments during my treatment when I was in such physical and emotional misery that death looked appealing. However, I would look to my loving family and realize that for them I had to get through this.

Following my treatment, I started to consider how many across the country were going through the same thing I was going through. I also thought about all the women who will go through this, but do not even know it yet. And I thought about my own daughter and realized that I must do something to end this disease.

In 1997 I gathered a small but mighty group of women in the Cedar Falls/Waterloo area. And together we created Iowa Breast Cancer Edu-Action, an education and advocacy group. Our first mission was to help women diagnosed with breast cancer make decisions about how to receive quality health care. With the distribution of 7,000 free copies of the Iowa Breast Cancer Resource Guide, our goal was to begin to empower Iowa women and men and help them seek the best possible treatment and healing. And empower them we did.

We joined forces with others and created an all Iowa network to advocate for the prevention and cure for breast cancer. At the same time, we joined more than 500 other organizations and tens of thousands of individuals and became members of the National Breast Cancer Coalition.

My participation in breast cancer activism has helped me to heal. It has also helped me channel my own fear and anger into advocacy and action. And perhaps most importantly, it has made me realize that we must not stop fighting until we have eradicated this disease.

Fortunately I am not alone in my determination. The momentum across the country around this issue is extraordinary. Women and their families affected by this disease have refused to take no for an answer. They have demanded that more continue to be done until we have a cure for this disease.

Just yesterday I was reminded of this incredible passion and power as I walked the halls of Congress with nearly 600 activists in town to advocate for the National Breast Cancer Coalition's agenda. We urged our senators and representatives to increase funding for peer-reviewed research, to increase access to high-quality treatment for all women diagnosed with breast cancer, and to ensure that breast cancer advocates have a seat at the table where decisions about breast cancer are made.

I urge you, Chairman Specter and Senator Harkin and members of the committee, please continue to make funding for breast cancer research a priority.

PREPARED STATEMENT

With your continued support, perhaps we will be able to answer the question of why, when someone is diagnosed with breast cancer. Perhaps we will be able to prevent another woman from getting it in the first place. And perhaps, if the research moves quickly enough, then I will be around to watch my daughter grow into a woman.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF CHRISTINE CARPENTER

Good morning. My name is Christine Carpenter, and I am from Cedar Falls Iowa. I am a 7-year breast cancer survivor. I am also a mother, a wife, a school psychologist, and a member of the National Breast Cancer Coalition.

Thank you, Chairman Specter, members of the Committee, and especially Senator Harkin, for your leadership and work on the issue of breast cancer. It is an honor to have the opportunity to testify today.

When I was diagnosed with breast cancer in 1993 at the age of 45, I did not think I would live to see my daughter, who was fourteen at the time, graduate from high school. I am thrilled that I lived long enough to attend her college graduation this month. Although seven and a half years have passed since my breast cancer diagnosis, there is not a day that goes by that I don't fear for the future. I am haunted by studies showing that more than half of the woman diagnosed with invasive breast cancer die within twenty years.

Breast cancer came as a shock. I had always been healthy—ate right, exercised regularly, never smoked, rarely drank alcohol. I was vigilant about doing monthly breast self-exams and had yearly mammograms. I had even breast fed my daughter for several years. And, I had no significant family history of breast cancer. So how could this happen to me?

After doing a self-breast exam and feeling a lump, I was relieved when a mammogram showed nothing. But then, a later biopsy confirmed breast cancer. I had been diagnosed with a disease for which there is no known cause, no prevention, no fool proof way of detecting, and no cure.

In the fall of 1993, I began my breast cancer treatment. I had a modified radical mastectomy, and six months of chemotherapy. I got intravenous injections that made me feel tired, achy and agitated. My whole body hurt. I lost my hair. I had to take pills to counter the side effects of the side effects medication. I felt shock, grief and depression about what was happening to me. There were moments during my treatment when I was in such physical and emotional misery that death looked appealing. However, I would look to my loving family and realize that for them, I had to get through this.

Following my treatment, I started to consider how many women across the country were going through the same thing as I was going through. I also thought of all the women who will go through this—but don't even know it yet. And I thought about my own daughter, and realized that I must do something to help ensure and end to this disease.

It 1997, I gathered a small but mighty group of women in the Cedar Falls/Waterloo area and together we created the Iowa Breast Cancer Edu-action, an education and advocacy group. Our first mission was to help women who had been diagnosed with breast cancer make decisions about how to receive quality health care. With the distribution of 7,000 free copies of our Breast Cancer Resource Guide, our goal was to begin to empower Iowa women and men, and help them seek the best possible treatment and healing.

And empower them we did.

In a few short years, we joined forces with others and created an all Iowa network to advocate for the prevention and cure for breast cancer. At the same time, we joined more than 500 other organizations and tens of thousands of individuals and became members of the National Breast Cancer Coalition.

My participation in breast cancer activism has helped me to heal. It has also helped me to channel my own fear and anger into advocacy and action. And, per-

haps most importantly, it has made me realize that we must not stop fighting until we have eradicated this disease.

Fortunately, I am not alone in my determination. The momentum across the country around this issue is extraordinary. Women and their families who have been affected by this disease have refused to take “no” for an answer. They have demanded that more continue to be done until we have a cure for this disease.

Just yesterday, I was reminded of this incredible passion and power as I walked the halls of Congress with nearly six hundred activists in town to advocate for the National Breast Cancer Coalition’s agenda. We urged our Senators and Representatives to increase funding for peer reviewed research, to increase access to high quality treatment for all women diagnosed with breast cancer, and to ensure that breast cancer advocates have a seat at the table where decisions about breast cancer are made.

I urge you, Chairman Specter and Senator Harkin—and members of the Committee—please continue to make funding for breast cancer research a priority. With your continued support, perhaps we will be able to answer the question “why” when someone is diagnosed with breast cancer. Perhaps we will be able to prevent another woman from getting it in the first place. And perhaps, if the research moves quickly enough, then I will be around to watch my daughter grow into a woman.

Senator SPECTER. Thank you very much, Ms. Carpenter, for sharing those very personal insights with us. We appreciate it very much.

STATEMENT OF PERI GILPIN, ACTRESS AND BREAST CANCER ADVOCATE, MEMBER, NATIONAL BREAST CANCER COALITION

Senator SPECTER. We turn now to Ms. Peri Gilpin, who has appeared on numerous television and theater productions, but is best known for her role as Roz Doyle in the NBC series “Frazier.” She is a member of the National Breast Cancer Coalition.

Along with “Frazier” co-star Jane Leeves, she has started a production company, Crystal Cities, where they are developing film and television projects. She studied drama at the University of Texas and the British-American Academy in London.

Welcome, Ms. Gilpin, and we look forward to your testimony.

Ms. GILPIN. Thank you.

Senator SPECTER. And just remember, you are being televised.

Ms. GILPIN. Thank you. As if I was not nervous enough.

Thank you very much for the opportunity to testify before the Senate Labor, Health and Human Services Subcommittee today. My name is Peri Gilpin, and I am a wife, an actress, and the daughter of a wonderful woman who died of cancer. I am also a proud breast cancer advocate and a member of the National Breast Cancer Coalition.

I want to begin by thanking, Chairman Specter and Senator Harkin and other members of this committee, for your outstanding commitment to the fight against breast cancer. Under your leadership and through the tireless work of breast cancer advocates like the women and men who make up the National Breast Cancer Coalition, breast cancer research funding has been significantly increased in the last decade.

Because of your unyielding commitment to furthering this critical research, developments in the past few years have begun to offer real hope that we will soon eradicate this disease. And now is the time to continue the investment you have made.

I am very pleased to be here on behalf of the millions of women who are living with breast cancer, or who are at risk for this deadly disease. As the daughter of a woman who died of cancer, I am also grateful for the opportunity to testify on behalf of families like

mine, whose lives are tragically forever changed by the ravages of this disease.

Yesterday I had the unique opportunity to spend the day on Capitol Hill with hundreds of extraordinary women, most of them breast cancer survivors and their families, to lobby Members of Congress on the National Breast Cancer Coalition's legislative agenda. Their spirit, focus and determination are incredible. And their sophisticated understanding of the NBCC's legislative agenda spoke to their commitment to furthering substantive breast cancer policy.

Their dedication represents the unbelievable momentum from all across the country to eradicate breast cancer. Not only was I empowered by their commitment and strength, but it reinforced my belief that breast cancer is not just a medical issue, but a political issue. My participation in the advocacy efforts of the coalition is teaching me what an incredible impact grassroots advocacy can have on an issue.

The work of these vibrant individuals has not just led to an increase in breast cancer research funding, but it has helped to ensure that more women have access to high-quality breast cancer treatment and a seat at the table where important decisions about breast cancer are made.

It is my belief that the grassroots advocates of the National Breast Cancer Coalition have been successful not only because of their passion and determination, but also because they refuse to accept that things have to remain the same. They are willing to fight the status quo and envision a new way of doing things. That is why they have been able to bring about vast increases in breast cancer funding. That is why they have been successful in increasing access to quality care for women diagnosed with breast cancer, and that is why, together with your support, they are going to be successful in eradicating this disease.

My mother would have loved to have been a member of the National Breast Cancer Coalition and to have participated in these advocacy activities. As she battled her illness, she advocated for a higher quality of care and for a meaningful role in the decisions regarding her treatment.

Unfortunately, my mother had to suffer not only through her illness, but also through a lack of information and mis-information that affected the quality of her treatment. I know my mom would have enthusiastically joined NBCC advocates to fight for a change in the system. She would have been in the front of the line to advocate for a higher quality of care and for answers about how to cure her disease and how to make sure others would not have to suffer through what she was going through.

I will never forget a story my mom and dad told me about a meeting with one of their physicians. The doctor had very solemnly told my mother that her radiology report looked very bad and that she probably only had 6 months to live. My parents were shocked by the doctor's remark. And they told him that it did not make any sense. Fortunately, they were very much on top of her care, and they pulled out a more recent report and said to him, "Look at this report. It does not say that at all."

And the doctor looked and said, "Oh, I am sorry. I must have been looking at an old report. You are right. This one looks pretty good."

The National Breast Cancer Coalition has given women like my mother a place to channel their determination, frustration and fear into advocacy and action. It has empowered them to be their own advocates and to have the courage to keep fighting so that others will not have to suffer what they are suffering. And it has given hope and emotional support to millions of women around the country who realize that they are not alone. Most importantly, these efforts have resulted in substantial change in breast cancer care.

Even though I am sad that my mother cannot be here today to thank you in person for your commitment to increasing critical breast cancer research, and even though she is not here to pound the pavement with other women like her, who have come to Capitol Hill to demand that Congress work with them to eradicate this disease, I am proud to be here on her behalf and in her memory.

PREPARED STATEMENT

I am here also so that we do not leave the legacy of this disease for yet another generation. I urge you not to give up on your commitment to ending this disease and to continue your important work with the National Breast Cancer Coalition to enact substantive breast cancer policy which will move us forward to prevent any more mothers, daughters, wives, or friends from losing their battle with cancer.

Thank you very much for the opportunity to testify today.
[The statement follows:]

PREPARED STATEMENT OF PERI GILPIN

Thank you for the opportunity to testify before the Senate Labor Health and Human Services Subcommittee today.

I am Peri Gilpin, and I am a wife, an actress, and the daughter of someone who died of cancer. I am also a proud breast cancer advocate and a member of the National Breast Cancer Coalition.

I want to begin by thanking you, Chairman Specter, Senator Harkin, and other members of this Committee, for your outstanding commitment to the fight against breast cancer. Under your leadership, and through the tireless work of breast cancer advocates like the women and men who make up the National Breast Cancer Coalition, breast cancer research funding has been significantly increased in the last decade. Because of your unyielding commitment to furthering this critical research, developments in the past few years have begun to offer real hope that we will soon eradicate this disease. Now is the time to continue the investment that you have made.

I am very pleased to be here on behalf of the millions of women who are living with breast cancer, or who are at risk for this deadly disease. As the daughter of a woman who died of cancer, I am also grateful for the opportunity to testify on behalf of families like mine whose lives are forever changed by this type of tragedy.

Yesterday, I had the unique opportunity to spend the day on Capitol Hill with hundreds of extraordinary women—most of them breast cancer survivors—and their families, to lobby Members of Congress on the National Breast Cancer Coalition's legislative agenda. Their spirit, focus and determination are incredible, and their sophisticated understanding of NBCC's legislative agenda spoke to their commitment to furthering substantive breast cancer policy. Their dedication represents the unbelievable momentum from all across the country to eradicate this deadly disease.

Not only was I empowered by their commitment and strength, but it reinforced my belief that breast cancer is not just a medical issue, but that it is also a political issue. My participation in the advocacy efforts of the Coalition is teaching me what an incredible impact grassroots advocacy can have on an issue. The work of these tireless individuals has not just led to an increase in breast cancer research funding,

but it has helped to ensure that more women have access to high quality breast cancer treatment and a seat at the table where important decisions about breast cancer are made.

It is my belief that the grassroots advocates of the National Breast Cancer Coalition have been successful not only because of their passion and determination, but also because they refuse to accept that things have to remain the same. They are willing to fight the status quo, and envision a new way of doing things. That is why they have been able to bring about vast increases in breast cancer funding. That is why they have been successful in increasing access to quality care for women diagnosed with breast cancer. That is why, together with your support, they are going to be successful in eradicating this disease.

My mother would have loved to have been a member of the National Breast Cancer Coalition, and participated in these advocacy activities. As she battled her illness, she advocated for a higher quality of care, and for a meaningful role in the decisions regarding her treatment. Unfortunately, my mother had to suffer not only through her illness, but also through a lack of information and misinformation that affected the quality of her treatment. I know my mother would have enthusiastically joined NBCC advocates to fight for a change in the system—to advocate for a higher quality of care—and for answers about how to cure her disease, and how to make sure others wouldn't have to suffer through what she was going through.

I will never forget the time my mother and father told me about their meeting with my mother's physician. The doctor, very solemn, told my mother that her radiology report looked very bad, and that she probably had only six months to live. My parents, shocked by the doctor's remark, told him that didn't make any sense. They were very much on top of her care, pulled out a very recent report and said to him: "Look at this report! It doesn't say that at all!" The doctor looked, and said, "Oh, I'm sorry, I must have been looking at an old report. Yes, you're right, this one looks great."

The National Breast Cancer Coalition has given women, like my mother, a place to channel their determination, frustration and fear into advocacy and action. It has empowered them to be their own advocates, and to have the courage to keep fighting so that others will not have to suffer what they are suffering. And, it has given hope and emotional support to millions of women around the country who realize that, they are not alone. Most importantly, these efforts have resulted in substantial change in breast cancer care.

Even though I am sad that my mother can't be here today to thank you in person for your commitment to increasing critical breast cancer research; and even though she is not here to pound the pavement with women like her—who have come to Capitol Hill to demand that Congress work with them to eradicate this disease—I am proud to be here on her behalf, and in her memory. I am also here so that we do not leave the legacy of this disease for another generation. I urge you not to give up on your commitment to ending this disease, and to continue your important work with the National Breast Cancer Coalition to enact substantive breast cancer policy which will move us forward to prevent any more mothers, daughters, wives or friends from losing their battle with breast cancer.

Thank you very much for the opportunity to testify today.

Senator SPECTER. Thank you very much, Ms. Gilpin.

It is very important to hear from daughters, sisters, as Ms. Brinker testified, and Ms. Carpenter, a breast cancer survivor herself, to give greater insight into the issue and to aware the public, which will be seeing this through the courtesy of C-SPAN.

STATEMENT OF LaSALLE D. LEFFALL, JR., M.D., F.A.C.S., CHAIRMAN-ELECT OF THE SUSAN G. KOMEN BREAST CANCER FOUNDATION

Senator SPECTER. We now turn to Dr. LaSalle Leffall, professor of surgery at the Howard University College of Medicine. He was chairman of the Department of Surgery at Howard from 1970 to 1995. The first African-American to become president of the American Cancer Society, Society of Surgical Oncology, Society of Surgical Chairmen, Washington Academy of Surgery. In 2001 he became chair-elect of the Susan Komen Breast Cancer Foundation.

At the young age of 18, he received his bachelor's degree Summa Cum Laude from Florida A&M and four years later his medical degree from Howard University, ranking first in his class.

Well, you bring extraordinary credentials to your new job, Dr. Leffall, and to this committee. I have asked Senator Harkin to take the gavel for the next few minutes, because I have to go to a Judiciary Committee meeting, where we are confirming the new Assistant Attorney General of the Criminal Division. But I shall return very, very briefly.

Dr. Leffall, the floor is yours. And, Senator Harkin, the gavel is yours.

Senator HARKIN [presiding]. Thank you.

Dr. LEFFALL. Thank you, Mr. Chairman. I was told that I had one minute for my testimony. And this morning I was told, Senator Harkin, I had five. But I am going to stick with my original thought that you had expressed, that I just stick to the one minute. And that, I will do. I hope the committee will appreciate that.

And I want to thank you, Senator Harkin and Senator Murray and the members who are not here, for the opportunity to be with you today to testify.

As a surgeon, oncologist, and medical educator, I have devoted most of my professional life to the study of cancer, especially as it relates to African-Americans. I joined the faculty at the Howard University College of Medicine in 1962. And as you heard, from 1970 to 1995 I was chairman of the Department of Surgery. In 1992 I became the Charles R. Drew professor of surgery at Howard, a position that I currently hold.

The Komen Foundation has accomplished much in its last 19 years, having raised more than \$300 million in the fight against breast cancer since 1982. As chair-elect, I look forward to moving the bar yet a notch higher. I will serve one year as chair-elect before beginning a two-year term next year as the chairman of the Susan G. Komen Breast Cancer Foundation Board.

One of the many reasons I have chosen to align myself with the Komen Foundation is its commitment through Komen affiliates across the country to funding non-duplicative breast cancer outreach projects for the medically underserved in their local communities. Efforts to stifle overall health care expenditures should not impede a patient's ability to receive necessary services. A patient's diagnosis, not fiscal constraints, should determine how and what care is provided.

PREPARED STATEMENT

I assure you that I will utilize my position as chair-elect of the Komen Foundation to further the interests of minorities and the medically underserved.

Thank you very much, Mr. Chairman.
[The statement follows:]

PREPARED STATEMENT OF LASALLE D. LEFALL, JR.

Thank you Chairman Specter, Senator Harkin and distinguished Members of the Subcommittee for the opportunity to be here with you this morning to testify.

As a surgeon, oncologist and medical educator, I have devoted most of my professional life to the study of cancer, especially as it relates to African Americans. I

joined the faculty at Howard University in 1962 as assistant professor. In 1970, I became chairman of the department of surgery, a position I've held for 25 years.

The Komen Foundation has accomplished much in the last 19 years, having raised more than 300 million dollars in the fight against breast cancer since 1982. As Chair-Elect, I look forward to moving the bar yet a notch higher. I will serve one year as chair-elect before beginning a two-year term as chairman in 2002.

One of the many reasons I have chosen to align myself with the Komen Foundation is its commitment, through Komen Affiliates across the country, to funding non-duplicative breast cancer outreach projects for the medically underserved in their local communities.

Efforts to stifle overall health care expenditures should not impede a patient's ability to receive necessary services. A patient's diagnosis, not fiscal constraints, should determine how and what care is provided.

I assure you that I will utilize my position as Chair-Elect of the Komen Foundation to further the interests of minorities and the medically underserved.

Senator HARKIN. Thank you very much, Dr. Leffall.

**STATEMENT OF DR. JOHN SEFFRIN, CHIEF EXECUTIVE OFFICER,
AMERICAN CANCER SOCIETY**

Senator HARKIN. Next we turn to John Seffrin. Dr. Seffrin is the Chief Executive Officer of the American Cancer Society, a group he has volunteered with for the past 20 years. He has served on the advisory committee to Congress on tobacco policy and public health and on the advisory committee to the Director of the U.S. Centers for Disease Control and Prevention.

Dr. Seffrin holds a doctorate of philosophy in health education at Purdue University, master science degree in health education from the University of Illinois.

Dr. Seffrin, welcome.

Dr. SEFFRIN. Good morning, Senator Harkin, distinguished members of the subcommittee. I am truly honored to be here today and want to thank you on behalf of our 28 million volunteers and supporters for the great and sustained leadership that you have given to this cause, the cause of breast cancer research and control, and indeed for other matters of importance relative to biomedical research.

As you know, Senator Harkin, the American Cancer Society is the Nation's largest community-based voluntary health organization. And we have some 28 million supporters and volunteers, 2 million of those volunteers are virtually full-time volunteers representing 3,000 communities across the country. And the society strongly believes that a significant reduction in the number of U.S. citizens suffering and dying from cancer in general, and breast cancer in particular, is not only feasible, but will happen, if we do the right thing.

But achieving this goal is not easy, and it depends on the continued and enhanced investment in and application of cancer research. Mr. Chairman, you have asked me to testify about a disease that for too long has been devastating the lives of women and their families across this country, as you have heard so poignantly here this morning. Indeed among American women, breast cancer is the second leading cause of cancer death and the most frequently diagnosed.

According to the American Cancer Society's database, we estimate that 192,000 new cases will be diagnosed this year. And over 40,000 women, our mothers, wives, sisters, daughters, and loved ones, will die of breast cancer, many of them, most of them, need-

lessly. Regrettably, many of these deaths and cases will occur disproportionately among women from predominantly low income and medically underserved communities.

For example, my friend, Dr. Lasalle Leffall, referred to the death rates among African-American women are 28 percent higher than among white women. We know that one of the contributing factors to this disparity is lower utilization of screening tests, such as mammography.

We have many challenges in beating this disease. But in cases in which we have the tools available that can help us detect this disease early, when it is most treatable, we must ensure that these tests are available to all who need them.

Now despite these grave statistics, it is becoming increasingly clear that breast cancer is not the automatic death sentence it once was. Indeed, we were looking at our data, and we have had great success in treating the disease when detected early, when it is localized and it has not spread.

According to the American Cancer Society's data, in the 1940s the 5-year survival rate for localized breast cancer was about 72 percent. With the development and use of improved early detection and better treatment methods, the 5-year survival rate for localized breast cancer has increased to 97 percent today.

Now we have come a long way, but, of course, there is much, much that still needs to be done. For example, while we know that early detection is currently a key to survival, we also know that the majority of Americans are not getting appropriate screening.

To help ensure that new scientific knowledge will be forthcoming to answer these yet-unanswered questions, we believe we must expand the national investment in breast cancer research. And therefore, the American Cancer Society and its partners in one voice against cancer believe strongly that Congress must remain steadfast in its commitment to double the NIH budget by 2003. And to that end, we are here today requesting a funding level of \$27.3 billion for fiscal year 2002 for the NIH.

We are also advocating \$5 billion to provide full funding of Dr. Klausner's, the Director of the NCI, bypass budget. This increase will allow the NCI to move forward with additional approved, yet currently unfunded, research grants and foster the development of new drugs to treat breast cancer more successfully.

Mr. Chairman and members of the committee, if we are to reduce the number of American women dying from breast cancer now in the immediate future, we must also provide adequate funding for the Centers for Disease Control and Prevention. The CDC is actually on this Nation's front lines in the battle against cancer, and their programs are critical to winning this war. We are advocating \$315 million for the cancer-related programs at our Centers for Disease Control and Prevention.

While all of these programs are important in our Nation's cancer control efforts, I will focus today on the National Breast and Cervical Cancer Early Detection Program in particular. It is extremely important, Senator Harkin, that we redouble our efforts in this area, because we are only reaching about 15 percent of the women who could benefit from this intervention program. A relatively small amount of money invested here of \$315 million could expand

dramatically the number of women who need this important service.

PREPARED STATEMENT

In conclusion, Senator Harkin and members of the committee, I want to thank you and the committee for your continued commitment to fighting the war on cancer. Because of this Nation's past commitment to research and its application, the diagnosis of breast cancer is no longer a death sentence for many women. But we have much work to do before we can say we have truly overcome this huge public health problem.

I thank you for this opportunity to testify, and the American Cancer Society stands ready to help you and our other partners in any way we can.

[The statement follows:]

PREPARED STATEMENT OF DR. JOHN SEFFRIN

Good morning, Mr. Chairman, Senator Harkin, and distinguished members of the Committee. I am John Seffrin, Chief Executive Officer of the American Cancer Society. I am honored to be here today, and I want to thank you on behalf of the more than 28 million volunteers and supporters of the Society for the opportunity to testify before you about the importance of research and prevention in breast cancer care. I am also pleased to have the opportunity to publicly thank both of you for your continued leadership in the Senate on behalf of cancer patients. It is no secret that the 8.9 million Americans with a history of cancer have benefited from the contributions that both of you and this Committee have made over the years in research and its application. Your personal commitment to defeating this disease, and your ability to work in a bipartisan fashion to lead the nation in the right direction, are to be applauded.

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer through research, education, advocacy and service. Nationwide, more than 28 million volunteers and supporters, including cancer survivors, researchers, healthcare providers and educators, contribute their time and resources to help advance the Society's goals. As the nation's largest cancer-fighting organization, we too are making hard choices and setting priorities for our community cancer control activities based on an evaluation of the success of current programs and interventions. The American Cancer Society has set ambitious goals for the year 2015 to reduce the number of people dying from and being diagnosed with cancer and to significantly improve the quality of life for all cancer patients, survivors, and their families. While we believe that national achievement of these goals is possible, we know that our success depends on the continued investment in and application of cancer research.

We have made tremendous progress in the battle against cancer. When the American Cancer Society was founded in 1913, cancer was a poorly understood disease that killed the great majority of people who had it. Today, because of what we have learned from research and its application, the diagnosis of cancer is no longer a death sentence. More and more people are surviving this disease and enjoying productive lives. We are learning more each day about how cancer cells develop and how environmental agents cause disease. This basic knowledge about the nature of cancer is providing critical insights into how we can prevent and detect cancer more effectively. And it is giving us the opportunity to improve treatments that lead to improved quality of life and longer survival.

To that end, I appreciate having the opportunity to share with you today the Society's views on the importance of research and prevention efforts in reducing the number of new breast cancer cases as well as the need for continued investments in this area.

CURRENT BREAST CANCER STATISTICS

Mr. Chairman, you have asked me to testify about a disease that for too long has been disrupting and devastating the lives of women and their families across this

country. Over the last decade alone, breast cancer has taken the lives of nearly one-half million American women.

Indeed, among women, breast cancer is the second leading cause of death behind lung cancer, and, after skin cancer, is the most frequently diagnosed. This year an estimated 40,600 women—our mothers, wives, sisters, daughters, and other loved ones—will die of breast cancer, and 192,000 new cases will be diagnosed. Regrettably, many of these deaths and cases will occur disproportionately among women from predominantly low income and medically underserved communities. An estimated 19,300 new cases of breast cancer and 5,800 deaths are expected to occur among African-American women in 2001. Breast cancer is the most common cancer among African-American women and the death rates are 28 percent higher than among white women.

This disease is also the most commonly diagnosed cancer among Hispanic women. An estimated 8,600 Hispanic women will be diagnosed with breast cancer and 1,800 will ultimately lose their battle with this disease. For Hispanic women, breast cancer is frequently diagnosed at a later stage and is the leading cause of cancer death. One of the contributing factors to later diagnosis among this population group is thought to be lower utilization of screening tests such as mammography.

Like many other forms of cancer, the risk of breast cancer increases with age. This means that as a woman grows older her chances of being stricken with and suffering from this terrible disease increase. According to the National Cancer Institute, about 70 percent of breast cancer cases are diagnosed in women age 55 and older; and 77 percent of deaths due to breast cancer occur in women age 55 and older.

Furthermore, underneath these staggering statistics lie behavioral, genetic, environmental and other factors that continue to challenge our fight against this deadly disease.

PROGRESS—BREAST CANCER RESEARCH

Mr. Chairman, and Members of the Committee, there is little question that breast cancer is having a terrible impact on women in this country, and that this disease, in particular, is disproportionately affecting women who are socioeconomically disadvantaged and medically underserved. However, despite these grave statistics, it is becoming increasingly clear that cancer, including breast cancer, is not the automatic death sentence it once was. In the 1940s, the five-year survival rate for localized breast cancer was only 72 percent. Through the development and use of improved early detection and treatment methods, the five-year survival rate for localized breast cancer has increased to 97 percent today. We have come a long way, but there is still much that needs to be done.

At the cornerstone of our progress in the war on breast cancer are breakthroughs in applied and behavioral science and the continued widespread use of preventive and early detection measures. However, our progress relies also on a continued investment in federal efforts that build the biomedical infrastructure necessary to improve the health of the Nation. One of the most important of these efforts is the continued emphasis on research that will result in answers to how breast cancer is best detected, treated and prevented.

Nearly every day, we are discovering and learning about new ways to combat this terrible disease. And, nowhere are the results of these discoveries more apparent than in the intensive breast cancer research being conducted at the National Institutes of Health (NIH), particularly through the National Cancer Institute (NCI), and at the Department of Defense (DOD).

Through the painstaking work of scientists and researchers in these programs, we have been able to make significant progress in further understanding the complexities of breast cancer. Indeed, we understand more than ever before how breast cancer cells develop and spread, the role environmental agents play, how nutrition and lifestyle are a factor, and why some women are more likely than others to be afflicted by the disease. Also, we are doing more to develop new treatments and medicines, like Tamoxifen, that appear to translate into longer survival and improved quality of life for breast cancer patients. Similarly, through research we are doing more to translate laboratory findings into real life applications that improve the prevention, detection, diagnosis and treatment of breast cancer.

However, while these advancements have been noteworthy, we still have a long way to go toward finding a cure for breast cancer and saving more people from succumbing to the disease. In fact, to date, the specific cause of breast cancer is unknown, and our current knowledge about the role of human genes vis-a-vis breast cancer is incomplete.

To help ensure that new scientific knowledge will be forthcoming to answer many of these questions, we must expand and increase the national investment in breast cancer research. For example, with a significant increase in funding as outlined in the Director's bypass budget, NCI will be able to move forward with additional approved—yet currently unfunded—research grants, and foster the development of new drugs to treat breast cancer successfully. In addition, they will be able to enhance methods of breast cancer detection and prevention, improve the quality of life for all cancer patients, and better understand and control cancer in minority and medically underserved communities and the disparities among ethnic and socioeconomic groups.

HOPE & ANSWERS—BREAST CANCER PREVENTION AND EARLY DETECTION

Mr. Chairman, and Members of the Committee, one of the efforts that is playing an important role in helping us win this war is that of screening and early detection, which are two of the key weapons in fighting breast cancer. Unfortunately, not all women have been able to access appropriate screening and early detection tools.

Research studies have proven that screening and early detection are critical for decreasing the mortality rates of breast cancer, and that increased use of mammography and other early detection methods can play an important role in helping to further reduce mortality rates. In fact, according to the Centers for Disease Control and Prevention (CDC), screening could prevent approximately 15–30 percent of all deaths from breast cancer among women over 40. However, despite making progress in increasing awareness about the importance of screening and early detection in fighting breast cancer, some groups of women continue to be left out when it comes to having access to these life saving services.

Mr. Chairman, and Members of the Committee, I am referring to women who are predominantly poor, medically underserved, and disproportionately impacted by breast cancer. These women continue to face financial, socio-cultural, geographic and educational barriers to screening and early detection services that threaten their ability to live a productive life. We cannot expect to reduce the incidence of breast cancer in this country, unless we do more to effectively reach and serve those who are the least likely to have access to the very services that could save their lives.

The CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is making an impact on the detection of this disease in poor and underserved women at earlier stages when the survival rates are highest. The NBCCEDP provides breast and cervical cancer screenings, outreach, and post screening diagnostic services in all 50 states to women who do not have health insurance coverage and who do not qualify for either Medicaid or Medicare. Now in its eleventh year, the program builds on existing public health infrastructure and involves all sectors of the community in outreach and delivery of services. The NBCCEDP has provided more than 2.7 million screening examinations, and has diagnosed over 8,600 breast cancers and 39,400 precancerous cervical lesions. Nearly half of all screenings were for minority women. In addition, the program has been successful in reaching women at earlier stages of their cancer, where more options are available for treatment and for improved quality of life. Furthermore, the program has enabled behavioral changes in participants that ensure continual care.

Cancer registries are also critical in our efforts to improve outreach and screening programs. For example, thanks to data from the Kentucky Central Cancer Registry, areas in the state with high incidence of breast cancer diagnosed at a late-stage were identified and effective outreach programs were developed through the NBCCEDP. The result was a shift from late-stage to early-stage diagnosis for many patients, meaning a greater chance for survival for those individuals, since we know that cancers caught earlier are more likely to be treatable. Cancer registry data was then linked to Medicare treatment cost data. The data analysis showed that Medicare treatment costs were reduced by more than \$4.7 million in a 2.5 year time period, proving that increasing early stage breast cancer diagnosis can have a significant impact on health care system costs.

Yet despite these successes, it has become evident that the NBCCEDP faces challenges in providing needed program services to eligible low-income and uninsured women. In fact, according to the CDC, while funding for the program in fiscal year 2001 was \$174 million, this amount allows the NBCCEDP to reach only approximately 12 percent to 15 percent of all eligible women. Like many of the other programs included in the CDC's Chronic Disease and Health Promotion budget line, this program received a cut in funding in the President's fiscal year 2002 budget. ACS and members of One Voice Against Cancer (OVAC) are advocating for a \$35.5 million increase in this program and we are concerned that the proposed budgetary

cuts will lead to more women being left behind—particularly among the underserved populations that currently rely on this program for screening. There is little doubt that without additional funding, the NBCCEDP will be hard pressed to sustain the successes it has achieved since its inception and will be unable to reach more eligible women. ACS looks forward to working with this Committee to ensure that funding for this vital cancer prevention and control program is increased.

Mr. Chairman, and Members of the Committee, the uncertainty of access to quality and timely care, coupled with the additional financial pressure of extreme financial burdens, are significant barriers that could preclude low-income and medically underserved women from getting the treatment they desperately need, and in some cases, could cost them their lives.

Fortunately, as part of the effort to tackle this problem, Congress passed the Breast and Cervical Cancer Treatment Act (BCCTPA) last year, which gives states the option to extend Medicaid coverage to women diagnosed with breast or cervical cancer under the CDC program. This landmark program offers women served through the CDC screening program peace of mind by providing explicit access to and coverage for treatment services, thereby allowing them the ability to focus their energies on fighting and conquering this disease.

Currently three states—Maryland, New Hampshire, and West Virginia—have already taken advantage of the Breast and Cervical Cancer Treatment and Prevention Act. ACS is working with the rest of the states to ensure that they too enact the necessary legislation at the state level. ACS is also working to ensure that the Native American Breast and Cervical Cancer Treatment Technical Amendment Act is adopted this year so that Native American women with breast or cervical cancer are also eligible for treatment.

Additionally, the Society is working on advancing the “Assure Access to Mammography Act.” This legislation, introduced by Senator Harkin and co-sponsored by Senator Specter and many others, will help us to ensure that this nation’s capacity to provide mammography services is preserved for future generations of American women. We have all grown concerned by recent reports that raise red flags about the availability of mammography screening services for all women who need them, and this legislation leads the way toward quality data to assess the problem and a means to address it so women will be adequately served.

CONCLUSION

Mr. Chairman, and Members of the Committee, I want to thank you and the Committee for your commitment to fighting the war on breast cancer. I could spend the rest of the day talking to you about all of the great projects and research being done on breast cancer, and how close we are to eradicating the disease. Today, because of what we have learned from research and its application, and through prevention and early detection, the diagnosis of breast cancer is no longer a death sentence for many women. More and more people are surviving this disease, enjoying productive lives and, most importantly, are living longer. But the point I want to make clear today is that research and its application are the keys to removing breast cancer as a threat in the lives of women. If this nation is serious about winning the War on Cancer, we must commit ourselves to investing the resources necessary to get us there. With the number of lives at stake, we cannot afford to do anything less. The American Cancer Society looks forward to working with you in partnership to ensure that this benefit reaches all women.

Senator HARKIN. Dr. Seffrin, thank you very much.

STATEMENT OF FRAN VISCO, J.D., PRESIDENT, NATIONAL BREAST CANCER COALITION

Senator HARKIN. Now we turn to Ms. Fran Visco. Ms. Visco is President of the National Breast Cancer Coalition, a member of its board of directors. Formed in May of 1991, the coalition is a grassroots advocacy group of more than 500 member organizations and over 60,000 individual members. Ms. Visco has been a member of the President’s Cancer Panel and the President’s Special Commission on Breast Cancer. She earned a bachelor’s degree from St. Joseph University and a J.D. from Villanova Law School, where she was the editor of the Villanova Law Review.

Fran, welcome again to the committee.

Ms. VISCO. Thank you very much. I want to thank you, Senator Harkin, and my chairman, Senator Specter, Senator Murray, and the other Members of the committee, not just for inviting me to testify today, but also for your long-standing support of appropriations for quality breast cancer research.

You have heard Dr. Klausner talk about how far we have come in terms of research. And we are beginning to find some of the answers. And more important, we are actually beginning to know which questions to ask. This is an important time to focus our resources on breast cancer, because we do know so much, and we are ready to move to the next level.

I am proud to be here as a breast cancer survivor, a 14-year breast cancer survivor, on behalf of the National Breast Cancer Coalition. Over the past several days, I have walked with more than 700 women and men from around the country who came here to Washington, D.C., to learn about advocacy, to learn about the update in breast cancer research, to meet with their members of Congress, to gain the skills and the tools they need to advocate, to be a political voice in the fight against breast cancer, and also advocates for themselves. They understand the importance of our collaboration with Congress. They understand the importance of the political fight against breast cancer.

We have found by your side for 10 years now. We are going into our 10th year. Working together, we have brought about significant increases at NIH and NCI for breast cancer research. And we are very proud of the fact that working together, and with you especially Senator Harkin, we brought about the Department of Defense peer-reviewed breast cancer research program, which to date has brought about more than \$1 billion of new funding for breast cancer research.

But it is not just about research. We know it is not enough simply to put more dollars to the disease. We have to make certain those funds are well spent. And so we, the National Breast Cancer Coalition, educate and train our advocates. We train them in the language and concept of science and in the system and structure of research, so that we are able to collaborate not just with you but with the scientific and medical community, to make sure that research is well designed and funds are spent appropriately.

In addition, we are giving our advocates the understanding, the skills and the tools to understand what is quality care. There is a great push for quality care and access to care. But we ask ourselves the question: What does that mean? What is quality care? What is quality care in breast cancer? How do I understand what it is I and my colleagues should be getting?

And so we have developed a project to help women answer that question, not give them the answers, but give them the tools and the skills that they need, so they can make their own decisions. And I am very proud and would like to introduce into the record the National Breast Cancer Coalition Fund's "Guide to Quality Breast Cancer Care," which was just released over this past weekend at our conference.

We know that we have come a long way in treating breast cancer. While the 5-year cure rates have gone up, we do not believe a 5-year rate is a cure for anyone. We need to make certain that

we truly know how to cure this disease for all women. We need to make certain that the treatments we give women are not toxic. And most importantly, we have to learn how to prevent this disease, so that women do not get breast cancer, so we can protect our daughters and future generations from getting this disease.

One component in our strategy to find that answer is, we are asking for support for the National Institute of Environmental Health Sciences with a \$30 million grant over 5 years to fund collaborative centers of excellence that will begin to look in a multidisciplinary, interdisciplinary way at the links between the environment and breast cancer. We simply can no longer afford to do this in a haphazard manner. People think we know the answer. We do not know the answer. We need an overall strategy to achieve that.

Dr. Klausner spoke about the complexity of this disease. And we, as advocates, have learned over 10 years how complex it is. We are beginning to understand the molecular basis of breast cancer and of many diseases. But we do not have protection in place for genetic discrimination, when we have predisposition to those diseases.

What is going to happen when we know more about who will get breast cancer, when we know more about whose breast cancer will respond to treatment and whose will not? The discrimination possibilities are overwhelming. Science must move forward, but we need to protect women and men in this country while that happens. We need strong genetic discrimination legislation.

PREPARED STATEMENT

I again am here proud to represent the women and men who have raised their voices and come together to focus on breast cancer, to make a difference in the fight to eradicate this disease. And I thank you for walking alongside with us. And I know we will reach our goal of eradicating this disease.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF FRAN VISCO

Thank you, Mr. Chairman and members of the Subcommittee for your dedication and leadership in working with the National Breast Cancer Coalition (NBCC) to help in our fight to eradicate breast cancer.

I especially want to thank Chairman Specter and Senator Harkin for your longstanding support for the invaluable research at the Department of Defense (DOD) Peer Reviewed Breast Cancer Research Program. Without your leadership, we would not be where we are today.

I am Fran Visco, a breast cancer survivor, a wife and mother, a lawyer, and President of the National Breast Cancer Coalition. On behalf of NBCC, and the more than 2.6 million women living with breast cancer, I would like to thank you for the opportunity to testify today.

As you know, the National Breast Cancer Coalition is a grassroots organization dedicated to ending breast cancer through the power of action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to design and implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women, and; expand the influence of breast cancer advocates in all aspects of the breast cancer decision making process. Nearly 600 NBCC advocates were up on the Hill yesterday to lobby their Senators and Representatives on a legislative agenda that reflects these goals. I truly believe that with their extraordinary deter-

mination and unbelievable spirit, combined with your continued support for high quality breast cancer research, we will be able to eradicate this deadly disease.

In the meantime, we also educate and train our advocates about how to become part of the research process. Through our advocacy training programs and publications, we empower advocates to collaborate with the breast cancer research and healthcare community to help find answers, to critically analyze information and to ensure access to high quality breast cancer treatment. Mr. Chairman, I would like permission to enter into the record NBCCF's recently issued "Guide to Quality Breast Cancer Care" which is a resource for breast cancer patients.

I want to focus my testimony on three major points:

First, I want to emphasize the advancements in breast cancer research that have come as a result of your longstanding support for this issue. Developments in the past few years have begun to offer breast cancer researchers fascinating insights into the biology of breast cancer and have brought into sharp focus the areas of research that hold promise and will build on the knowledge we have gained. We are at a point in where so much has been learned about the disease that we are now able to target genes and begin to know how to address one woman's breast cancer in a different way from another's woman's. This breakthrough is leading us forward in finding the answers to how to prevent breast cancer, as well as how to detect it earlier, and treat it more effectively. Now is precisely the time to continue your support for this important research.

Second, I want to urge your support for increased appropriations for breast cancer research at the National Institute of Environmental Health Sciences (NIEHS). Recently, Senators Chafee, Reid, Hatch and Leahy introduced S. 830, the Breast Cancer and Environmental Research Act. (Representatives Lowey and Myrick introduced the House companion bill, H.R. 1723.) This legislation would establish Breast Cancer and Environmental Research Centers of Excellence at the National Institute of Environmental Health Sciences to support research on environmental factors that may be related to the etiology of breast cancer.

We recommend that the Committee provide \$30 million to fund up to 8 multi-institutional, multi-disciplinary breast cancer and environmental research centers, which would make grants using a peer review and programmatic review process that involves consumers. NBCC urges the Committee to use the tremendously successful DOD BCRP as a model for the structure of this research program.

It is generally believed that the environment plays some role in the development of this disease, but the extent of that role is not yet understood. NBCC believes that a strategy must be developed and more research done to determine the impact of the environment on breast cancer. It is only when we understand what causes this disease that we will have a better idea of how to prevent it, how to treat it more effectively, and how to cure it.

Finally, I want to discuss the issue of accountability and collaboration among consumer advocates, NIH and Congress, to create mechanisms to ensure a higher level of accountability for federally funded breast cancer research. The National Breast Cancer Coalition understands that the level of funding is meaningless unless the funds are allocated appropriately.

I have been a member of the President's Cancer Panel and the National Cancer Policy Board, and sit on various committees at the Institute of Medicine, and in the private sector. Despite NBCC's inclusion in scientific decision-making, we still don't see a strategy on how to best use the federally funded breast cancer resources appropriately. The National Breast Cancer Coalition would like to work with Members of this Committee on this issue.

As we are all aware, this is the taxpayer's money. We owe it to all our constituencies to assure them that this investment is spent wisely. The National Breast Cancer Coalition supports increased appropriations for breast cancer research so that we can eradicate this disease as soon as possible. It is vital that the public understand how the funds are being spent.

We believe that NIH and NCI are as committed as we are to finding a cure for this disease. However, it is often difficult when one is involved in a process to be able to evaluate that process. We urge the Committee to explore the question of whether changes may be needed in the grant mechanisms and the research structure at these Institutes. Any time an institution exists and grows for so many years, outside evaluation is necessary to update processes or to uproot outmoded or duplicative efforts that no longer make sense.

We believe that the call for increased accountability should be a collaborative effort—and want to work with the Committee and with NIH and NCI. The Programmatic Review Group (PRG), which Dr. Klausner convened in 1998 to provide an account of NCI's plan to eradicate breast cancer, was a good beginning.

But many questions remain.

Chairman Specter, Senator Harkin, and members of the Subcommittee, thank you again for the incredible investment you have made in helping us work to eradicate breast cancer. NBCC looks forward to continuing to work with you to end this disease. Thank you again for the opportunity to testify today. I would be happy to answer any questions.

Senator HARKIN. Thank you very much, Fran.

Thank you all on the panel for your very poignant testimony.

I am now going to recognize Senator Murray for any opening statement or comments that Senator Murray might have. We would like to do that at this time. And if you have any questions for the panel, you can just follow up.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Very good.

Well, first of all, Senator Harkin, thank you to you and the chairman, Senator Specter, for having this hearing. This is really incredible, sitting here and having a hearing on breast cancer.

I think how far we have come. I remember talking to my mother several years back about having heard of one more friend who had been diagnosed with breast cancer whether not in her generation there had been this many women who were my age, when she was my age, who had been diagnosed with breast cancer. And she thought about it, and she said, "You know, there may have been, but we did not talk about it."

We are talking about it. And I am just really grateful to all of you who have taken time out of your lives and taken your lives to participate in this really, really important discussion. I think we all want to find a cure, but we all want to know what we can do when we are young, whether it is something we are not supposed to eat or something we are not supposed to be around, tell us, because we want to prevent this disease from happening.

And I am delighted to be a co-sponsor of Senator Chafee's bill on the environmental study issue. I think that is critically important, so we know what we can do to prevent this disease. And frankly, that is what many young women say to me, when I travel to colleges in my State. Do the research and tell me what I can do to protect myself. So it is a sound investment for us to move in that direction.

I want to really thank the Susan G. Komen Foundation for the incredible work you do. It is, I think, so important for all of us to be aware of this issue, to talk about it, to be able to share our experiences. And one of my treasures in my office is this huge poster of me with a number of women from the Race for the Cure, hundreds of women behind me.

And the only reason you can find me is I am the only one without a pink hat. And I am so proud of that picture and the women who participated in that and the women who support the women in that race. And you have made an incredible difference, and I really appreciate it.

There is so much we can do. Certainly research in many, many areas. And we also have to talk about what we do for women who have been diagnosed with breast cancer to cure them, but we also have to talk about what happens to those women after they have had mastectomies. And I think one of my biggest concerns coming

up in the last few years is the lack of attention and focus on recovery and rehabilitation needs for women who have undergone mastectomies or other radical surgery.

And I have seen insurance companies deny reimbursement. I have talked to women who have just had tragic experiences after all they have gone through, after they have had a mastectomy and just trying to get insurance coverage for recovery. And I have offered amendments during patient bill of rights. I hope that we can bring that back up, so we can get that through and have its help.

But I would like to ask, I am concerned that there is little done within the research community on outcomes of mastectomies and little focus on providing post-operative care. And I would really appreciate any comments you have on that end of this whole discussion from any of you.

Ms. VISCO. Well, if I could, I can speak certainly to the Department of Defense in terms of the behavioral aspect of the research and the psycho-social aspect of the research, in that last year recognizing how underfunded that was, that we established—it was a \$20 million set-aside to fund Centers of Excellence around the country, looking at that issue in breast cancer. And it is certainly an issue that is of utmost importance to the grassroots advocates of the National Breast Cancer Coalition.

So we support your call for that. And we know that we need more in that area.

Senator MURRAY. I appreciate that. And I want to work with you on that.

And the other area I wanted to just ask about is, getting access for minority women is a real concern of mine. We know that they are three times more likely to die from breast cancer. And certainly there are cultural language barriers that prevent them from somehow being diagnosed early, whether they are Asian or Native American or African-American. Are we doing more to find out how we can reach out to minority women and better those numbers about the survival rates?

Dr. LEFFALL. I would like to respond to that, if I may. The answer to that is yes. We are doing more, but we are still not doing enough. The Susan Komen Foundation, the American Cancer Society, particularly, the Breast Cancer Coalition, all have programs related to outreach for those population groups that really do not take advantage of the opportunities that are there for screening, for diagnosis.

So more and more funds are being given for that. But still, we must do more to be sure that that disparity, or those disparities, do not exist.

Senator MURRAY. Ms. Brinker.

Ms. BRINKER. Thank you. And it is again, Senator, a great honor to be here. And thank you for your kind remarks. I think being here, however, is not really where all cancer occurs in the United States. We at the Komen Foundation know that one of the greatest battles we have is at the community level and meeting the needs of medically underserved patients.

While it is beautiful, wonderful and exciting for all of us to consider what is happening in the research lab, we know that you cannot cure disease in the laboratory alone. And until we fully fix the

transportation system, the translation of what happens from the laboratory into the deepest, darkest pockets of this country, we will have no cure. We will have cancer. Breast cancer, particularly, is now two diseases. It really is a disease of a medically underserved population and those of us who are served well.

And it is frightening to me, who has been in this movement for over 25 years, to see that we still have not made enough noticeable progress. And there are all kinds of cultural barriers. It is not all the fault of the health care delivery system.

But we have to fix it. And it is so deadly because so many women are now single mothers. And it is a disease mostly women, as you know, are diagnosed with. But there are so many single mothers today raising children, who, when this disease strikes, it is often at the prime of their life, just when they are reaching income levels where they can educate, feed, clothe their children.

So it is a prime concern of ours. And we are as perplexed as anyone as to how to make more significant gains. We are working on it, and we continue to want to fund the highest levels possible. But it is going to take a concentrated effort in this country to really make progress.

Senator MURRAY. I agree with you. And there are cultures within our communities where they still are not allowed to talk about this—

Ms. BRINKER. Right.

Senator MURRAY [continuing]. Or to admit that it is a health problem in their own family. And we have to continue to work to make sure that that happens, because there are women who are very frightened today and not telling anybody and not talking about it and not getting treated.

Ms. BRINKER. Right.

Senator MURRAY. And until we get past that, we will not have solved this. So I really appreciate your attention and would love to work with you in any way we can towards that goal.

But again, thank you to all of you for your passion and your advocacy. And as we work to increase the levels for spending on all of these issues, I will keep all of our advocates in mind, all the people who are survivors, but certainly all of the women I have known in my own life who are not here. They are the ones who we will remember the most.

So thank you very much.

Senator SPECTER [presiding]. Thank you very much, Senator Murray.

Again, I express my regrets for having missed some of the testimony, but the schedules here frequently place us in several committees at the same time. And the Assistant Attorney General for the Criminal Division is a very important part of the Judiciary Committee work. So I had to excuse myself for a few moments, but I have reviewed the testimony of Dr. Leffall, Dr. Seffrin and Ms. Visco.

And I would like to turn to Ms. Visco for the first question, regarding your request for \$30 million to fund up to eight multi-institutional, multi-disciplinary breast cancer and environmental research centers, and on the issues which were raised on environmental concerns. I would like to have you expand on your thinking

and your views with your broad experience in the field, to devote that much money to this specific kind of a project.

Ms. VISCO. Well, Senator Specter, we spend a great deal of time at the National Breast Cancer Coalition doing research and analysis before we come to a position. And what we have seen over the past 10 years is that there is much talk and much focus in particular communities about the issue of the environment and breast cancer. We have already invested a great deal of money, not enough, but a great deal of money, in looking at specific links to breast cancer.

So what we have said as an organization is, what we really need is a strategy. We should not just have pockets of this research happening. We should not have people convinced that it is pesticides, another group that it is chemicals or air. Let us actually focus money on looking at an overall strategy, the right way to ask the questions. Let us see what we have already answered and yet no one knows. Let us make certain we do it in a multi-disciplinary, interdisciplinary way.

So we felt that this was the best approach and, in the long run, the most cost-effective approach that will get us the questions more quickly.

Senator SPECTER. Thank you.

Moving to another subject, the issue of stem cells is in the forefront of medical research today. And there have been extraordinary achievements on stem cells since it burst upon the scene in November of 1998. This subcommittee has held seven hearings on the subject. And legislation has been introduced by Senator Harkin, other Senators, and myself to remove the prohibition which eliminates Federal funding for research on stem cells, rather to extract stem cells from embryos.

There is an opinion by the general counsel to the Department of Labor, the Department of Health and Human Services, that Federal funds can be used for research on the stem cells once extracted. It is my view that when those embryos are going to be destroyed because they are more created for in vitro fertilization than can be used, that it makes good sense to use them to save lives, since they are not going to be used to produce life.

I would be interested, Dr. Leffall and Dr. Seffrin—and we may turn back to our first panel on this for a brief comment as well—as to your views on the prospects for stem cells on breast cancer. We have already seen the preliminary success on Parkinson's, spinal cords, juvenile diabetes, and some early indicators on Alzheimer's.

Dr. Seffrin, you are nodding in the affirmative. What do you think about the potential for stem cells on breast cancer?

Dr. SEFFRIN. Well, let me say that we took about a 6-month period of time, our board of directors did, and looked into this matter. And I think there is no question but what stem cell research in general, and embryonic stem cell research in particular, holds great promise for virtually any disease process that we are currently aware of.

Senator SPECTER. Including breast cancer?

Dr. SEFFRIN. Including breast cancer.

Senator SPECTER. Let me get Dr. Leffall before my time runs out.

Dr. LEFFALL. Yes. I agree with that, Senator Specter. It seems as though some very good information, some vital information, can be gained if we do stem cell research, not only for breast cancer but for other diseases, too. And we believe that the information that we gain can be of value in helping us not only in the diagnosis, treat, but perhaps even prevent breast disease.

Senator SPECTER. Dr. Klausner, aye or nay on stem cell placenta potential for breast cancer?

Dr. KLAUSNER. There are multiple ways that I think—

Senator SPECTER. Rick, the yellow light is on.

I want to get Dr. Marks before the red light goes on.

Dr. KLAUSNER. Yes. We think there are several ways in which stem cell research can benefit.

Senator SPECTER. Dr. Marks, yes or no?

Dr. MARKS. The CDC program, once those things are found, we want to get it out then to the women that need it.

Senator SPECTER. Well, I raise that question here because the Breast Cancer Coalition is one of the most powerful, if not the most powerful, in our society.

And we need some active contacts with Members of Congress to cut the restrictions on medical science on developing stem cells. And you have heard four prominent physicians testify in the affirmative.

My red light is on. And unless there is something else from the panel members, I am going to conclude the hearing.

You have not asked any questions? The hearing is concluded—no, no.

Senator Harkin, I did not realize you had not asked questions.

Senator HARKIN. Just Senator Murray.

Again, I thank the panel. I want to get into two areas, one that Ms. Brinker brought up about the translation of the research and the things out to the general community. And you pointed out time and again that there is this gap. And you made mention that it is not just the medical community's fault. It has to do with, I think, backgrounds, perhaps cultural influences, things like that.

But I still want to get a better handle on why we cannot do a better job of getting the information we have out to women all over this country in a meaningful manner. Now we have utilized the Centers for Disease Control and Prevention in terms of the Breast Cancer and Cervical Screening Program. And that has done a tremendous job of reaching low income women around America. But we know that in certain areas it has not been that effective.

So I just want to elaborate a little bit more with you and perhaps anyone else on the panel as to how we can get a better translation of the findings and what we know now out to the general populace of women. Is there anything more we can do here to stimulate that, to promote that?

Ms. BRINKER. Senator, in answer to your question, I think, first of all, we have to continue with our levels of funding. I think we have to fix some of the issues with HCFA, I think in some of the States which Medicaid is not existent or there are gaps between payment for services.

I mean, in every area of health care delivery and health care receipt, there is a major problem. And you have pointed some of them

out already, the cultural problem, there is the payment problem, there is the physician problem, in that sometimes there are not enough physicians to get around to get to rural communities, to outreach to people who live there. They will not come and cannot come for treatment.

There are cultural and treatment problems with patients arriving at public hospitals. And by the way, in the United States we have some of the finest public hospitals in different communities. But there is a problem when a patient actually comes to the hospital. And the Komen Foundation in that effort has funded sort of a widespread program in some of our communities called Patient Navigator Programs, where people are met and spoken to in the language they can understand, if that is the issue, walked through the treatment system.

But then again, there are issues with women leaving their jobs to be treated, transportation. And it keeps going down the line, child care—it is such a multifaceted problem. However, we do believe that along the way there are solutions to each of these problems.

But it will take a sustained examination of what they are, setting realistic goals, and including, again not just government payment—and I keep stressing this. Though dollars are greater here, it is not always government dollars that make things happen, particularly in communities. It is a steady and a concentrated combination of the private and public sector working together to make things happen.

Ms. VISCO. Senator Harkin, can I say, too, though, that I think one of the largest problems we have in this country is that we do not have universal access to quality health care in this country. And we can try to get the word out, and we do try to get the early detection word out. But detecting cancer is only the very first step. We need to treat it. And people do not have access to treatment. And we need to change that in this country. And then I think we will take a major step forward to addressing cultural issues.

Because I think one of the major issues we hear from a very diverse constituency is that, who is going to pay for my care, if I step forward? Who is going to pay for it? And we need to address that issue.

Senator HARKIN. It is a most human, I think, reaction to say, “Why? Why should I go in and get screened, if in fact I cannot do anything about, and I do not have the money? I do not know anything about it. Maybe it will go away.”

I think that is what is happening.

Ms. VISCO. And charity care is not enough.

Senator HARKIN. I am sorry?

Ms. VISCO. Charity care; the system of charity care in this country is not enough. Women have to understand that there is a system that they can depend on that will be there for them when they step forward.

Senator HARKIN. Closely akin to this—I want to get back to Dr. Klausner—is clinical trials, and what is happening with the mix of clinical trials, and are we doing more clinical trials so that it gets out to the public. What is the status of that now?

Dr. KLAUSNER. Well, we are doing more clinical trials. But the clinical trial system is still underfunded, so that the time it takes to get an answer is too slow. Before you came in, Senator, I listed a large number of entirely new drugs beginning to enter the clinical trial system, 130 different trials that are beginning to test targeted therapies against breast cancer.

The problem is the system is very underfunded, at all levels, so that the speed by which the trial happens, the rate at which we can open these trials, in order to get these answers very quickly that Senator Specter asked me when we are going to get the answers, is way too slow by, I think, at least a factor of two to three.

Senator HARKIN. What are you doing—I see just one area here that there has been a lot of focus on lately. And that is angiogenesis. Are you doing some more trials?

Dr. KLAUSNER. We are. We are doing a large number of trials on about 50 to 60 different agents that are attempting to block the development of new blood vessels, or to destroy the new blood vessels, that nourish tumors.

As I said, there are a lot of clinical trials. We do not yet know, and so far there have been no overwhelming home runs with these, it is still in early days. It is an area of great interest and a lot of research.

Senator HARKIN. I have just two other things. Christine, you have done a lot of work in terms of getting more knowledge out to people and sort of how you get people more aware. Any further thoughts that you might have on anything that we might be looking at here or coordinating with the private sector, with great organizations like the Breast Cancer Coalition, the Komen Foundation, others? I mean, I guess the thing is, it is just awareness and understanding and how you get that out, especially to young people, getting it out to our schools.

I will say something else publicly, that it seems to me that there is a reticence among our education system in the secondary level. I do not know whether it is school boards or superintendents or teachers or maybe it is just—Senator Murray said breast cancer is just something we did not talk about.

And I find a great reticence in our secondary schools to have teaching about bringing awareness to young women in our secondary schools about the importance of self-examination, mammogram screening, and early detection and warning signs. It is just something you do not talk about. How do you get over that?

Ms. CARPENTER. Well, as a school psychologist who is working in the schools, one of the things is our school day is still 5½ hours, as it was 5 years ago—I mean 50 years ago. And think of the massive amount of new information.

And so teachers are trying to teach all this new information; you know, technology and all the new science and all the—you know, just all of the things that we know that we did not know in the past 50 years. And so there is always the problem of fitting one more thing into the curriculum.

Then, you know, sometimes communities are a little sensitive about touching those body part issues.

Senator HARKIN. That is what I am talking about.

Ms. CARPENTER. Right. And so teachers will just not do it, so that they do not have to take the flack occasionally.

Senator HARKIN. That is right. We need your help in overcoming that. You have done a great job in Iowa. We just need others to get over this and get this information out.

Ms. CARPENTER. Right. You know, Iowa is becoming more and more diverse. And we have created the Iowa Breast Cancer Resource Guide, and we have had requests now for copies in Spanish. And we have a great Bosnian population. So I have had a request for Serbian-Croatian.

And I am having a hard time figuring out how to get it translated, because I do not know—and I want it to be perfect. So I am even having a hard time figuring out how to get it translated.

Senator HARKIN. Well, thank you. I see my red light is on. Let me just close with this. I thank you all for the many hours that all of you have spent, professionals, the nonprofessionals, those of you who have been volunteering. Senator Specter, Senator Murray and I, and I can speak for other members on this panel, we are committed to making sure that we fulfill our obligation to double the funding for NIH over 5 years.

We are going to move aggressively. We have formed a great partnership, Senator Specter and I have, in moving this forward and making sure that we have the money in the budget and that we appropriate the money for it in our appropriations process. So we are committed to that.

We need your help to continue to work with others here and in the administration, so that we have the backing that we need to get this through.

Lastly, do not forget about the tremendous need we have to continue the funding for the Center for Disease Control and Prevention for outreach, for breast and cervical cancer screening. That has been cut in this next budget. We cannot allow that to happen. So do not take your eyes off of that.

Please continue to advocate and to fight as strong as you can to make sure that we not only continue but that we expand, as has been so eloquently stated here, to minority sections, to new immigrants in this country, to rural areas, where we need to really expand the breast and cervical cancer screening. It has proven it has done a great job in the past, but we are only reaching a fraction of the people that we need to.

So I really ask for your help in helping us get the funding we need for the Center for Disease Control and Prevention.

With that, I thank you so much.

Senator SPECTER. Thank you, Senator Harkin.

I thank you, Senator Murray.

ADDITIONAL COMMITTEE QUESTIONS

Thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO THE NATIONAL CANCER INSTITUTE

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. If you could identify in writing your projections as to the results that you anticipate, this is a three-part writing.

Number one, what have you been able to do with the existing increases?

Answer. The funding increases in fiscal year 2001 and earlier years have supported a sorely needed expansion of cancer research. A point in evidence of this pent up need is that although we are funding substantially more awards, our success rate, or the percent of quality grant applications funded, has dropped from 33 percent in fiscal year 1998 to 26 percent in fiscal year 2000. To date, the funding increases have allowed us to:

- Fund an additional 1000 research project grants (RPGs), increasing the number of RPGs funded from 3,744 in fiscal year 1997 to 4,747 in fiscal year 2001.
- Support a rapid, substantial increase in minority training, from 144 trainees in fiscal year 1999 to 363 trainees in fiscal year 2001.
- Increase transdisciplinary cancer research: as an example, increased the number of Special Programs of Research Excellence (SPORES) from 14 to 29 SPORES.
- Launch NCI's Center to Reduce Cancer Health Disparities.
- More than double the amount of money supporting minority health and assistance, from \$124 million in fiscal year 1997 to \$263 million in fiscal year 2001.
- Increase support for cancer clinical trials by 61 percent or \$256 million; from \$418 million to \$674 million. Currently NCI supports 1200 cancer clinical trials.

PRIORITY SETTING AND STRATEGIC PLANNING

NCI uses several well-defined processes for priority setting and strategic planning. The results of these strategic reviews are updated and articulated annually in our Bypass Budget Request, *The Nation's Investment in Cancer Research*, (<http://plan.cancer.gov>).

An integral part of our priority-setting and strategic-planning processes is the extensive, formal use of experts that include prominent members of the scientific, medical, industry and advocacy communities in addition to NCI's inhouse staff and leadership. Through the use of Progress Review Groups, program reviews, several external advisory boards and panels, and specialized annual review groups, the broad spectrum of cancer research activities are reviewed. Emerging technologies are examined, new advances in knowledge are identified, existing research portfolios are evaluated, and scientific opportunities are identified and prioritized.

The Bypass Budget is the primary tool we use to identify to the public and the scientific research community, including NCI staff, a prioritized, annual snapshot on scientific research direction and opportunities in cancer research. As additional funds become available, we allocate these funds to the initiatives and priorities identified in the Bypass. Some specific examples of what the funding increases have supported include:

- Mouse Models of Human Cancer Consortium (MMHCC)—this recently launched initiative is designed to develop mouse models that closely mimic human cancers. These models will help researchers, in pre-clinical settings, to greatly improve our understanding of molecular changes associated with the development, prevention and treatment of human cancers. In fiscal year 2001, the additional funding has allowed MMHCC investigators to: develop a novel mouse cross-breeding strategy to localize a human breast cancer modifier gene in record time and to verify its function; use a new lung cancer model to initiate prevention trials of COX2 inhibitors, therapy trials of signal pathway inhibitors, and localize a human tumor suppressor gene; and make 8 new mouse models (2 breast, 1 leukemia and 5 colon cancers) available to the research community.
- Transdisciplinary Tobacco Use Research Centers (TTURCs)—is an initiative funded in late 1999, in collaboration with the National Institute on Drug Abuse (NIDA) and the Robert Wood Johnson Foundation (RWJF), to study new ways to combat tobacco use and its consequences. Each center is organized around a special theme and researchers are tackling a wide range of studies that include culture, genetics, animal models of behavior, innovative treatments, and tobacco policy. The TTURCs were highlighted as a model in a recent Institute of Medicine report entitled *Bridging Disciplines in the Brain, Behavioral and Clinical Sciences*. Results emerging from the first year of funding include:
 - Created a computer-based system to help control depression, using cognitive behavior therapy, for people trying to quit smoking;

- Created a special mouse strain to study the relationship between nicotine receptors and depression;
- Developed a spectroscopic positron emission computed tomography (SPECT) radiopharmaceutical to quantify nicotine receptor levels in the human brain to enable scientists to investigate, via neuroimaging, the effects of smoking on the brain;
- Developed new measures of culture and smoking that will help develop a multicultural and culturally-adapted curriculum to prevent smoking in youths of Chinese, Vietnamese, Korean, Filipino, Mexican, South and Central American, and Middle East descent.
- Special Programs of Research Excellence (SPORES) program—SPORES support innovative, multidisciplinary research with the potential to have an immediate impact on cancer care and prevention. The increase in fiscal year 2001 funding along with the exceptionally high quality of SPORE applications have given NCI the opportunity to support more SPOREs than was thought possible, even as recently as a few months ago. As many as 7 additional SPORES will be funded, bringing a breadth and depth to research in areas of breast, ovarian, prostate, genitourinary, lung, and gastrointestinal cancers that is both promising and exciting.
- NCI's Surveillance, Epidemiology and End Result (SEER) program has been the gold standard for cancer registries worldwide for over 30 years. In fiscal year 2001, through our increase in funds, we are funding a major expansion of the program that will include California, Louisiana, Kentucky and New Jersey. SEER will now cover 26 percent of the U.S. population and will increase the coverage of the rural population by 150 percent, the population below the poverty line by 200 percent, Asian Americans by 200 percent, non-Mexican Hispanics by 70 percent and Native Americans by 36 percent.

MOLECULAR TARGETING

One broad set of research areas that is particularly reaping the benefit of increased funding is molecular targeting, encompassing a wide range of initiatives aimed at using emerging knowledge of the human genome to revolutionize the way we detect, diagnose, treat and prevent cancer.

- Cancer Genome Anatomy Project (CGAP)*.—Will complete its Human Tumor Gene Index in fiscal year 2001, ahead of schedule, thereby providing key information to the research community toward reading the molecular signatures of cancer. This online resource is used widely by the community and has become the preeminent gene expression database of human cancer. CGAP also built an online version of the Mittleman Database of Chromosomal Aberrations in Cancer, thereby displaying in a user friendly format, information from years of cancer chromosomal analysis and providing a means to link changes in the genome with changes in gene expression patterns. Although this project was not expected to be launched this year, its progress was accelerated based on scientific opportunity and the increased appropriations.
- Early Detection Research Network (EDRN)*.—A major new initiative made possible through NCI's increased funding, is one of the new approaches, based on genomics and other emerging technologies, to systematically pursue the goal of developing effective and reliable tests for the earliest possible detection of all cancers and even of pre-cancers. EDRN will create, for the first time, a national R&D enterprise to discover molecular biomarkers of cancer, develop reliable tests and validate them with clinical studies. EDRN is a partnership of NCI, other government agencies, industry and academics. In its first year, dozens of potential markers are being studied and 3 are moving toward validation studies.
- Director's Challenge—Toward a Molecular Classification*.—Initiated 2 years ago, results are emerging and demonstrate that cancers currently diagnosed as a single type of cancer are actually several, molecularly distinct diseases. This molecular distinction may explain why some patients do well with current therapy but other patients, with the same diagnosis, fare poorly. For instance, it appears that diffuse large B-cell lymphoma is actually at least 2 different diseases, one of which is almost always cured by current therapy and the other of which is almost never cured.
- Molecular Targets Drug Discovery (MTDD)*.—This new initiative will support researchers who will identify and use molecular targets for the discovery of new anticancer agents based on the molecular mechanisms that underlie cell transformation to cancer, cancer growth and metastasis—over 170 applications were received and 37 grants funded.

- Interdisciplinary Research Teams for Molecular Target Assessment (IRT/MTA)*.—Is a new approach to developing clinically useful assays to measure and monitor cancer in patients according to the actual molecular targets where the treatment is directed. We expect to fund 2 to 3 teams/centers.
- Chemistry/Biology Centers of Excellence*.—Funded 6 centers to bring chemists and biologists together to discover chemicals that report on or affect the molecular machinery of cancer.
- National Molecular Target Laboratories (MTLs)*.—MTLs are envisioned as genomic-scale efforts to discover molecular probes for all potential cancer relevant molecular targets. We hope to establish 1 to 3 large laboratories.
- Rapid Access to Interventional Development (RAID) and the Rapid Access to Preventive Intervention Development (RAPID) programs*.—Closely related to the above initiatives, these programs were established in 1999 and 2000, respectively, to take potential therapeutics from academic or small business laboratories and turn them into drugs ready to be tested in phase I clinical trials. These programs are intended to remove the most common barriers between laboratory discoveries and clinical trials of new molecular entities. In its first two years, RAID is supporting 51 novel agents and we hope that 11 will reach the clinic by the end of this year. During its first year, RAPID is supporting 12 novel agents and we hope 1 to 3 will reach the clinic by the end of 2002.
- In vivo Cellular and Molecular Imaging Centers (ICMICs)*.—NCI recently initiated major efforts to nurture and develop an exciting new field of research called “molecular imaging,” which has the potential to substantially improve the way we detect, diagnose and treat cancer. Molecular imaging integrates the rapid advances in molecular biology, genomics, and chemistry with cutting-edge imaging techniques. This field requires communications between diverse groups of scientists who usually did not interact together in the past, and thus, is in its very infancy. The additional funding support we received enabled NCI to support 16 planning grants, and in fiscal year 2001, the startup of 3 multidisciplinary ICMICs.

As a final example, the additional funds have allowed NCI to accelerate the implementation of our strategic plan to address pressing questions in cancer disparities through our Quality of Cancer Care initiatives, our newly formed Center to Reduce Cancer Health Disparities and our Comprehensive Minority Biomedical Programs. Eighteen Special Population Networks for Cancer Awareness, Research and Training have been launched as have 12 new partnership programs between NCI-funded Cancer Centers and Minority Serving Institutions. These and other activities are aimed at increasing our understanding of cancer disparities, increasing the participation of minority and underserved communities in the cancer research enterprise, and finding ways to address the disparities in cancer burden.

Question. Two, what will you be able to do with an 11 percent increase?

Answer. The 11.8 percent increase in the fiscal year 2002 President’s Budget will allow NCI to support about 250 more research projects in fiscal year 2002 than in fiscal year 2001. While many of the new research projects will be investigator-initiated and therefore, hard to identify at this time, we have identified through NCI’s fiscal year 2002 Congressional Justification and the fiscal year 2002 Bypass Budget a wide range of research or research support activities that NCI will initiate or expand as funding and scientific opportunities permit. Examples of activities NCI will support at the 11.8 percent funding level include:

- Centers of Excellence in Cancer Communications*.—This initiative reflects the broadening awareness that effective communications can and should be used to narrow the enormous gap between research discovery and its application, and to help reduce health disparities among our citizens. The centers will provide essential infrastructure to facilitate rapid advances in knowledge about cancer communications, translate theory and programs into practice, and train scientists in health communications. We expect to fund 4 to 5 centers in fiscal year 2002.
- Mouse Models of Human Cancer Consortium (MMHCC)*.—Expand from 10 to 30 mouse models that mimic human cancers.
- Cancer Genome Anatomy Project (CGAP)*.—Accelerate the completion of the Mouse Tumor Gene Index to fiscal year 2002.
- Specialized Projects of Research Excellence (SPOREs)*.—Fund a total of 2 more SPOREs among the following research areas: head and neck, brain, lymphoma and gynecologic cancers.
- Minority Serving Institution/Cancer Center Partnership and Collaboration*.—Initiatives to develop partnerships or close collaborations between cancer centers and minority serving institutions such as historical black colleges or universities, hispanic serving institutions or tribal institutions/colleges. The over-

arching goal is to develop a stronger national cancer program aimed at understanding the reasons behind the significant cancer disparities and its impact on minority populations. We expect to fund 2 comprehensive grants and 24 planning grants in collaboration with the National Center on Minority Health and Health Disparities.

- In vivo Cellular and Molecular Imaging Centers (ICMICs)*.—Continues our support of this new field of “molecular imaging” and we expect to fund 2 additional ICMICs in fiscal year 2002.
- Rapid Access to Interventional Development (RAID) program*.—We can support the initial, pre-clinical development of 3 to 6 highly promising drugs in fiscal year 2002.
- Rapid Access to Preventive Intervention Development (RAPID) program*.—We can support the initial, pre-clinical development of 3 to 5 highly promising cancer prevention agents.
- Molecular Targets Drug Discovery (MTDD)*.—This initiative continues our efforts from fiscal year 2001 and is designed to support researchers who will identify and use molecular targets for the discovery of new anticancer agents based on the molecular mechanisms that underlie cell transformation to cancer, cancer growth and metastasis. We expect to fund about 10 grants.
- Clinical Trials*.—Expand the number of clinical trials that NCI supports by 30 to 50 so that more cancer patients may have access to enrolling in a clinical trial.

Question. And three, what will you be able to do with a 20 percent increase?

Answer. In our Bypass Budget, we have set forth, based on our best professional judgment, the realistic goals, objectives, and milestones we feel we could achieve in fiscal year 2002 with the appropriate funding. In general, the larger the funding increase is, the more initiatives in the Bypass we can support. A 20 percent funding increase will allow us to support almost 50 percent of the initiatives in the Bypass. The following are examples of some of our major initiatives:

- Centers for Population Health*.—Create 2 to 4 centers to accelerate advances in our knowledge of finding ways to reduce cancer-related health disparities through fundamental cancer control and population research.
- Special Populations Networks for Cancer Awareness Research and Training (SPN)*.—Fund an additional 2 to 6 SPN sites to enhance research infrastructure and training to underserved communities.
- Cancer Centers*.—Establish 6 to 10 Advanced Technology Programs and Informatics Planning Activities in cancer centers to accelerate the access of the newest technologies and informatics capabilities to solve important problems in cancer research.
- SPOREs*.—Fund an additional 4 to 6 SPOREs among the following research areas: head and neck, brain, lymphoma and gynecologic cancers.
- Molecular Targets Drug Discovery (MTDD)*.—Expand the MTDD program to fund an additional 20 to 30 grants.
- Interdisciplinary Research Teams for Molecular Target Assessment (IRT/MTA)*.—Expand from 2 or 3 centers to 7 to 10 centers to develop a “toolbox” of valid assays for assessing a drug’s effect on its intended target, thereby speeding movement of candidate drug molecules to the clinic.
- Clinical Trials Outreach Program*.—Create this program to increase participation by underrepresented populations; establish clinical trials units at historically black medical institutions; strengthen clinical trials units at minority-based community oncology sites.
- Clinical Trials*.—Fund Cooperative Groups and other programs to allow physician and patient participation in clinical trials to increase by at least 20 percent.
- Phased Innovation Awards*.—Double the number of Phased Innovation Awards in the Innovative Molecular Analysis Technologies (IMAT) Program to 20 new awards to accelerate development of technologies relevant to discovering and measuring molecular signatures of cancer and precancer.
- Early Detection Research Network*.—Expand funding for additional work in the discovery, development, and validation of new early detection tests for all major human cancers.
- Research Project Grants (RPGs)*.—Fund an additional 100 to 200 investigator initiated RPGs.
- RAID and RAPID*.—Expand funding to support the development of an additional 5 to 8 highly-promising drugs in each program.

QUESTIONS SUBMITTED TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. What will be the impact of fiscal year 2002 cut in funding for Cancer Prevention and Control, specifically breast and cervical cancer?

Answer. A \$9.2 million reduction in fiscal year 2002 appropriations in the Breast and Cervical Cancer Mortality Prevention Act line would result in CDC's National Breast and Cervical Cancer Early Detection Program receiving a decrease of \$5.6 million awarded to States for the early detection of breast and cervical cancer. This reduction will result in average cut to States, tribes, and territories of \$81,159 and an estimated 26,880 screenings for breast or cervical cancer would not be provided to underserved women (approximately 336 women per program. wouldn't be screened). About one half of the women who benefit from these screens are women of racial/ethnic minorities. In addition, CDC would be forced to assess its work with partners and cut back on support for key national organizations. The organizations are currently funded to increase utilization of breast and cervical cancer early detection services, particularly minority and older women. A cut of this magnitude could result in the dismantling of networks, partnerships and the public health infrastructure for breast and cervical cancer early detection at both the State and national levels. States are mandated to spend a minimum of 60 percent of their awards for screening and follow-up services, therefore, there is a direct link between the amount of the appropriation and the number of screenings provided.

Question. How does CDC view mammography screening for women ages 40 and above?

Answer. Mammography is currently the single most effective method for diagnosing breast cancer early, with an estimated ability to detect abnormalities between 76 and 94 percent of the time. The longer breast cancer remains undetected and untreated, the greater the likelihood it will spread. Death from breast cancer can be reduced substantially if the tumor is discovered at an early stage. Early detection and appropriate follow-up could prevent approximately 15–30 percent of breast cancer deaths in women over age 40. Through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), CDC provides low or no cost screening services (a physical examination of the breasts and mammography) to women who are at or below 250 percent of the Federal poverty level, uninsured, underinsured, and ages 40 to 64 for mammography or older but not otherwise eligible for Medicare services part B.

Question. What would it take to reduce racial/ethnic differences in breast cancer?

Answer. Racial and ethnic differences in breast cancer could be reduced by: modifying current authorizing language to permit more funding for expand outreach efforts for these hard to reach women; fully funding CDC's program and allocating funding to specifically target these women so they are screened; taking advantage of the Breast and Cervical Cancer Prevention and Treatment Act of 2000 to provide medical care and treatment for women diagnosed through CDC's program; and, examining the quality of cancer care these women receive.

Identifying, educating and motivating women who have rarely or never been screened for breast cancer is an enormous challenge. To be successful in these cases, the community outreach efforts of CDC's program often become a door-to-door, one-on-one campaign to reduce community and individual barriers that impede a woman's ability or decision to obtain the lifesaving benefits of early detection. Barriers such as fear, lack of transportation and child care, linguistic and cultural differences, and lack of physician referral are all common hurdles that must be overcome. Many outreach strategies are employed to overcome these barriers.

Moreover, NBCCEDP authorizing language (Public Law 101-354) constrains the states' level of effort in conducting outreach activities stating that no more than 40 percent of a Federal grant awarded to a state may be spent on such activities as: public education and outreach, coalitions and partnerships, management, professional education, and surveillance and evaluation. Increasing the percentage allocated for outreach efforts in the authorizing language would enable states to better reach these women.

Although CDC has received increases in funding, we are continuing to only screen 15 percent of the eligible women. Over the years, more and more women have become eligible for screening under CDC's program (i.e., more women are underinsured or uninsured). Even though increases in funding have permitted CDC to screen more women over time, the number of women eligible increased at the same rate. Fully funding CDC's NBCCEDP could contribute to creating parity among all racial and ethnic groups. CDC estimates that there are approximately 3.6 million

women aged 40 to 64 who are eligible for the NBCCEDP. The Federal costs of reaching these women would be about \$1 billion.

Even after outreach and screening occur, minority women (and all women for that matter) need access to treatment. States need to take advantage of the recently passed "Breast and Cervical Cancer Prevention and Treatment Act of 2000". This Act allows States the option to choose Federal Medicaid matching funds to provide medical care and treatment to low-income women who have been diagnosed with breast or cervical cancer through CDC's program. As of May 11th, HCFA approved requests from Maryland, New Hampshire, Rhode Island, and West Virginia to use this option and it has received requests from North Dakota and Utah. Other States are in various stages of their own approval processes.

Finally, we need to review the type of care these women are receiving. Using cancer registry data, CDC can monitor and assess patterns of cancer care to help ensure that quality cancer care is being provided.

Senator SPECTER. Thank you, ladies and gentlemen who have come in to testify. The groups who have worked so hard to fight breast cancer are of enormous importance. The National Breast Cancer Coalition, the Komen Foundation, and the others are really of enormous, enormous help and have stimulated a lot of congressional support to lead us to the kind of increases that we have made.

And Senator Harkin puts his finger right on the critical issue about acquainting women, young women, middle-aged women, older women, all women, about the problems of breast cancer. And that really has to be done.

And the avant-garde issue now is the stem cell issue. And again, I say to you that that is where we really need to focus our attention right now, because that may be in the Senate for a vote during this month or perhaps next month, so globalize one of the greatest advocacy groups in America.

CONCLUSION OF HEARING

Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:33 p.m., Wednesday, May 9, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]