

Breast Cancer:
A Report on the Fight to
Prevent, Treat, and Cure the Disease

Breast Cancer: A Report on the Fight to Prevent, Treat, and Cure the Disease

Thirty years ago, people only whispered the words breast cancer, and a diagnosis of breast cancer meant a virtual death sentence. Today, breast cancer is at the forefront of the nation's health care agenda, and we have made tremendous strides to prevent, detect, and treat the disease. Since 1993, the Clinton Administration has been committed to waging this battle on numerous fronts. First, the Administration has made a significant investment in research--reaching over \$500 million in 1998. Second, we have improved the quality and availability of early detection tools like mammography. Third, we have worked to improve access to treatment and quality of care for women with breast cancer. The Administration has fostered cooperation and communication among the government, experts, survivors, and advocates, primarily through the National Action Plan on Breast Cancer, a public-private partnership. The Administration has also worked to increase collaboration among government agencies through the Federal Coordinating Committee on Breast Cancer.

Breast cancer mortality rates have improved markedly in the United States, declining 4.6 percent between 1991 and 1995 alone. However, breast cancer remains the second leading cause of cancer deaths among American women. Today, one in eight women will develop breast cancer, up from one in 20 just two decades ago. In 1998, approximately 180,000 new cases of breast cancer will be diagnosed and the disease will claim nearly half a million lives in this decade.

Faced with these still daunting statistics, the Administration has made a tremendous investment in breast cancer research, prevention, and treatment. In FY1998 alone, the Clinton Administration invested almost \$700 million in the fight against breast cancer. The Department of Health and Human Services, which includes research by the National Institutes of Health (NIH) and screening through Centers for Disease Control (CDC), has nearly doubled its discretionary spending on breast cancer from \$283 million in FY1993 to an estimated \$550 million today. Additionally, the Department of Defense's Breast Cancer Research Program spent \$135 million in FY1998 on innovative peer-reviewed breast cancer research. The Clinton Administration has also expanded its investment in breast cancer through the Medicaid and Medicare programs which provide mammograms and breast cancer treatment to countless women.

In recent years, intensive research has yielded important breakthroughs. A 1994 study revealed two genes that increase a woman's risk of developing breast cancer, and President Clinton has announced \$30 million of additional funding to explore further the role of genes in breast cancer susceptibility. This year, tamoxifen was shown to reduce the incidence of breast cancer by 49 percent in women at high risk for the disease. The Food and Drug Administration (FDA) has recently approved new detection and treatment devices, and is putting drugs for women with breast cancer on a fast track for approval. Drugs recently approved by the FDA include Herceptin, a drug that may help slow the progress of the disease once it has spread to other parts

of the body, and Taxol, a drug that when used with chemotherapy helps patients whose cancer has reached the lymph nodes. And more ground breaking research is ongoing, including studies of environmental factors contributing to breast cancer; the NIH's Women's Health Initiative, which is examining opportunities to reduce breast cancer through diet; and the Cancer Anatomy Genome Project, which since its launch in 1997 has already identified more than 300,000 DNA sequences and 12,000 new genes in an effort to understand better the genetics of breast cancer -- double what the National Cancer Institutes (NCI) originally anticipated.

The Administration has also worked to educate women about and improve access to mammography and other tools of early detection. This year, due to the President's leadership, Medicare began covering annual mammograms for all beneficiaries age 40 and over and made them more affordable by waiving the deductible. On October 9, the President signed the reauthorization of the Mammography Quality Standards Act, under which the FDA sets high standards to ensure that mammograms are safe and accurate and certifies those facilities that meet its standards. The Clinton Administration has also spearheaded a number of outreach initiatives and programs to ensure that women have access to mammograms. The First Lady launched a campaign in 1995 to encourage older women to take advantage of the mammography benefit offered by Medicare, and this campaign continues each year with the support of the Health Care Financing Administration and numerous private partners. This year's effort focuses on improving mammography rates among minority women. CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to uninsured, low-income, elderly, and minority women.

The Administration has also fought tirelessly to improve access to treatment and quality of health care for women with breast cancer. The President has fought to prevent health plans and employers from discriminating against individuals based on their genetic information, so that advances in genetic research can be used to help detect breast cancer rather than to discriminate. He has also urged Congress to pass a patients' bill of rights that will guarantee critical protections to patients with breast cancer -- including access to specialists and a fair appeals process. To help breast cancer patients participate in clinical trials, last month the President directed NCI to implement a new system that will make it easier for physicians to enroll patients in clinical trials. The Administration has also urged Congress to pass legislation that would allow Medicare to cover patient care costs for cancer clinical trials. To address racial disparities in treatment, access to care, and health status, the Administration has proposed an initiative to address health disparities in six major areas, including cancer. And finally, building on unprecedented efforts begun at the Department of Defense and the FDA, next year NCI will fully integrate patients and advocates into policy planning and grant reviews. With each of these advances we are moving closer to discovering the cure for breast cancer.

Significant challenges remain. We must continue to fight for legislation ending discrimination against individuals based on their genetic information. We must continue to fight for strong, enforceable patients' bill of rights legislation. We must continue to increase access to clinical trials. We must continue to work to end racial disparities that still exist in breast cancer

mortality, mammography rates, and access to treatment. We must continue to integrate advocates in planning the cancer research agenda. And, most important, we must continue to support research that builds on the dramatic research breakthroughs we have seen in recent days to find a cure, and finally an end, for breast cancer.

FIRST LADY ANNOUNCES RECORD FUNDING INCREASE FOR CANCER RESEARCH, NEW BREAST CANCER CLINICAL TRIAL, AND OTHER NEW STEPS TO FIGHT BREAST CANCER

October 21, 1998

"We are facing a critical juncture in the fight against breast cancer. Our national commitment is beginning to pay off as we witness enormous progress against the disease. With more investment at this critical time, we can truly hope for successful ways to prevent, detect, treat, and one day cure this cancer that strikes so many women."

First Lady Hillary Rodham Clinton

Today, in honor of Breast Cancer Awareness Month, First Lady Hillary Rodham Clinton announced: the largest funding increase in the history of the National Cancer Institute (NCI); a new clinical trial of drugs to reduce the risk of breast cancer; and an expanded mammography outreach campaign. The First Lady also released a five-year report from the Federal Coordinating Committee on Breast Cancer charting extraordinary progress in breast cancer research, prevention and treatment. The First Lady:

Announced Record Funding Increase for the National Cancer Institute. As part of the recent budget agreement, Congress passed a significant down-payment on the President's 21st Century Research Fund. Today, the First Lady announced that the National Cancer Institute will receive a total budget of over \$2.9 billion in FY 1999, about a \$400 million increase, that was strongly advocated by the Vice President. This increase will enable NCI to fund critical new research activities including: initiatives to increase patient participation in clinical trials (over 10 percent of funding will be used for this purpose); efforts to meet the President and Vice President's challenge to translate progress in genetics to create diagnostic techniques for every major cancer by the year 2000; and investments to develop new early detection methods. This increase will also fund ten new breast cancer treatment clinical trials, including a trial to expand the use of Herceptin to treat breast cancer earlier. This budget will build on historic increases in breast cancer at the NIH during the Clinton Administration from \$283 million in FY 1993 to an estimated \$480 million in FY 1999. The Department of Defense will spend an additional \$135 million in FY 1999 on innovative peer-reviewed breast cancer.

Announced Largest Clinical Trial of Drugs With Potential to Reduce the Risk of Developing Breast Cancer. The First Lady also announced a new clinical trial to examine tamoxifen, a drug that has been shown to reduce the risk of developing breast cancer, and raloxifene, which researchers believe may also reduce the risk of breast cancer. The unique STAR trial will involve 22,000 women at increased risk of breast cancer and is scheduled to open at approximately 400 sites across the United States and Canada early next year. Underscoring the need to examine all aspects of breast cancer, the First Lady also highlighted an important trial underway at NIH examining the relationship between a low-fat diet and prevention of breast cancer.

Unveiled Report on Progress Against Breast Cancer in the Last Five Years. The First Lady also released a new report from the Federal Coordinating Committee on Breast Cancer highlighting accomplishments in breast cancer over the past five years, since the Administration took office. This report underscores critical progress the Administration has made, including:

- A significant investment in research--reaching over \$600 million in 1999 that has led to historic advances in breast cancer, such as the identification of new breast cancer genes, and promising new treatments, such as Taxol and Herceptin;
- Improved the quality and availability of prevention tools like mammograms, through efforts such as a new Medicare mammography benefit, an unprecedented outreach campaign to encourage older women to get mammograms, as well as improvements in the quality of mammograms through the Mammography Quality Standards Act;
- Enhanced access to treatment and quality of care for women with breast cancer by increasing access to cancer clinical trials, new projects to improve detection and care among low-income and minority women;
- Innovative interagency and public-private partnerships to apply the latest in defense and space technology to better detect cancerous tissues and to develop less intrusive surgery methods for patients.

Expanded Awareness Campaign To Help Ensure Women Get Recommended Mammograms. The First Lady also unveiled an expanded outreach and education campaign to encourage women ages 65 years and older to get regularly scheduled mammograms. This year's campaign will emphasize the new mammography Medicare benefit that the President proposed and signed into law that covers annual mammograms and makes them more affordable. HHS is also expanding outreach efforts to special populations --low-income and minority women --who tend to have the highest breast cancer mortality rates. For example, the Health Care Financing Administration has initiated a pilot program to provide mammograms and to air public service announcements in key cities targeted to minority communities, and HHS has developed and distributed educational materials to underserved communities around the country. The First Lady also commended the private sectors organizations who have made an ongoing commitment to promoting breast cancer awareness.

Highlighted That Congress Has Adjourned Without Passing Critical Legislation to Advance the Fight Against Breast Cancer. The First Lady also outlined the agenda that has yet to be finished by this Congress, including:

- **A Patients' Bill of Rights.** The Clinton Administration has repeatedly urged the Congress to pass a strong, enforceable patients' bill of rights that would assure Americans the quality health care they need. A patients' bill of rights contains critical patient protections for women with breast cancer, such as assuring access to specialists, continuity of care so that women are not required to change doctors in the middle of treatment, and an independent appeals process to address concerns that health plans are unfairly delaying or denying care.

- **Legislation to End Genetic Discrimination.** Studies show that a leading reason women do not get new genetic testing for susceptibility to breast cancer is because they worry about discrimination. To ensure that new advances in genetics are used to improve health rather than to discriminate against individuals, the President has called for legislation prohibiting health plans and employers from discriminating against individuals on the basis of their genetic information.
- **Bipartisan Initiative Authorizing Coverage of Cancer Clinical Trials for Medicare Beneficiaries.** Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. Older Americans, however, frequently cannot participate in cutting-edge cancer clinical trials because Medicare does not pay for experimental treatments. The Congress has adjourned without passing the Administration's proposal, similar to legislation supported by Senators Mack and Rockefeller, that authorizes coverage of clinical trials for Medicare beneficiaries without harming the Trust Fund.

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

Breast Cancer Information eXchange



October 1998

Mayors Work with American Cancer Society

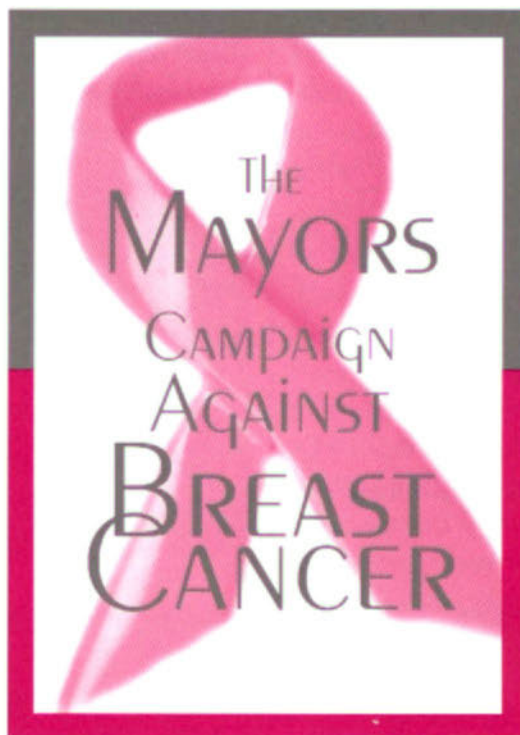
In developing the Mayors' Campaign Against Breast Cancer, The United States Conference of Mayors (USCM) found that cities had forged strong links with local offices (called units) of the American Cancer Society (ACS) to conduct awareness, screening and follow-up initiatives to address this disease. USCM has entered into the same type of collaboration at the national level with the ACS National Home Office, which has sponsored forums and provided materials for the Campaign.

This first issue of the *Breast Cancer Information Exchange* represents another type of national collaboration with ACS - - the development of a publication that presents models of city cooperation with local ACS units. In each of the four cities described - - Philadelphia, Boston, Virginia Beach, and Washington, D.C. - - the mayor has taken a leadership role in promoting teamwork among city agen-

cies, medical facilities, advocacy groups, and the local ACS unit.

The *Information Exchange* publication is a core activity of the Mayors' Campaign Against Breast Cancer. Launched by USCM in November 1997 and supported by a five-year cooperative agreement with the Centers for Disease Control and Prevention (CDC), the goal of the campaign is to save lives through the early detection of breast cancer. CDC has provided more than 1.5 million screenings since 1991 through its National Breast and Cervical Cancer Early Detection Program and, with the support of the nation's mayors, hopes to increase this number substantially.

ACS believes the mayors can play a pivotal role in addressing breast cancer, especially in outreach for screening. According to ACS projections, 178,700 new cases of breast cancer will be diagnosed in 1998 and will result in 43,900 deaths.



In This Issue:

"Mayors and ACS Promote Breast Cancer Awareness"

page 3

Mayor Rendell Helps ACS Launch Breast Cancer Partnership

page 3

Mayor Menino Saves a Life from Breast Cancer

page 4

Mejera Oberdorf Survives Breast Cancer and Reaches Out to Others

page 5

"Building Upon Past Collaborations"

page 6

"Good News About Cancer Rates, But Challenges Lie Ahead"

page 7

"District of Columbia - American Cancer Society:
A Model for Collaboration"

page 8

Sign-up Form for the Mayors' Campaign Against Breast Cancer

page 11

Members of the Mayors' Campaign Against Breast Cancer

pages 14-15

**Five Year Report on Breast Cancer
Internal Questions & Answers
(October 21, 1998)**

General

Q. What are general guidelines for women and breast cancer screenings?

A. The National Cancer Institute recommends that women in their forties or older get screening mammograms on a regular basis, every one to two years.

Women who are at increased risk for breast cancer should seek medical advice about when to begin having mammograms and how often to be screened. (For example, a doctor may recommend that a women at increased risk begin screening before age 40 or change her screening intervals to every year.)

In fact, for women ages 50-69, having regular mammograms can reduce the chance of death from breast cancer by one third or more. Despite the potential benefit, one third of women ages 50-64, and 45 percent of women over age 65 reported not receiving a mammogram during the past two years.

As of January 1, 1998 Medicare helps pay for annual mammograms by waiving the Part B deductible. We encourage all Medicare beneficiaries to take advantage of this preventive benefit.

Q. Will more mammograms cause more invasive and possibly unneeded procedures for older women?

A. A recent study suggested that women age 70 and older had a number of follow up procedures after abnormal mammograms. However, other studies would need to be done to determine the significance of this finding. A woman's chance of developing breast cancer in her lifetime rises significantly after age 60, so no woman should consider herself too old for regular screening mammograms.

The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to older women of low income. For more information on how to get a free or low-cost mammogram and the nearest location, women should contact their local health department or the National Cancer Institute's Cancer Information at 1-800-4-CANCER. Through March 1998, the program has provided more than 1.7 million screenings.

Q. What has the Administration accomplished on breast cancer since 1993?

A. In recent years, we have invested in research, prevention and early detection and treatment of breast cancer.

- Scientists understand now more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, and why some tumors are more aggressive than others.
- We have translated these discoveries into therapies that improve cancer-free survival and initiated the Office of Cancer Survivorship at NCI to help improve the quality of life for those continuing to live with the disease.
- With new interagency collaborations and forging private-public partnerships, we have refined technologies for detecting and diagnosing breast cancer and launched awareness and education campaigns targeted at older, low income and minority women usually – who tend to have the highest breast cancer
- mortality rates, and improved outcomes and supportive care during and after treatments for patients.

Q. We hear about different scientific progress/investigations/trials every day - are we close to a cure? Does the Administration believe we will find a preventive drug or cure soon?

A. In recent years, intensive research into all aspects of breast cancer has led to a flurry of important new discoveries. Scientists understand now more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, and why some tumors are more aggressive than others. We are having increasing success in translating these discoveries into therapies that improve cancer-free survival and improve the quality of life for those continuing to live with the disease and into more refined technologies for detecting and diagnosing breast cancer.

But, there is still much work to be done to remove the threat of breast cancer from women's lives. This nation's investment in cancer research and carefully conducted basic research and clinical trials helps make each advance possible, bringing us closer to an end to this disease.

Q. What are the latest studies on incidence and mortality on breast cancer? Is there a direct correlation between Administration's increased funding for research and results?

A. From 1991 to 1995, overall breast cancer incidence rates have leveled off after being on the increase for nearly two decades. This decline was most evident for white and Hispanic women. Breast cancer death rates dropped 1.9 percent per year in white and

Hispanic women in the same time frame.

Perhaps most encouraging is that incidence of advanced breast cancers (Stage III and IV), which have the highest mortality rates, have dropped by over 11% in whites and about 18% in black women over the last ten years.

Increased funding for cancer research makes it possible for cancer researchers to seize extraordinary opportunities to further the progress that is brought about by previous research successes. It also speeds the translation of important new discoveries into the daily practice of medicine that will benefit everyone. Undoubtedly, the increased funding since 1993 has made a difference.

Specific

Q. What is National Cancer Institute getting in new the budget agreement and what will it be used for?

A. The National Cancer Institute will receive the largest funding increase in its FY 1999 total budget -- \$2.9 billion, a 15% increase over FY 1998. This is the largest funding increase (in total dollars) for the National Cancer Institute. Breast Cancer spending for FY 1999 will be \$388 million and will have increased by \$40 million for FY 1999 over last year. It will allow NCI to fund many more research grants, including more than \$40 million new dollars for breast cancer research. NCI will expand its activities in four fundamental cancer research areas that will have a direct impact on breast cancer: an understanding of the biology of cancer; identifying who is at risk and why; developing interventions to prevent, detect, diagnose, and treat cancer, and to enhance survivorship from cancer; and bringing research discoveries to the public and to medical practice.

Q. Should all women take tamoxifen?

A. Tamoxifen is only appropriate for women with an increased risk of breast cancer, and the drug may not be right for every women at high risk. In September, NCI made available a computer-based tool to help health professionals project a woman's individualized estimate of breast cancer risk, allowing a woman and her health care provider an opportunity to discuss the potential benefits and risks of taking tamoxifen.

The National Cancer Institute has also been clear that there are side effects, including increasing a women's chances of three rare, but life threatening health problems, endometrial cancer (cancer of the lining of the uterus), blood clots in large veins, and blood clots in the lung. Women under age 50 appeared to suffer no excess risk of serious effects from tamoxifen. That's one reason for the STAR clinical trial were announcing today.

Q. We've heard so much about tamoxifen this past year - is this the one drug that is better than the rest?

A. The Breast Cancer Prevention Trial, which showed tamoxifen can reduce breast cancer by half, was not an end, but a promising beginning, that tells us that it is possible to prevent breast cancer. Tamoxifen has shown a major benefit for high-risk women, but may cause serious side effects. Researchers are already creating and testing a second generation of drugs which may reduce a woman's risk of breast cancer, such as raloxifene, a drug similar to tamoxifen, which may also reduce the risk of breast cancer in women with high risk. That is why we are initiating the STAR trial.

Q. Has tamoxifen been overblown?

A. The Breast Cancer Prevention Trial demonstrated a 49% reduction in new breast cancer cases for women at high risk for the disease. Because of the clearly positive results, the study was released more than a year earlier than anticipated. Tamoxifen, however, is not for all women. Tamoxifen is only appropriate for women with an increased risk of breast cancer, and the drug may not be right for every woman at high risk. For some women, the risks of side effects need to be weighed against the breast cancer reduction benefits. In September, NCI made available a computer-based tool to help health professionals project a woman's individualized estimate of breast cancer risk, allowing a woman and her health care provider an opportunity to discuss the potential benefits and risks of taking tamoxifen.

The purpose of the STAR trial is to build on the success of the Breast Cancer Prevention Trial.

Q. How do the Federal Coordinating Committee and the National Action Plan complement each other?

A. In an effort to foster interagency collaborations among breast cancer programs across the federal government, the Federal Coordinating Committee on Breast Cancer was established as a liaison to the National Action Plan on Breast Cancer. The Federal Coordinating Committee was designed to ensure collaboration between the National Action Plan and other government and non-government agencies and organizations conducting breast cancer activities while the FCC is solely a government coordinating effort, the National Action Plan on Breast Cancer has focused on forging partnerships with the private sector. The groups are developing more complementary activities so that all parts of the government and private sector can be unified to find a cure for breast cancer.

Q. How do these clinical trials work? Is there FDA approval immediately following clinical trials?

A. The goal of clinical trials is to find out whether, in the case of the STAR trial, cancer drugs which may reduce a woman's risk of breast cancer --are safe and effective. A clinical trial is one of the final stages of a long and careful cancer research process. The studies involve thousands of participants, and take years to complete. Researchers follow rigorous guidelines and patient safety is monitored closely throughout the entire process. Results from clinical trials are published in scientific journals and analyzed through a peer-review process. If the trial results indicate a significant benefit, researchers submit a new drug application. The clinical trials data is then submitted to FDA for review.

Q. What significance does the STAR preventive trial have in the search for a cure to breast cancer?

A. As we continue our quest for a drug to help reduce the risk of breast cancer for all women, we can mark the discovery and development of tamoxifen as a major milestone that established a new avenue of research that should continue to foster cancer reducing discoveries and successes in the future. The STAR trial will build on the success of the earlier tamoxifen study, and will study raloxifene, a drug similar to tamoxifen. The clinical trial will evaluate the benefits and risks of reducing a woman's risk of breast cancer.

The breast cancer clinical trials are part of a comprehensive, broad range approach to breast cancer research into finding effective ways to detect, treat, cure, and ultimately prevent the disease.

Q. How can a woman join the STAR trial?

A. Women can be put on a mailing list to receive information about STAR by Internet (<http://www.nsabp.pitt.edu>), by mail (National Surgical Adjuvant Breast and Bowel Project, Box 21, Pittsburgh, PA 15261), or by fax (412-330-4660). Once the trial has begun, women can get information from NCI's Cancer Information Service at 1-800-4-CANCER and the NCI web site for clinical trials information (<http://cancertrials.nci.nih.gov>).

Breast Cancer:
A Report on the Fight to
Prevent, Treat, and Cure the Disease

from the Federal Coordinating Committee on Breast Cancer

Breast Cancer:
A Report on the Fight to
Prevent, Treat, and Cure the Disease

From
The Federal Coordinating Committee on Breast Cancer

Table of Contents

Executive Summary	1
Overview	4
<i>Background</i>	<i>4</i>
<i>Declining Mortality Rates</i>	<i>4</i>
<i>Increased Funding</i>	<i>4</i>
Scientific Progress in the Fight Against Breast Cancer	6
<i>Advances in Prevention</i>	<i>6</i>
<i>Advances in Treatment</i>	<i>8</i>
<i>Advances in Detection</i>	<i>9</i>
<i>Further Steps to a Cure</i>	<i>11</i>
<i>Marking Progress</i>	<i>11</i>
<i>Other Federal Research Activities</i>	<i>12</i>
<i>Department of Defense</i>	
<i>Environmental Protection Agency</i>	
Commitments To Early Detection of Breast Cancer	13
Quality of Care and Access To Treatment	15
New Approaches in Addressing the Disease	18
<i>National Action Plan on Breast Cancer</i>	<i>18</i>
<i>Federal Coordinating Committee on Breast Cancer</i>	<i>20</i>
<i>Other Collaborations</i>	<i>22</i>
Challenges and New Frontiers	25

Breast Cancer: A Report on the Fight to Prevent, Treat, and Cure the Disease

Thirty years ago, people only whispered the words breast cancer, and a diagnosis of breast cancer meant a virtual death sentence. Today, breast cancer is at the forefront of the nation's health care agenda, and we have made tremendous strides to prevent, detect, and treat the disease. Since 1993, the Clinton Administration has been committed to waging this battle on numerous fronts. First, the Administration has made a significant investment in research--reaching over \$500 million in 1998. Second, we have improved the quality and availability of early detection tools like mammography. Third, we have worked to improve access to treatment and quality of care for women with breast cancer. The Administration has fostered cooperation and communication among the government, experts, survivors, and advocates, primarily through the National Action Plan on Breast Cancer, a public-private partnership. The Administration has also worked to increase collaboration among government agencies through the Federal Coordinating Committee on Breast Cancer.

Breast cancer mortality rates have improved markedly in the United States, declining 4.6 percent between 1991 and 1995 alone. However, breast cancer remains the second leading cause of cancer deaths among American women. Today, one in eight women will develop breast cancer, up from one in 20 just two decades ago. In 1998, approximately 180,000 new cases of breast cancer will be diagnosed and the disease will claim nearly half a million lives in this decade.

Faced with these still daunting statistics, the Administration has made a tremendous investment in breast cancer research, prevention, and treatment. In FY1998 alone, the Clinton Administration invested almost \$700 million in the fight against breast cancer. The Department of Health and Human Services, which includes research by the National Institutes of Health (NIH) and screening through Centers for Disease Control and Prevention (CDC), has nearly doubled its discretionary spending on breast cancer from \$283 million in FY1993 to an estimated \$550 million today. Additionally, the Department of Defense's Breast Cancer Research Program spent \$135 million in FY1998 on innovative peer-reviewed breast cancer research. The Clinton Administration has also expanded its investment in breast cancer through the Medicaid and Medicare programs which provide mammograms and breast cancer treatment to countless women.

In recent years, intensive research has yielded important breakthroughs. A 1994 study revealed two genes that increase a woman's risk of developing breast cancer, and President Clinton has announced \$30 million of additional funding to explore further the role of genes in breast cancer susceptibility. This year, tamoxifen was shown to reduce the incidence of breast cancer by 49 percent in women at high risk for the disease. The Food and Drug Administration (FDA) has recently approved new detection and treatment devices, and is putting drugs for women with breast cancer on a fast track for approval. Drugs recently approved by the FDA include Herceptin, a drug that may help slow the progress of the disease once it has spread to other parts

of the body, and Taxol, a drug that when used with chemotherapy helps patients whose cancer has reached the lymph nodes. And more ground breaking research is ongoing, including studies of environmental factors contributing to breast cancer; the NIH's Women's Health Initiative, which is examining opportunities to reduce breast cancer through diet; and the Cancer Anatomy Genome Project, which since its launch in 1997 has already identified more than 300,000 DNA sequences and 12,000 new genes in an effort to understand better the genetics of breast cancer -- double what the National Cancer Institutes (NCI) originally anticipated.

The Administration has also worked to educate women about and improve access to mammography and other tools of early detection. This year, due to the President's leadership, Medicare began covering annual mammograms for all beneficiaries age 40 and over and made them more affordable by waiving the deductible. On October 9, 1998, the President signed the reauthorization of the Mammography Quality Standards Act, under which the FDA sets high standards to ensure that mammograms are safe and accurate and certifies those facilities that meet its standards. The Clinton Administration has also spearheaded a number of outreach initiatives and programs to ensure that women have access to mammograms. The First Lady launched a campaign in 1995 to encourage older women to take advantage of the mammography benefit offered by Medicare, and this campaign continues each year with the support of the Health Care Financing Administration and numerous private partners. This year's effort focuses on improving mammography rates among minority women. CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to uninsured, low-income, elderly, and minority women.

The Administration has also fought tirelessly to improve access to treatment and quality of health care for women with breast cancer. The President has fought to prevent health plans and employers from discriminating against individuals based on their genetic information, so that advances in genetic research can be used to help detect breast cancer rather than to discriminate. He has also urged Congress to pass a patients' bill of rights that will guarantee critical protections to patients with breast cancer -- including access to specialists and a fair appeals process. To help breast cancer patients participate in clinical trials, last month the President directed NCI to implement a new system that will make it easier for physicians to enroll patients in clinical trials. The Administration has also urged Congress to pass legislation that would allow Medicare to cover patient care costs for cancer clinical trials. To address racial disparities in treatment, access to care, and health status, the Administration has proposed an initiative to address health disparities in six major areas, including cancer. And finally, building on unprecedented efforts begun at the Department of Defense and the FDA, next year NCI will fully integrate patients and advocates into policy planning and grant reviews. With each of these advances we are moving closer to discovering the cure for breast cancer.

Significant challenges remain. We must continue to fight for legislation ending discrimination against individuals based on their genetic information. We must continue to fight for strong, enforceable patients' bill of rights legislation. We must continue to increase access to clinical trials. We must continue to work to end racial disparities that still exist in breast cancer

mortality, mammography rates, and access to treatment. We must continue to integrate advocates in planning the cancer research agenda. And, most important, we must continue to support research that builds on the dramatic research breakthroughs we have seen in recent days to find a cure, and finally an end, for breast cancer.

OVERVIEW

Background

Breast cancer is the most commonly diagnosed cancer, excluding skin cancer, and the second leading cause of cancer deaths among American women. There is no proven way yet to lower the risk for breast cancer, so early detection through mammography and clinical breast exams is essential.

In 1998, approximately 180,000 new cases of breast cancer will be diagnosed, and about 43,500 women are expected to die from breast cancer. Epidemiological studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.

While the lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago, this rate increase can be substantially attributed to improved detection of the disease.

Declining Mortality Rates

Mortality rates have steadily declined for most women. With early detection and proper treatment, the chances of surviving breast cancer are improving. Death rates from the disease remain highest among older, African-American, and low-income women. During the most recent 5-year period, death rates among white women declined for all decades of ages from 30 to 79 years. Among black women, rates were down for all decades of ages from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups or women ages 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women ages 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

A study in the medical journal *Cancer* (July 1998) attributes the decrease or leveling off in breast cancer mortality to a trend toward progressively earlier diagnosis of cancer which is more treatable than later stage cancers. According to this study, the number of patients diagnosed with the earliest stages of the disease increased from 42 percent in 1985 to 46 percent in 1995. For women ages 50 to 69, having regular mammograms can reduce the chance of death from breast cancer by one-third or more. Despite these numbers, 33 percent of women ages 50 to 64, and 45 percent of women age 65 and older reported not having had a mammogram during the past two years.

Increased Funding

The Clinton Administration is committed to fighting the threat posed by the disease on many fronts with investments in research, outreach and education.

Because cancer research is vital to understanding how to prevent, detect, and treat breast cancer, the Clinton Administration has dramatically increased investments in breast cancer research. The Department of Health and Human Services (DHHS) discretionary funding for breast cancer has nearly doubled in the years since 1993 from approximately \$283 million in FY 1993 to nearly \$550 million today. At the National Institutes of Health (NIH) alone funding increased from \$237 million in FY1993 to an estimated \$433 million in FY1998.

As the Centers for Disease Control and Prevention (CDC) have worked to increase access for all women to mammography screening and follow up services, its resources devoted to breast cancer services have increased from an estimated \$43 million in FY 1993 to \$85 million in FY 1998. The Department of Health and Human Services also helps provide access to treatment for breast cancer through the Medicare and Medicaid programs and the Indian Health Service.

The Department of Defense (DoD) will invest \$135 million in FY1999 for innovative, peer reviewed breast cancer research.

In addition, President Clinton directed \$30 million in new funding for research into the genetic basis of breast cancer, through a collaborative initiative between the Department of Defense (DOD) and the Department of Health and Human Services in October 1996. This collaboration utilizes the Department of Defense's and the National Cancer Institute's breast cancer research programs to explore further the genetic basis of breast cancer and the most effective methods of treating those genetically predisposed to the disease.

Finally, this past summer, the U.S. Postal Service issued a breast cancer research stamp, valid for the 32 cent first-class rate but selling for 40 cents. The additional 8 cents (minus U.S. Postal Service costs) will be donated to breast cancer research, with 70 percent of the proceeds going to National Institutes of Health and 30 percent to the Department of Defense's medical research program.

SCIENTIFIC PROGRESS IN THE FIGHT AGAINST BREAST CANCER

In recent years, intensive research into all aspects of breast cancer has led to a flurry of important new discoveries. Scientists understand now more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, and why some tumors are more aggressive than others. Indeed, we are witnessing not only advances in treatment and detection, but for the first time, serious advances in prevention of breast cancer. These discoveries are leading to more refined technologies for detecting and diagnosing breast cancer, to better care and improved outcomes for patients during and after treatment, and ultimately, to prevention of the disease completely.

The Administration's increased efforts against this deadly disease have yielded promising results. At the forefront of the battle to fight breast cancer are the National Cancer Institute at the National Institutes of Health, which leads the nation's efforts in cancer research, and the Food and Drug Administration, which reviews and approves cancer drugs and devices while maintaining safe standards. Additionally, interagency collaborations continue on scientific research regarding other potential risk factors for breast cancer, including high-fat diet, hormonal therapies and environmental toxins.

The Administration has made a critical commitment to improve research by integrating advocates in planning and setting the cancer research agenda. Over the past six years, the breast cancer program at the Department of Defense has grown into one of the most renowned research programs in the nation. This unprecedented partnership between the military, scientists, physicians, and the community to fund grants to invigorate breast cancer research actively involves breast cancer survivors in defining this program and sitting on the scientific panel review boards. The Food and Drug Modernization Act of 1997 also included new efforts to integrate patients and advocates in setting the research agenda. Finally, the National Cancer Institute has also made new efforts to integrate patients and advocates. In fact, last month the President and Vice President announced that, by next year, NCI will fully integrate patients and advocates into a wide range of critical activities such as reviewing grant proposals and planning policy.

Advances in Prevention

Prevention of breast cancer is the overall goal of scientific research. A breakthrough achievement this year showed that breast cancer can be prevented for some women at high risk for the disease. Studies in cancer genetics are also providing unprecedented insight into the development and evolution of cancer and are generating knowledge about the most basic processes involved in the onset of breast cancer -- those at the molecular level.

New Drugs Approved that will Save Lives. A medical breakthrough has been the discovery of a breast cancer agent -- Tamoxifen -- earlier this year that has been shown to reduce the incidence

of breast cancer by 49 percent in women at high risk for the disease. Its discovery was a product of the *Breast Cancer Prevention Trial*, a national clinical trial, sponsored by the National Cancer Institute. This clinical trial proved for the first time that it is possible to reduce the short term incidence of breast cancer in women at high risk of breast cancer. In September 1998, a Food and Drug Administration advisory committee recommended approval of Tamoxifen to reduce incidence of breast cancer in high risk women. The NCI is now developing an education program to help physicians and patients decide who should consider taking tamoxifen.

Identifying New Markers for Breast Cancer. A 1994 study on women with a history of breast cancer revealed two different breast cancer susceptibility genes, BRCA1 and BRCA2, which increase a woman's risk for developing breast cancer. This study was conducted by the National Institute for Environmental Health Sciences in conjunction with the University of Utah and Myriad Genetics. Scientists have found that alterations in these two important genes are associated with most inherited breast cancers. While only 5 to 10 percent of all breast cancers are the result of an inherited anomaly, these findings hold promise for development of new prevention, early detection and treatment strategies. Women who choose to be tested for these genes, once tested, may be able to take preventive steps in consultation with their physicians to reduce the chances that they will succumb to the disease.

In October 1996, President Clinton announced \$30 million in funding for a new research initiative which will focus on a broad range of investigations related to the role of genes in the development of breast cancer. This collaborative effort between the Department of Defense and the National Institutes of Health may enable high-risk women to prevent breast cancer before it strikes.

Current Clinical Trials which will Lead to Prevention Breakthroughs. The National Heart, Lung and Blood Institute is leading a consortium of NIH institutes engaged in the Women's Health Initiative (WHI). The initiative includes one of the largest set of clinical trials ever conducted on the causes and prevention of breast cancer. The trial is studying the relationship between diet and the disease in a clinical trial of over 49,000 women, which may lead to information that women can use in order to deter the onset of breast cancer. The observational study of over 92,000 women will be looking for new risk factors, including genetic factors, for breast cancer. The major results of the Women's Health Initiatives are expected after 2005.

Environmental Factors and Breast Cancer. In August 1994, the DHHS Public Health Service's Office on Women's Health established a Federal Interagency Coordinating Committee on the Environment and Women's Health that focuses on how home, work, atmospheric pollutants, exogenous hormones, drugs, and other environmental factors may contribute to the risk of breast cancer and other disorders. Studies supported by the NCI and National Institute for Environmental Health Sciences (NIEHS) are currently underway on the role of the environment in cancer risk in the northeast and mid-Atlantic portions of the U.S. These studies are testing the risk from organochlorine compounds, PCBs, and estrogen-like chemicals, such as DDT, DDE, and other pesticides. To date, there does not seem to be increased risk of breast cancer from

these chemicals overall. However, there are some groups of women who may be more susceptible to the effects of DDT. For example, women who never breast-fed and some women who have certain genetic alterations may be at increased risk if exposed to these chemicals. Likewise, some forms of PCBs (called congeners) may be more estrogenic, making them possible risk factors for breast cancer. Studies are needed on exposures during a woman's childhood or adolescence, when she is more vulnerable to chemical exposures.

Advances in Treatment

Over the last five years, there have been incredible advances in treatment of breast cancer, which has given more women with the disease a chance to fight it. Indeed, it is in part due to these recent advances in treatment that death rates for this disease are dropping. New treatment approaches are evolving, including the sequencing of chemotherapies, the development of monoclonal antibodies shown to boost the immune systems to fight cancer growth, new drugs for advanced breast cancer, and medications to help prevent the disease from occurring.

FDA's Fast Track for Review and Approval of Cancer Drugs. Since 1996, the Food and Drug Administration (FDA) has accelerated the review and approval of new drugs and has improved the therapy review process by ensuring that all FDA cancer-therapy advisory committee meetings include an *ad hoc* member who has personal experience with the illness for which a new product is being considered.

FDA's Initiatives on Reinventing of Cancer Drugs. On March 26, 1996, President Clinton announced the Food and Drug Administration (FDA)'s Initiatives on Reinventing of Cancer Drugs outlining several initiatives to enhance cancer drug development and to provide opportunities for cancer patients to be actively involved in the FDA's cancer drug advisory committee process. The President's initiative enhanced FDA's strong commitment to both rapid and thorough evaluation of therapies for serious and life-threatening diseases.

Recently approved drugs that will provide women with advanced breast cancer options for treatment are Herceptin, Zoladex (gosereline acetate implant), Arimidex (anastrozole), Taxotere (docetaxel), Xeloda (capecitabine), Femara (letrozole), Fareston (toremifene citrate), and Aredia (pamidronate disodium).

Herceptin. On September 25, 1998, FDA approved Herceptin, the first genetically-engineered antibody therapy for patients with metastatic breast cancer. Developed by a biotechnology firm working with the National Cancer Institute, Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells that produce a protein called HER2 or HER2/neu. Studies indicate that Herceptin can help 25 to 30 percent of patients with advanced breast cancer.

Taxol. Early findings of a large, NCI multi-center trial show that the drug Taxol, when used in combination with other standard chemotherapy agents, has a small but significant benefit for

breast cancer patients whose disease has spread to nearby lymph nodes. Although the survival advantage is small at this point in the trial, the study is considered important because it is the first to show that Taxol may be beneficial in the initial, post-surgical treatment of some women with localized, node positive breast cancer.

Study of Tamoxifen and Raloxifene (STAR) Trial. The NCI will sponsor another large-scale study in early 1999 to compare five years of tamoxifen to five years of raloxifene for the reduction of invasive breast cancer in high-risk women. Nearly 200 institutions across the United States are expected to participate in the study of 22,000 post-menopausal women over the age of 35.

NASA Technology. NASA uses the microgravity of space to grow human tissue for research and transplantation and to gain valuable knowledge important to the treatment of breast and ovarian cancer. The NASA-designed Bioreactor is a unique tissue culture chamber that grows cells in three-dimensions. These tissues, similar to tissues found in the body, will help scientists understand cancer growth and how the human immune system responds.

Advances in Detection

As scientists work on the cure for this disease that strikes so many women, the Clinton Administration is also investing in the research needed to find better detection methods for breast cancer. As we know, early detection is the key to survival with breast cancer, and therefore, these new research methods are saving lives.

FDA's New Frontiers. The Food and Drug Administration (FDA) has recently approved several different types of devices for the detection and treatment of breast cancer including:

- Serum tumor markers (CA15-3 and CA27-29) used to monitor breast cancer patients' responses to therapy and the recurrence of the disease;
- Assays to measure HER2/neu protein in breast cancer tissues;
- An ultrasound system (Advanced Technology Labs HDI 3000) to be used in conjunction with mammography to help differentiate benign from malignant or suspicious lesions; and,
- A computer-based system (R2 Technology Model M1000 Image Checker) that identifies regions of interest on routine screening mammograms to bring them to the attention of the radiologist after the initial reading has been completed.

The Cancer Genome Anatomy Project (CGAP). Launched in 1997, the CGAP is working to identify the genetic differences among normal, precancerous, and cancerous cells. This project

identify the genetic differences among normal, precancerous, and cancerous cells. This project will help foster the discovery of genes that are directly expressed in cancer. These can be used to identify early precancerous cells, and thus enhance early detection methods. The CGAP initiative will also aid in the ability to match individual patients with the most appropriate treatments. Although this project is designed to collect data for all cancers, researchers are initially concentrating on five major cancers, including breast cancer.

The project has already identified more than 300,000 DNA sequences and 12,000 new genes -- double what the NCI initially expected. The Administration is committed to ensure that progress in understanding the genetics of cancer is used to develop new innovative techniques to detect and treat cancer. That is why last month, the President and Vice President issued a historic challenge to scientists to use the CGAP to develop new diagnostic techniques in the next two years for every major cancer.

NASA's technology. Collaborations with NASA and its investigations into the mysteries of the universe have resulted in technology to better detect breast cancer. Some of the highlights include:

- Silicon chips used in the Hubble Space Telescope were adapted so doctors can easily detect tiny spots in breast tissue and analyze the tissue using a needle rather than subject a patient to painful surgery. This procedure also eliminates scarring or disfigurement, requires half the time of traditional techniques, reduces exposure to x-rays, and reduces costs from \$3500 to \$850.
- Mars Pathfinder technology developed to enhance pictures is being modified to make three-dimensional models of breast tissue. Combining ultrasound with advanced computing, the imaging device discerns cancerous from healthy tissue by comparing changes in shape and analyzing the ultrasound signal. This enables doctors to differentiate tissue more accurately without using painful invasive procedures.

Breast Cancer Surveillance Consortium. Established in October 1994 by NCI, the Breast Cancer Surveillance Consortium is comprised of nine academic and public institutions and private organizations. The consortium's three main objectives are:

- To better understand breast cancer screening practices in the United States by assessing the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer mortality and other outcomes, such as survival;
- To foster collaborative research among Consortium participants that examines issues such as regional and health care system differences in the provision of screening and follow-up evaluations; and

- To provide a foundation for conducting clinical and basic science research, especially basic research on biological mechanisms, that can improve our understanding of the natural history of breast cancer.

By the year 2000, it is estimated that the Consortium's database, with data collected from nine participating sites across the country, will contain information on nearly 3.2 million mammograms and over 24,000 cases of breast cancer. The data will enable researchers to compare mammography screening practices among different regions of the country.

Further Research Steps to a Cure

Current clinical trials now underway will provide much needed data on the optimal adjuvant treatment for node positive breast cancer patients. One of these trials should finish recruiting patients soon, and early findings could be available in the next one or two years. Another clinical trial using Taxotere, a drug similar to Taxol, in the treatment of node positive patients is still open to patients.

Marking Progress

In September 1998, NCI's Breast Cancer Progress Review Group examined progress in the eight major areas of breast cancer research, as well as broad research directions and infrastructure needs of breast cancer research. The Group made the following recommendations to continue and accelerate the prevention, detection, diagnosis and treatment of this disease:

- Enhanced understanding of normal breast biology and genetics;
- Better model systems for premalignant and malignant breast disease;
- Fuller understanding of molecular changes through the continuum of breast cancer progression;
- Identification of biomarkers and surrogate endpoints for epidemiologic, prevention, and therapy trials;
- Ensured investigator access to necessary technology;
- Enhanced infrastructure at academic health centers;
- Modifications of existing mechanisms to promote translational, prevention, and therapy trials;
- Improved communications efforts and more patient-focused outcome;
- Research in basic behavioral change, decision making, and communication;
- Recruitment, training, and retention of translational investigators;
- Enhanced communication among investigators in various disciplines;
- Reassessment of funding strategies to target innovation and accommodate longitudinal studies; and,
- Streamlined consent process for clinical research.

Other Federal Research Activities

Department of Defense Breast Cancer Research Program

The United States Army Medical Research and Materiel Command has been responsible for administering targeted appropriations for breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, and osteoporosis. In Fiscal Year 1992 the Breast Cancer Research Program (BCRP) was established, funded at \$25 million for breast cancer research. Since 1993, the program's funding has increased steadily to \$135 million to further breast cancer research.

In 1995, in response to Congressional directives, 21 special mammography projects were funded through the BCRP. Fiscal Year 1996 saw a change in the type of research awards offered. The program supported Idea awards and Clinical Translational Research awards. These new award categories provided support for research that was not offered by other agencies, such as the National Cancer Institute. In Fiscal Year 1997, in response to Congressional directives, \$6 million was earmarked for computer-based decision support systems and \$2.3 million for research on calcium signaling/cancer cell proliferation. Finally, in 1998, consistent with previous programs, the Breast Cancer Research Program continued to encourage a unique, broad-based research agenda, attracting talented new as well as established investigators to the field of breast cancer.

Environmental Protection Agency

The Environmental Protection Agency's Office of Prevention, Pesticides, and Toxic Substances is leading the charge on research into the emerging issue of endocrine disrupters and their link to breast cancer. Pesticides, toxic substances, and other forms of pollution can interfere with and mimic the body's natural estrogen, a known agent in breast cancer etiology.

COMMITMENTS TO EARLY DETECTION OF BREAST CANCER

The Clinton Administration has worked to educate and to improve access to mammography screening among all women, particularly older women and minority populations.

New Mammography Benefits. Proposed by President Clinton and adopted under the Balanced Budget Act of 1997, Medicare expanded its coverage of several preventative procedures, including mammograms, on January 1, 1998. The expanded benefits include coverage to help pay for annual screening mammograms for all Medicare beneficiaries age 40 and over. Under the expanded benefits, Medicare waives the Part B deductible for screening mammograms, providing women ages 65 and older greater access to this important benefit. In addition to mammography, the Balanced Budget Act also expanded a variety of preventative benefits for women, including pap smears, colorectal screening, bone mass measurement, and flu and pneumococcal shots.

Mammography Awareness Campaign Aimed at Older Americans. Committed to educating older women about the importance of detecting breast cancer early, First Lady Hillary Rodham Clinton launched a mammography awareness campaign in 1995. Aimed at women 65 and older, the campaign urges older women who are less likely than younger women to get mammograms, to have annual mammograms and promotes the use of Medicare coverage for mammogram screenings. As part of this ongoing education campaign, President Clinton and the First Lady have appeared in television public service announcements encouraging older women to get annual mammogram screenings.

Mammography Quality Standards Act (MQSA). On October 9, 1998, President Clinton signed the reauthorization of the Mammography Quality Standards Act. The Act gives the FDA the authority to set high standards for mammography facilities and certifies those which meet the standards. The estimated 10,000 mammography facilities nationwide certified by the FDA must meet quality standards for equipment, personnel, quality assurance, and record keeping, and are inspected annually.

MQSA regulations require facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled physicians to interpret the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that necessary follow-up testing or treatment can begin.

The FDA has included a list of all FDA certified mammography facilities in the United States on its Internet home page, <http://www.fda.gov/cdrh/faclist.html>, and this list is available by calling the NCI's Cancer Information Service at 1-800-4-CANCER.

Mammography for Underserved Americans. The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) offers free or low-cost mammography screening to uninsured, low-income, elderly, and minority women nationwide. These underserved populations tend to have the highest breast cancer death rates.

The program, which now encompasses all fifty states, five territories, the District of Columbia, and fifteen American Indian/Alaska Native organizations, has provided over 1.7 million screening tests to more than 1.2 million medically underserved women since its inception. The NBCCEDP is able to screen 12-15 percent of the eligible population for these cancers.

HORIZON Grants to Improve Mammography Rates Among Minority Women. The Health Care Financing Administration has included a new focus to improve its mammography rates among minority Medicare beneficiaries. HCFA launched the Horizon Project grants, a three-year initiative in six major cities (Atlanta, Chicago, Cleveland, Los Angeles, Philadelphia, and San Antonio) which focuses efforts on increasing mammography rates among Hispanic and African-American Medicare beneficiaries. These comprehensive efforts will not only encourage more women in these areas to get regular mammograms but provide insight on how to overcome barriers that prevent women from getting mammograms, such as language barriers and misconceptions that only women of childbearing are at risk for breast cancer.

HCFA has partnered with the Washington, D.C. ABC-TV affiliate and Safeway Food Stores on two PSAs that aired in May, 1998. Building on the success of this Mother's Day campaign, HCFA is broadcasting a series of 30-second TV ads for National Breast Cancer Awareness Month in October, 1998. These spots will air in five of the six multi-city mammography sites -- Atlanta, Philadelphia, Chicago, Cleveland, Los Angeles and D.C. The PSAs are geared to African-American Medicare beneficiaries, a population at particular risk.

Mammography for Women with Addictive and Mental Disorders. Women who are in need of or receive substance abuse or mental health services often lack appropriate primary health care, including breast cancer education, screening, and treatment. Women-focused substance abuse and mental health programs, funded by the Substance Abuse and Mental Health Services Administration (SAMHSA), are designed to be comprehensive and to deliver primary health care services to women, many of whom are medically underserved. These services include education on breast self-examination, mammography services, and counseling on risks for breast cancer.

Mobile Digital Telemammography Breast Cancer Center. Inter-departmental collaborations are also underway for developing a Mobile Breast Care Center that will generate and transmit a patient's digital mammogram via satellite to a breast screening center, where a radiologist will interpret the images and relay any need for additional evaluation back to the mobile unit. The Mobile Breast Care Center will benefit medically underserved populations, particularly women living in rural and remote areas.

QUALITY OF CARE AND ACCESS TO TREATMENT

Improving Access and Increasing Participation in Clinical Trials. The Administration has made unprecedented efforts in helping breast cancer patients participate in clinical trials. Currently, only 3 percent of cancer patients participate in cancer clinical trials. Many scientists believe that higher participation in clinical trials could lead to faster development of therapies for more of those in need, as it often takes between 3 and 5 years to enroll enough participants in a cancer clinical trial to make the results scientifically legitimate and statistically meaningful. Also, cure rates for many childhood cancers are approaching 80 percent, in part because almost all children with cancer are either enrolled in clinical trials or treated according to protocols developed through clinical trials.

To increase participation in clinical trials, last month the President directed NCI to fully implement a new system to make it easier for physicians to enroll patients in clinical trials. Under the directive, NCI will complete this simplified system for breast, colon and prostate cancers by next spring and expedite the system for other cancers as well. This new system will ensure that physicians are informed about cutting-edge cancer clinical trials and will allow them to enroll patients on the spot. This effort will give tens of thousands of cancer patients improved access to cancer clinical trials.

The Administration has also asked Congress to pass legislation that would allow coverage of cancer clinical trials for Medicare beneficiaries. Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. Older Americans, however, frequently cannot participate in cutting-edge cancer clinical trials because Medicare does not pay for experimental treatments. This legislation would give older Americans access to cutting edge treatments.

Eliminating Racial and Health Disparities. The President has also proposed a comprehensive race and health initiative designed to eliminate racial health disparities in six critical health areas, including cancer. This effort includes \$450 million over five years to test innovative approaches. To learn more about that includes a grant program for new community-based approaches to address disparities. Successful approaches identified in these projects will be applied throughout all new programs and initiatives at the Department of Health and Human Services. The President has also proposed \$300 million to build on successful programs that have proven effective at addressing these disparities, including the breast cancer screening and treatment program at the Indian Health Service.

Office of Cancer Survivorship. On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. There now are more than 8 million cancer survivors of which about 2 million American women are breast

cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects, factors that predispose survivors of cancer, second malignancies, reproductive problems following cancer treatment, and their unique insurance and employment issues. In August 1998, NCI committed \$15 million over the next five years to cancer survivorship grants that will be overseen by this office. These grants support top-of-the-line research on issues faced by long-term cancer survivors.

Cancer Information Service (CIS). In its 26th year, the National Cancer Institute's Cancer Information Service is a national information and education network, providing the latest, most accurate cancer information for patients, the public, and health professionals. Approximately 25 percent of all CIS calls are related to breast cancer. Specifically, trained staff provide the latest scientific information in understandable language, and will offer the location of the caller's nearest FDA certified mammography facility. With staff available to answer questions in English and Spanish, the CIS responds to about 600,000 phone calls annually through its toll-free number (1-800-4CANCER).

Ensuring Rights for Breast Cancer Patients. The Clinton Administration has urged Congress to pass a strong, enforceable Patients' Bill of Rights to protect the rights of all health care consumers and their families and to assure that the health care system is fair and responsive to consumers' needs. Among the patient protections proposed by the President's Advisory Commission last year, there are special protections for breast cancer patients: guaranteed access to specialists, which would allow cancer patients to have direct access to their oncologists without having to see a primary care physician for a referral; and transitional care, which would allow patients to continue with an oncologist for a period of time, even if their insurance changes or if the doctor leaves or is terminated from a managed care plan. President Clinton has already taken steps to apply these patient protections to all federal health care programs and plans that serve 85 million Americans, including Medicare, Medicaid, and the Federal Employees Health Benefits program.

Privacy of Genetic Information and Breast Cancer. President Clinton has also supported bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage or to set premiums. The Administration has also asked Congress to pass legislation that prevents employers from discriminating on the basis of genetic information. In many diseases, such as breast cancer, scientists are beginning to identify genetic alterations that may place a woman at increased risk. Women who test positive may increase cancer detection efforts, may elect to have preventive surgery, or may join a cancer prevention research study. However, genetic information may be used by insurance companies and others to discriminate and stigmatize individuals and groups of people. In fact, studies show that one of the leading reasons women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.

Access to Important Medical Procedures. The Congress has just passed and the President will soon sign into law, new protections to assure that women whose health plan covers mastectomies also cover breast reconstructive surgery for those women who chose it.

The President has also endorsed bipartisan legislation that ensures that women are not forced out of the hospital before they are ready because of pressure from their health plan. DHHS also sent a letter to all Medicare managed care plans making it clear that they may not set time limits for inpatient hospital treatment or requirements for outpatient treatment, and that rather a woman and her doctor should make decisions about what is medically necessary.

Department of Veterans Affairs. Department of Veterans Affairs (VA) is an active partner with many other federal, state, and local organizations to meet the health care needs of women veterans. The VA is also one of the largest breast health service providers in our nation.

NEW APPROACHES IN ADDRESSING THE DISEASE

The Administration has responded by forming unprecedented collaborations within the federal government and forging public-private partnerships to reach all communities, particularly populations that are underserved.

National Action Plan on Breast Cancer

Under President Clinton's direction and under the leadership of DHHS Secretary Donna Shalala, the National Action Plan on Breast Cancer (NAPBC) was developed in 1993 to spearhead the national response to breast cancer and foster cooperation and communication with experts inside and outside government. The NAPBC is co-chaired by Wanda K. Jones, Dr.P.H., Deputy Assistant Secretary for Health (Women's Health) and Fran Visco, Esq., President of the National Breast Cancer Coalition.

The plan has identified the following six priority areas: biological resources, etiology, hereditary susceptibility, clinical trials, consumer involvement and information dissemination. Six working groups were formed to identify and implement specific initiatives within these priority areas. Through its six working groups, the NAPBC has played a pivotal role in catalyzing national efforts, including activities of governmental and non-governmental organizations, agencies, and individuals in the fight against breast cancer.

Accomplishments of the NAPBC include:

Building Partnerships: One-Time Grants. In September 1995, the NAPBC awarded over \$9 million in one-time grants for 99 innovative research and outreach projects, with a special emphasis on the development of public-private partnerships targeted in the six original priority areas. These grants focused on the broad topic areas with the NAPBC working groups including, biological resources, etiology, hereditary susceptibility, public education, clinical trials and consumer involvement.

Raising Awareness about Health Insurance and Workplace Discrimination. The NAPBC played a pivotal role raising awareness on the basis of an individual's genetic predisposition to disease by developing recommendations for federal and state policies. Both sets of recommendations were published in the medical journal *Science* in October 1995 and March 1997 respectively. The Administration has developed a set of principles based on these recommendations and, in the summer of 1997, the President called upon Congress to pass legislation that would prohibit discrimination against individuals predisposed to the disease.

Linking Women to Breast Cancer Information. In October 1996, President Clinton launched the NAPBC Internet Web site (<http://www.napbc.org>). The web site serves as a gateway to information on breast cancer research, prevention, detection, and treatment. The number of hits on this site was last reported to average around 40,000 hits per month.

The NAPBC web site provides answers on frequently asked questions about breast cancer, as well as information on the NAPBC, breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences, publications, and government and private resources.

Bridging the Gap Initiative Pilot Project. A pilot project designed and implemented in which five community-based organizations across the nation are finding innovative ways to link informationally-underserved women with breast cancer information through new technology such as the Internet and WebTV. The five existing sites included Bowling Green, Kentucky; Boston, Massachusetts; Little Rock, Arkansas; San Francisco, California; and Anchorage, Alaska.

Involving Consumers. A survey was conducted to assess the extent of consumer involvement in activities in areas such as breast cancer research, service delivery, education and outreach, and public policy. The ultimate goal is to identify and implement ways to bridge the gaps between the current status and potential status of consumer involvement.

Overcoming Barriers to Participation in Clinical Trials. An extensive literature search was conducted to reveal barriers to participation in clinical trials and identify potential means of reducing those barriers. This information is now being analyzed and will be compiled into a critical review of the literature that will be submitted for publication early next year.

Developing "Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals." This outline serves as a framework for high-quality, customized education and training for health care professionals on the implications of genetic testing for breast cancer susceptibility.

Developing "Genetic Testing for Breast Cancer Risk: It's Your Choice." This video was developed and over 30,000 copies were distributed to medical practitioners, cancer centers and breast cancer organizations. The video addresses the pros and cons as well as psychosocial issues involved in genetic testing to assist consumers in making informed choices about genetic testing.

Developed a Breast Cancer Comprehensive Questionnaire. This questionnaire was developed and focus-group tested in order to understand the causes of this disease. Six etiologic areas -- addressing environmental exposures, sociodemographic factors, occupational exposures, medical history, lifestyle, and diet -- and long and short versions of a core questionnaire provide a standardized set of questions, for use by all researchers on risk factors linked to breast cancer.

Publishing. Papers were published on "Hormones, Hormone Metabolism, Environment, and Breast Cancer" in a supplement to the journal, *Environmental Health Perspectives*, in April 1997.

Publishing Proceedings. Three papers summarizing the November 1997 "Workshop on Physical Activity and Breast Cancer" were published in a supplement to the medical journal, *Cancer*, on August 1, 1998.

Conducting Focus Groups. Telephone focus groups were conducted in the Fall 1997 in order to design a plan for a marketing campaign, intended to demystify breast cancer clinical trials, promote awareness, and encourage women to learn about and enroll in such trials. The design of a plan for the marketing plan is expected to be completed in early 1999, at which time partner organizations will be sought to implement its components.

Advancing Research. Through public and private partners, a network of tissue banks was designed and implemented to assist researchers needing biological materials for breast and other cancer research studies. This network can be accessed through the NAPBC Web site.

Creating Guidelines. Guidelines were developed for Institutional Review Boards (IRBs) and others. A model patient consent form, and a patient fact sheet on donating tissue samples for research were also produced.

Federal Coordinating Committee on Breast Cancer

Under the Clinton Administration, all federal agencies have mobilized and joined in the battle against breast cancer through establishment of the Federal Coordinating Committee on Breast Cancer (FCCBC). The FCCBC was formed at the direction of the Secretary in response to the Secretary's 1993 Conference on Breast Cancer as a liaison group to the National Action Plan on Breast Cancer. It is comprised of representatives from all DHHS agencies, and other departments across the federal government including the Department of Defense, Department of State, Veterans Affairs, Environmental Protection Agency, Department of Labor, and the Department of Housing and Urban Development. The group fosters focuses attention on the disease across agencies, collaboration and cooperation in crosscutting initiatives, and reduces unnecessary duplication of efforts. The FCCBC has developed an Internet-accessible inventory of all government breast cancer activities.

FCCBC Supplement Grant Program. In September 1997, the FCCBC provided supplemental funding for a diverse portfolio of grants that increase knowledge of the causes of breast cancer, improve early detection, prevention and treatment of the disease, and bring lifesaving outreach and education programs to many medically underserved women across the nation.

The program awarded \$2.7 million to fund 22 innovative projects, with 50 percent of funding directed to programs which address the needs of underserved populations. Emphasizing interagency collaborations, the Supplemental Grant Program's highlights include:

- A research project supported by the Agency for Health Care Policy and Research to better

understand the frequency of “drive-through” mastectomies in the era of managed care.

- An Indian Health Service project to expand the training and support of community health aides in the delivery of breast cancer early detection services to Alaska Native women in rural Alaskan villages.
- A project supported by the Health Resources and Services Administration to expand breast cancer services to Hispanic farm workers.
- A research project conducted by the National Institute of Environmental Health Sciences that will provide the foundation for a novel approach to identifying environmental chemicals with the potential to cause breast cancer.
- A National Cancer Institute project that is collecting in-depth survey information to evaluate the impact of a no-cost cancer screening program for low income, African-American women.
- The development of a database sponsored by the Health Care Financing Administration to measure the impact of breast cancer screening interventions for Hispanic Medicare beneficiaries.
- A Centers for Disease Control and Prevention research study to investigate a common variation of the protein p53, which appears to be a susceptibility factor for breast cancer. The study defines the link between this variant and different environmental and occupational exposures. The study may assist in determining why breast cancer in African-Americans and Hispanics often differs from Caucasians.
- A study by the Food and Drug Administration to reduce toxicity and improve the effectiveness of a chemotherapy drug, amino glutethimide, and a standard treatment of choice for cancer patients who no longer respond to tamoxifen.
- A Department of Agriculture outreach project to underserved women in Northern Appalachia to educate them about breast health and the possible preventative benefits of proper nutrition.
- A Department of Energy project to develop imaging technology to validate positive mammograms and thereby help reduce unnecessary biopsies.

FCCBC Partnering Workshop. In September 1998, the FCCBC convened a workshop entitled “Partnering to Improve Outcomes: Opportunities for Collaboration in Government Breast Cancer Programs.” The workshop highlighted federal activities related to breast cancer and encouraged the formation of new partnerships while strengthening existing interagency collaborations in breast cancer research, policy, services, and public health. The closing session

of the workshop outlined barriers to and facilitators of federal partnerships throughout the conference.

Other Collaborations

Federal Multi-Agency Consortium on Imaging to Improve Women's Health. In July 1994, the Public Health Service's Office on Women's Health, in collaboration with NCI, began an initiative to examine technologies currently under exploration for improving breast imaging. The Federal Multi-Agency Consortium on Imaging to Improve Women's Health is exploring the applications of technologies from other fields to improve the early detection and diagnosis of illnesses and conditions affecting women.

The Department of Health and Human Services has been working with the Department of Defense, the Central Intelligence Agency, National Aeronautics and Space Agency, and other public and private entities to enhance the ability to detect breast cancer at its earliest stages and to explore opportunities in telemedicine.

In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection and treatment at its earliest stages. In October 1996, DHHS awarded \$1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community—originally used for missile guidance and target recognition—to improve the early detection of breast cancer.

In October 1996, the Food and Drug Administration (FDA) sponsored a conference "The Transfer of Defense, Intelligence, Space and Energy Technologies to the Early Detection and Control of Cancers in Women," in an effort to facilitate such public/private partnerships.

National Mammography Campaign. The Health Care Financing Administration and the National Cancer Institute have entered into an inter-agency agreement to develop, implement, and promote a short term joint health promotion campaign targeting Medicare beneficiaries. The purpose of the campaign is to increase awareness of the importance of the expanded Medicare benefit and regularly scheduled mammography screening among women ages 65 and older.

As part of the agreement, NCI has developed mammography publications to target older women. The new publications include a poster and bookmark featuring an older woman and the Medicare message, as well as a large-print, easy-to-read brochure. All materials will include information on Medicare's expanded benefit and will be printed in English and Spanish.

Centers for Disease Control and Prevention's Public/Private Partnerships. Partnerships are critical to the CDC's cancer control efforts. A successful national program to control breast and cervical cancers, such as the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), depends on the involvement of a variety of committed partners and national organizations. CDC collaborates with state and local governments, health care professionals and

organizations, social service and voluntary organizations, and academia.

Through these critical partnerships, CDC assists private and public nonprofit organizations in the following program areas:

- Developing, implementing, and evaluating national and community-based interventions for cancer prevention and early detection;
- Testing new methods and replicating proven strategies to educate their constituents about breast and cervical cancers; and,
- Increasing access to breast and cervical cancer screening among underserved women.

CDC and Partners Helping Underserved Women. In October 1993, a unique public-private partnership was established among CDC, Avon Products Inc., the YWCA of the U.S.A., the National Alliance of Breast Cancer Organizations (NABCO), and the National Cancer Institute. The partnership seeks to educate women about breast health and to improve access to early detection services. Avon's Breast Cancer Awareness Crusade has raised more than \$25 million for breast cancer programs nationwide through the sale of its Breast Cancer Awareness pink ribbon products.

Since 1993, about 300 community-based programs in 49 states and Puerto Rico have received funding, from Avon's Crusade through the YWCA of the U.S.A. and NABCO, to educate women about breast cancer and to provide underserved women with access to early detection services. Earlier this year, all funding of community-based programs was consolidated under the Breast Health Access Fund administered by NABCO.

CDC and Partners Assisting At-Risk Populations. Partnerships that focus their prevention efforts on those at greater risk are essential for understanding and alleviating the disparities that exist. Deaths due to breast cancer are decreasing among white women, but not as steadily among African-American women. Both mammography and Pap tests are underutilized by women who are members of racial and ethnic minority groups, have less than a high school education, are older, or live below the poverty level.

To address these differences in the burden of cancer and in the use of cancer prevention services, CDC funds a strong and effective network of partners that are well-positioned in the communities at risk including:

- The U.S. Conference of Mayors' Research and Education Foundation
- The National Center for Farmworkers Health, Inc.
- The American Social Health Association
- The Association of Asian Pacific Community Health Organizations
- The National Hispanic Council on Aging
- The Baylor College of Medicine "Salud en Accion Program"
- The Institute for the Advancement of Social Work Research

- The Mautner Project for Lesbians with Cancer
- The National Asian Women's Health Organization
- The National Association of Community Health Centers
- The National Education Association Health Information Network
- The National Caucus and Center on Black Aged, Inc.
- The Witness Project
- The World Education

These partners have developed projects that focus on specific at-risk populations and cover a wide range of prevention and research activities. For example, many projects are involved with developing low literacy, bilingual, and culturally appropriate educational campaigns. These prevention techniques and research efforts result in increasing knowledge and awareness of breast and/or cervical cancer and promoting screening for early detection in communities around the nation.

CHALLENGES AND NEW FRONTIERS

While continuing to work toward the ultimate goal of eradicating breast cancer, the Clinton Administration is striving to meet new challenges in its ongoing campaign against this deadly disease:

1. We must ensure adequate and sustained support for research. Only research can unlock tomorrow's medical discoveries and treatments.
2. We can only defeat breast cancer if researchers and scientists continue to work together, across agency lines, departmental walls, and the public-private divide.
3. We must work to increase participation in cancer clinical trials to assure that breast cancer patients have access to cutting-edge research and to help speed up discoveries.
4. We must continue to work to ensure that advances and breakthroughs translate into high quality care for breast cancer patients. We have heard too many stories about breast cancer patients who could not see the needed specialist or who had critical treatment denied or delayed until it was too late. We must work to enact protections that breast cancer patients need and deserve.
5. As we crack the genetic code, it should be used to improve treatment, not increase discrimination. No person should have their health care or their job put at risk because they are genetically at risk for cancer.
6. We must continue efforts to expedite new cutting edge treatments for breast cancer, while maintaining our commitment to quality and public health.
7. We must renew our scientific efforts to discover the cause of racial disparities in breast cancer rates between white women and women of color in order to close the gaps. This will help ensure that all women, regardless of race or ethnicity, benefit from our progress against breast cancer.
8. We must improve early detection so that more women catch breast cancer at its earliest and most treatable stages.
9. We must learn more about the environmental factors that cause breast cancer; and
10. We must find ways to send young women clear messages about the importance of a healthy lifestyle to prevent breast cancer, and other diseases, before they start.

To address the devastating disease of breast cancer in the new millennium will require that we strengthen our partnerships across the government and within the private sector to move forward an agenda that will eventually lead to the eradication of this devastating disease. In the first six months of 1999 we will join together consumers, policymakers, researchers and advocacy organizations for a day of dialogue on breast cancer. We will reflect upon all that has been accomplished to conquer this disease over the past five years, including progress that has been made in breast cancer research, policies, services, and health outcomes, and chart the course for addressing the disease over the next five years.

Breast Cancer:
A Report on the Fight to
Prevent, Treat, and Cure the Disease

from the Federal Coordinating Committee on Breast Cancer

Breast Cancer:
A Report on the Fight to
Prevent, Treat, and Cure the Disease

From
The Federal Coordinating Committee on Breast Cancer

Table of Contents

Executive Summary	1
Overview	4
<i>Background</i>	<i>4</i>
<i>Declining Mortality Rates</i>	<i>4</i>
<i>Increased Funding</i>	<i>4</i>
Scientific Progress in the Fight Against Breast Cancer	6
<i>Advances in Prevention</i>	<i>6</i>
<i>Advances in Treatment</i>	<i>8</i>
<i>Advances in Detection</i>	<i>9</i>
<i>Further Steps to a Cure</i>	<i>11</i>
<i>Marking Progress</i>	<i>11</i>
<i>Other Federal Research Activities</i>	<i>12</i>
<i>Department of Defense</i>	
<i>Environmental Protection Agency</i>	
Commitments To Early Detection of Breast Cancer	13
Quality of Care and Access To Treatment	15
New Approaches in Addressing the Disease	18
<i>National Action Plan on Breast Cancer</i>	<i>18</i>
<i>Federal Coordinating Committee on Breast Cancer</i>	<i>20</i>
<i>Other Collaborations</i>	<i>22</i>
Challenges and New Frontiers	25

Breast Cancer:

A Report on the Fight to Prevent, Treat, and Cure the Disease

Thirty years ago, people only whispered the words breast cancer, and a diagnosis of breast cancer meant a virtual death sentence. Today, breast cancer is at the forefront of the nation's health care agenda, and we have made tremendous strides to prevent, detect, and treat the disease. Since 1993, the Clinton Administration has been committed to waging this battle on numerous fronts. First, the Administration has made a significant investment in research--reaching over \$500 million in 1998. Second, we have improved the quality and availability of early detection tools like mammography. Third, we have worked to improve access to treatment and quality of care for women with breast cancer. The Administration has fostered cooperation and communication among the government, experts, survivors, and advocates, primarily through the National Action Plan on Breast Cancer, a public-private partnership. The Administration has also worked to increase collaboration among government agencies through the Federal Coordinating Committee on Breast Cancer.

Breast cancer mortality rates have improved markedly in the United States, declining 4.6 percent between 1991 and 1995 alone. However, breast cancer remains the second leading cause of cancer deaths among American women. Today, one in eight women will develop breast cancer, up from one in 20 just two decades ago. In 1998, approximately 180,000 new cases of breast cancer will be diagnosed and the disease will claim nearly half a million lives in this decade.

Faced with these still daunting statistics, the Administration has made a tremendous investment in breast cancer research, prevention, and treatment. In FY1998 alone, the Clinton Administration invested almost \$700 million in the fight against breast cancer. The Department of Health and Human Services, which includes research by the National Institutes of Health (NIH) and screening through Centers for Disease Control and Prevention (CDC), has nearly doubled its discretionary spending on breast cancer from \$283 million in FY1993 to an estimated \$550 million today. Additionally, the Department of Defense's Breast Cancer Research Program spent \$135 million in FY1998 on innovative peer-reviewed breast cancer research. The Clinton Administration has also expanded its investment in breast cancer through the Medicaid and Medicare programs which provide mammograms and breast cancer treatment to countless women.

In recent years, intensive research has yielded important breakthroughs. A 1994 study revealed two genes that increase a woman's risk of developing breast cancer, and President Clinton has announced \$30 million of additional funding to explore further the role of genes in breast cancer susceptibility. This year, tamoxifen was shown to reduce the incidence of breast cancer by 49 percent in women at high risk for the disease. The Food and Drug Administration (FDA) has recently approved new detection and treatment devices, and is putting drugs for women with breast cancer on a fast track for approval. Drugs recently approved by the FDA include Herceptin, a drug that may help slow the progress of the disease once it has spread to other parts

of the body, and Taxol, a drug that when used with chemotherapy helps patients whose cancer has reached the lymph nodes. And more ground breaking research is ongoing, including studies of environmental factors contributing to breast cancer; the NIH's Women's Health Initiative, which is examining opportunities to reduce breast cancer through diet; and the Cancer Anatomy Genome Project, which since its launch in 1997 has already identified more than 300,000 DNA sequences and 12,000 new genes in an effort to understand better the genetics of breast cancer -- double what the National Cancer Institutes (NCI) originally anticipated.

The Administration has also worked to educate women about and improve access to mammography and other tools of early detection. This year, due to the President's leadership, Medicare began covering annual mammograms for all beneficiaries age 40 and over and made them more affordable by waiving the deductible. On October 9, 1998, the President signed the reauthorization of the Mammography Quality Standards Act, under which the FDA sets high standards to ensure that mammograms are safe and accurate and certifies those facilities that meet its standards. The Clinton Administration has also spearheaded a number of outreach initiatives and programs to ensure that women have access to mammograms. The First Lady launched a campaign in 1995 to encourage older women to take advantage of the mammography benefit offered by Medicare, and this campaign continues each year with the support of the Health Care Financing Administration and numerous private partners. This year's effort focuses on improving mammography rates among minority women. CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to uninsured, low-income, elderly, and minority women.

The Administration has also fought tirelessly to improve access to treatment and quality of health care for women with breast cancer. The President has fought to prevent health plans and employers from discriminating against individuals based on their genetic information, so that advances in genetic research can be used to help detect breast cancer rather than to discriminate. He has also urged Congress to pass a patients' bill of rights that will guarantee critical protections to patients with breast cancer -- including access to specialists and a fair appeals process. To help breast cancer patients participate in clinical trials, last month the President directed NCI to implement a new system that will make it easier for physicians to enroll patients in clinical trials. The Administration has also urged Congress to pass legislation that would allow Medicare to cover patient care costs for cancer clinical trials. To address racial disparities in treatment, access to care, and health status, the Administration has proposed an initiative to address health disparities in six major areas, including cancer. And finally, building on unprecedented efforts begun at the Department of Defense and the FDA, next year NCI will fully integrate patients and advocates into policy planning and grant reviews. With each of these advances we are moving closer to discovering the cure for breast cancer.

Significant challenges remain. We must continue to fight for legislation ending discrimination against individuals based on their genetic information. We must continue to fight for strong, enforceable patients' bill of rights legislation. We must continue to increase access to clinical trials. We must continue to work to end racial disparities that still exist in breast cancer

mortality, mammography rates, and access to treatment. We must continue to integrate advocates in planning the cancer research agenda. And, most important, we must continue to support research that builds on the dramatic research breakthroughs we have seen in recent days to find a cure, and finally an end, for breast cancer.

OVERVIEW

Background

Breast cancer is the most commonly diagnosed cancer, excluding skin cancer, and the second leading cause of cancer deaths among American women. There is no proven way yet to lower the risk for breast cancer, so early detection through mammography and clinical breast exams is essential.

In 1998, approximately 180,000 new cases of breast cancer will be diagnosed, and about 43,500 women are expected to die from breast cancer. Epidemiological studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.

While the lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago, this rate increase can be substantially attributed to improved detection of the disease.

Declining Mortality Rates

Mortality rates have steadily declined for most women. With early detection and proper treatment, the chances of surviving breast cancer are improving. Death rates from the disease remain highest among older, African-American, and low-income women. During the most recent 5-year period, death rates among white women declined for all decades of ages from 30 to 79 years. Among black women, rates were down for all decades of ages from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups or women ages 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women ages 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

A study in the medical journal *Cancer* (July 1998) attributes the decrease or leveling off in breast cancer mortality to a trend toward progressively earlier diagnosis of cancer which is more treatable than later stage cancers. According to this study, the number of patients diagnosed with the earliest stages of the disease increased from 42 percent in 1985 to 46 percent in 1995. For women ages 50 to 69, having regular mammograms can reduce the chance of death from breast cancer by one-third or more. Despite these numbers, 33 percent of women ages 50 to 64, and 45 percent of women age 65 and older reported not having had a mammogram during the past two years.

Increased Funding

The Clinton Administration is committed to fighting the threat posed by the disease on many fronts with investments in research, outreach and education.

Because cancer research is vital to understanding how to prevent, detect, and treat breast cancer, the Clinton Administration has dramatically increased investments in breast cancer research. The Department of Health and Human Services (DHHS) discretionary funding for breast cancer has nearly doubled in the years since 1993 from approximately \$283 million in FY 1993 to nearly \$550 million today. At the National Institutes of Health (NIH) alone funding increased from \$237 million in FY1993 to an estimated \$433 million in FY1998.

As the Centers for Disease Control and Prevention (CDC) have worked to increase access for all women to mammography screening and follow up services, its resources devoted to breast cancer services have increased from an estimated \$43 million in FY 1993 to \$85 million in FY 1998. The Department of Health and Human Services also helps provide access to treatment for breast cancer through the Medicare and Medicaid programs and the Indian Health Service.

The Department of Defense (DoD) will invest \$135 million in FY1999 for innovative, peer reviewed breast cancer research.

In addition, President Clinton directed \$30 million in new funding for research into the genetic basis of breast cancer, through a collaborative initiative between the Department of Defense (DOD) and the Department of Health and Human Services in October 1996. This collaboration utilizes the Department of Defense's and the National Cancer Institute's breast cancer research programs to explore further the genetic basis of breast cancer and the most effective methods of treating those genetically predisposed to the disease.

Finally, this past summer, the U.S. Postal Service issued a breast cancer research stamp, valid for the 32 cent first-class rate but selling for 40 cents. The additional 8 cents (minus U.S. Postal Service costs) will be donated to breast cancer research, with 70 percent of the proceeds going to National Institutes of Health and 30 percent to the Department of Defense's medical research program.

SCIENTIFIC PROGRESS IN THE FIGHT AGAINST BREAST CANCER

In recent years, intensive research into all aspects of breast cancer has led to a flurry of important new discoveries. Scientists understand now more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, and why some tumors are more aggressive than others. Indeed, we are witnessing not only advances in treatment and detection, but for the first time, serious advances in prevention of breast cancer. These discoveries are leading to more refined technologies for detecting and diagnosing breast cancer, to better care and improved outcomes for patients during and after treatment, and ultimately, to prevention of the disease completely.

The Administration's increased efforts against this deadly disease have yielded promising results. At the forefront of the battle to fight breast cancer are the National Cancer Institute at the National Institutes of Health, which leads the nation's efforts in cancer research, and the Food and Drug Administration, which reviews and approves cancer drugs and devices while maintaining safe standards. Additionally, interagency collaborations continue on scientific research regarding other potential risk factors for breast cancer, including high-fat diet, hormonal therapies and environmental toxins.

The Administration has made a critical commitment to improve research by integrating advocates in planning and setting the cancer research agenda. Over the past six years, the breast cancer program at the Department of Defense has grown into one of the most renowned research programs in the nation. This unprecedented partnership between the military, scientists, physicians, and the community to fund grants to invigorate breast cancer research actively involves breast cancer survivors in defining this program and sitting on the scientific panel review boards. The Food and Drug Modernization Act of 1997 also included new efforts to integrate patients and advocates in setting the research agenda. Finally, the National Cancer Institute has also made new efforts to integrate patients and advocates. In fact, last month the President and Vice President announced that, by next year, NCI will fully integrate patients and advocates into a wide range of critical activities such as reviewing grant proposals and planning policy.

Advances in Prevention

Prevention of breast cancer is the overall goal of scientific research. A breakthrough achievement this year showed that breast cancer can be prevented for some women at high risk for the disease. Studies in cancer genetics are also providing unprecedented insight into the development and evolution of cancer and are generating knowledge about the most basic processes involved in the onset of breast cancer -- those at the molecular level.

New Drugs Approved that will Save Lives. A medical breakthrough has been the discovery of a breast cancer agent -- Tamoxifen -- earlier this year that has been shown to reduce the incidence

of breast cancer by 49 percent in women at high risk for the disease. Its discovery was a product of the *Breast Cancer Prevention Trial*, a national clinical trial, sponsored by the National Cancer Institute. This clinical trial proved for the first time that it is possible to reduce the short term incidence of breast cancer in women at high risk of breast cancer. In September 1998, a Food and Drug Administration advisory committee recommended approval of Tamoxifen to reduce incidence of breast cancer in high risk women. The NCI is now developing an education program to help physicians and patients decide who should consider taking tamoxifen.

Identifying New Markers for Breast Cancer. A 1994 study on women with a history of breast cancer revealed two different breast cancer susceptibility genes, BRCA1 and BRCA2, which increase a woman's risk for developing breast cancer. This study was conducted by the National Institute for Environmental Health Sciences in conjunction with the University of Utah and Myriad Genetics. Scientists have found that alterations in these two important genes are associated with most inherited breast cancers. While only 5 to 10 percent of all breast cancers are the result of an inherited anomaly, these findings hold promise for development of new prevention, early detection and treatment strategies. Women who choose to be tested for these genes, once tested, may be able to take preventive steps in consultation with their physicians to reduce the chances that they will succumb to the disease.

In October 1996, President Clinton announced \$30 million in funding for a new research initiative which will focus on a broad range of investigations related to the role of genes in the development of breast cancer. This collaborative effort between the Department of Defense and the National Institutes of Health may enable high-risk women to prevent breast cancer before it strikes.

Current Clinical Trials which will Lead to Prevention Breakthroughs. The National Heart, Lung and Blood Institute is leading a consortium of NIH institutes engaged in the Women's Health Initiative (WHI). The initiative includes one of the largest set of clinical trials ever conducted on the causes and prevention of breast cancer. The trial is studying the relationship between diet and the disease in a clinical trial of over 49,000 women, which may lead to information that women can use in order to deter the onset of breast cancer. The observational study of over 92,000 women will be looking for new risk factors, including genetic factors, for breast cancer. The major results of the Women's Health Initiatives are expected after 2005.

Environmental Factors and Breast Cancer. In August 1994, the DHHS Public Health Service's Office on Women's Health established a Federal Interagency Coordinating Committee on the Environment and Women's Health that focuses on how home, work, atmospheric pollutants, exogenous hormones, drugs, and other environmental factors may contribute to the risk of breast cancer and other disorders. Studies supported by the NCI and National Institute for Environmental Health Sciences (NIEHS) are currently underway on the role of the environment in cancer risk in the northeast and mid-Atlantic portions of the U.S. These studies are testing the risk from organochlorine compounds, PCBs, and estrogen-like chemicals, such as DDT, DDE, and other pesticides. To date, there does not seem to be increased risk of breast cancer from

these chemicals overall. However, there are some groups of women who may be more susceptible to the effects of DDT. For example, women who never breast-fed and some women who have certain genetic alterations may be at increased risk if exposed to these chemicals. Likewise, some forms of PCBs (called congeners) may be more estrogenic, making them possible risk factors for breast cancer. Studies are needed on exposures during a woman's childhood or adolescence, when she is more vulnerable to chemical exposures.

Advances in Treatment

Over the last five years, there have been incredible advances in treatment of breast cancer, which has given more women with the disease a chance to fight it. Indeed, it is in part due to these recent advances in treatment that death rates for this disease are dropping. New treatment approaches are evolving, including the sequencing of chemotherapies, the development of monoclonal antibodies shown to boost the immune systems to fight cancer growth, new drugs for advanced breast cancer, and medications to help prevent the disease from occurring.

FDA's Fast Track for Review and Approval of Cancer Drugs. Since 1996, the Food and Drug Administration (FDA) has accelerated the review and approval of new drugs and has improved the therapy review process by ensuring that all FDA cancer-therapy advisory committee meetings include an *ad hoc* member who has personal experience with the illness for which a new product is being considered.

FDA's Initiatives on Reinventing of Cancer Drugs. On March 26, 1996, President Clinton announced the Food and Drug Administration (FDA)'s Initiatives on Reinventing of Cancer Drugs outlining several initiatives to enhance cancer drug development and to provide opportunities for cancer patients to be actively involved in the FDA's cancer drug advisory committee process. The President's initiative enhanced FDA's strong commitment to both rapid and thorough evaluation of therapies for serious and life-threatening diseases.

Recently approved drugs that will provide women with advanced breast cancer options for treatment are Herceptin, Zoladex (gosereline acetate implant), Arimidex (anastrozole), Taxotere (docetaxel), Xeloda (capecitabine), Femara (letrozole), Fareston (toremifene citrate), and Aredia (pamidronate disodium).

Herceptin. On September 25, 1998, FDA approved Herceptin, the first genetically-engineered antibody therapy for patients with metastatic breast cancer. Developed by a biotechnology firm working with the National Cancer Institute, Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells that produce a protein called HER2 or HER2/neu. Studies indicate that Herceptin can help 25 to 30 percent of patients with advanced breast cancer.

Taxol. Early findings of a large, NCI multi-center trial show that the drug Taxol, when used in combination with other standard chemotherapy agents, has a small but significant benefit for

breast cancer patients whose disease has spread to nearby lymph nodes. Although the survival advantage is small at this point in the trial, the study is considered important because it is the first to show that Taxol may be beneficial in the initial, post-surgical treatment of some women with localized, node positive breast cancer.

Study of Tamoxifen and Raloxifene (STAR) Trial. The NCI will sponsor another large-scale study in early 1999 to compare five years of tamoxifen to five years of raloxifene for the reduction of invasive breast cancer in high-risk women. Nearly 200 institutions across the United States are expected to participate in the study of 22,000 post-menopausal women over the age of 35.

NASA Technology. NASA uses the microgravity of space to grow human tissue for research and transplantation and to gain valuable knowledge important to the treatment of breast and ovarian cancer. The NASA-designed Bioreactor is a unique tissue culture chamber that grows cells in three-dimensions. These tissues, similar to tissues found in the body, will help scientists understand cancer growth and how the human immune system responds.

Advances in Detection

As scientists work on the cure for this disease that strikes so many women, the Clinton Administration is also investing in the research needed to find better detection methods for breast cancer. As we know, early detection is the key to survival with breast cancer, and therefore, these new research methods are saving lives.

FDA's New Frontiers. The Food and Drug Administration (FDA) has recently approved several different types of devices for the detection and treatment of breast cancer including:

- Serum tumor markers (CA15-3 and CA27-29) used to monitor breast cancer patients' responses to therapy and the recurrence of the disease;
- Assays to measure HER2/neu protein in breast cancer tissues;
- An ultrasound system (Advanced Technology Labs HDI 3000) to be used in conjunction with mammography to help differentiate benign from malignant or suspicious lesions; and,
- A computer-based system (R2 Technology Model M1000 Image Checker) that identifies regions of interest on routine screening mammograms to bring them to the attention of the radiologist after the initial reading has been completed.

The Cancer Genome Anatomy Project (CGAP). Launched in 1997, the CGAP is working to identify the genetic differences among normal, precancerous, and cancerous cells. This project

identify the genetic differences among normal, precancerous, and cancerous cells. This project will help foster the discovery of genes that are directly expressed in cancer. These can be used to identify early precancerous cells, and thus enhance early detection methods. The CGAP initiative will also aid in the ability to match individual patients with the most appropriate treatments. Although this project is designed to collect data for all cancers, researchers are initially concentrating on five major cancers, including breast cancer.

The project has already identified more than 300,000 DNA sequences and 12,000 new genes -- double what the NCI initially expected. The Administration is committed to ensure that progress in understanding the genetics of cancer is used to develop new innovative techniques to detect and treat cancer. That is why last month, the President and Vice President issued a historic challenge to scientists to use the CGAP to develop new diagnostic techniques in the next two years for every major cancer.

NASA's technology. Collaborations with NASA and its investigations into the mysteries of the universe have resulted in technology to better detect breast cancer. Some of the highlights include:

- Silicon chips used in the Hubble Space Telescope were adapted so doctors can easily detect tiny spots in breast tissue and analyze the tissue using a needle rather than subject a patient to painful surgery. This procedure also eliminates scarring or disfigurement, requires half the time of traditional techniques, reduces exposure to x-rays, and reduces costs from \$3500 to \$850.
- Mars Pathfinder technology developed to enhance pictures is being modified to make three-dimensional models of breast tissue. Combining ultrasound with advanced computing, the imaging device discerns cancerous from healthy tissue by comparing changes in shape and analyzing the ultrasound signal. This enables doctors to differentiate tissue more accurately without using painful invasive procedures.

Breast Cancer Surveillance Consortium. Established in October 1994 by NCI, the Breast Cancer Surveillance Consortium is comprised of nine academic and public institutions and private organizations. The consortium's three main objectives are:

- To better understand breast cancer screening practices in the United States by assessing the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer mortality and other outcomes, such as survival;
- To foster collaborative research among Consortium participants that examines issues such as regional and health care system differences in the provision of screening and follow-up evaluations; and

- To provide a foundation for conducting clinical and basic science research, especially basic research on biological mechanisms, that can improve our understanding of the natural history of breast cancer.

By the year 2000, it is estimated that the Consortium's database, with data collected from nine participating sites across the country, will contain information on nearly 3.2 million mammograms and over 24,000 cases of breast cancer. The data will enable researchers to compare mammography screening practices among different regions of the country.

Further Research Steps to a Cure

Current clinical trials now underway will provide much needed data on the optimal adjuvant treatment for node positive breast cancer patients. One of these trials should finish recruiting patients soon, and early findings could be available in the next one or two years. Another clinical trial using Taxotere, a drug similar to Taxol, in the treatment of node positive patients is still open to patients.

Marking Progress

In September 1998, NCI's Breast Cancer Progress Review Group examined progress in the eight major areas of breast cancer research, as well as broad research directions and infrastructure needs of breast cancer research. The Group made the following recommendations to continue and accelerate the prevention, detection, diagnosis and treatment of this disease:

- Enhanced understanding of normal breast biology and genetics;
- Better model systems for premalignant and malignant breast disease;
- Fuller understanding of molecular changes through the continuum of breast cancer progression;
- Identification of biomarkers and surrogate endpoints for epidemiologic, prevention, and therapy trials;
- Ensured investigator access to necessary technology;
- Enhanced infrastructure at academic health centers;
- Modifications of existing mechanisms to promote translational, prevention, and therapy trials;
- Improved communications efforts and more patient-focused outcome;
- Research in basic behavioral change, decision making, and communication;
- Recruitment, training, and retention of translational investigators;
- Enhanced communication among investigators in various disciplines;
- Reassessment of funding strategies to target innovation and accommodate longitudinal studies; and,
- Streamlined consent process for clinical research.

Other Federal Research Activities

Department of Defense Breast Cancer Research Program

The United States Army Medical Research and Materiel Command has been responsible for administering targeted appropriations for breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, and osteoporosis. In Fiscal Year 1992 the Breast Cancer Research Program (BCRP) was established, funded at \$25 million for breast cancer research. Since 1993, the program's funding has increased steadily to \$135 million to further breast cancer research.

In 1995, in response to Congressional directives, 21 special mammography projects were funded through the BCRP. Fiscal Year 1996 saw a change in the type of research awards offered. The program supported Idea awards and Clinical Translational Research awards. These new award categories provided support for research that was not offered by other agencies, such as the National Cancer Institute. In Fiscal Year 1997, in response to Congressional directives, \$6 million was earmarked for computer-based decision support systems and \$2.3 million for research on calcium signaling/cancer cell proliferation. Finally, in 1998, consistent with previous programs, the Breast Cancer Research Program continued to encourage a unique, broad-based research agenda, attracting talented new as well as established investigators to the field of breast cancer.

Environmental Protection Agency

The Environmental Protection Agency's Office of Prevention, Pesticides, and Toxic Substances is leading the charge on research into the emerging issue of endocrine disrupters and their link to breast cancer. Pesticides, toxic substances, and other forms of pollution can interfere with and mimic the body's natural estrogen, a known agent in breast cancer etiology.

COMMITMENTS TO EARLY DETECTION OF BREAST CANCER

The Clinton Administration has worked to educate and to improve access to mammography screening among all women, particularly older women and minority populations.

New Mammography Benefits. Proposed by President Clinton and adopted under the Balanced Budget Act of 1997, Medicare expanded its coverage of several preventative procedures, including mammograms, on January 1, 1998. The expanded benefits include coverage to help pay for annual screening mammograms for all Medicare beneficiaries age 40 and over. Under the expanded benefits, Medicare waives the Part B deductible for screening mammograms, providing women ages 65 and older greater access to this important benefit. In addition to mammography, the Balanced Budget Act also expanded a variety of preventative benefits for women, including pap smears, colorectal screening, bone mass measurement, and flu and pneumococcal shots.

Mammography Awareness Campaign Aimed at Older Americans. Committed to educating older women about the importance of detecting breast cancer early, First Lady Hillary Rodham Clinton launched a mammography awareness campaign in 1995. Aimed at women 65 and older, the campaign urges older women who are less likely than younger women to get mammograms, to have annual mammograms and promotes the use of Medicare coverage for mammogram screenings. As part of this ongoing education campaign, President Clinton and the First Lady have appeared in television public service announcements encouraging older women to get annual mammogram screenings.

Mammography Quality Standards Act (MQSA). On October 9, 1998, President Clinton signed the reauthorization of the Mammography Quality Standards Act. The Act gives the FDA the authority to set high standards for mammography facilities and certifies those which meet the standards. The estimated 10,000 mammography facilities nationwide certified by the FDA must meet quality standards for equipment, personnel, quality assurance, and record keeping, and are inspected annually.

MQSA regulations require facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled physicians to interpret the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that necessary follow-up testing or treatment can begin.

The FDA has included a list of all FDA certified mammography facilities in the United States on its Internet home page, <http://www.fda.gov/cdrh/faclist.html>, and this list is available by calling the NCI's Cancer Information Service at 1-800-4-CANCER.

Mammography for Underserved Americans. The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) offers free or low-cost mammography screening to uninsured, low-income, elderly, and minority women nationwide. These underserved populations tend to have the highest breast cancer death rates.

The program, which now encompasses all fifty states, five territories, the District of Columbia, and fifteen American Indian/Alaska Native organizations, has provided over 1.7 million screening tests to more than 1.2 million medically underserved women since its inception. The NBCCEDP is able to screen 12-15 percent of the eligible population for these cancers.

HORIZON Grants to Improve Mammography Rates Among Minority Women. The Health Care Financing Administration has included a new focus to improve its mammography rates among minority Medicare beneficiaries. HCFA launched the Horizon Project grants, a three-year initiative in six major cities (Atlanta, Chicago, Cleveland, Los Angeles, Philadelphia, and San Antonio) which focuses efforts on increasing mammography rates among Hispanic and African-American Medicare beneficiaries. These comprehensive efforts will not only encourage more women in these areas to get regular mammograms but provide insight on how to overcome barriers that prevent women from getting mammograms, such as language barriers and misconceptions that only women of childbearing are at risk for breast cancer.

HCFA has partnered with the Washington, D.C. ABC-TV affiliate and Safeway Food Stores on two PSAs that aired in May, 1998. Building on the success of this Mother's Day campaign, HCFA is broadcasting a series of 30-second TV ads for National Breast Cancer Awareness Month in October, 1998. These spots will air in five of the six multi-city mammography sites -- Atlanta, Philadelphia, Chicago, Cleveland, Los Angeles and D.C. The PSAs are geared to African-American Medicare beneficiaries, a population at particular risk.

Mammography for Women with Addictive and Mental Disorders. Women who are in need of or receive substance abuse or mental health services often lack appropriate primary health care, including breast cancer education, screening, and treatment. Women-focused substance abuse and mental health programs, funded by the Substance Abuse and Mental Health Services Administration (SAMHSA), are designed to be comprehensive and to deliver primary health care services to women, many of whom are medically underserved. These services include education on breast self-examination, mammography services, and counseling on risks for breast cancer.

Mobile Digital Telemammography Breast Cancer Center. Inter-departmental collaborations are also underway for developing a Mobile Breast Care Center that will generate and transmit a patient's digital mammogram via satellite to a breast screening center, where a radiologist will interpret the images and relay any need for additional evaluation back to the mobile unit. The Mobile Breast Care Center will benefit medically underserved populations, particularly women living in rural and remote areas.

QUALITY OF CARE AND ACCESS TO TREATMENT

Improving Access and Increasing Participation in Clinical Trials. The Administration has made unprecedented efforts in helping breast cancer patients participate in clinical trials. Currently, only 3 percent of cancer patients participate in cancer clinical trials. Many scientists believe that higher participation in clinical trials could lead to faster development of therapies for more of those in need, as it often takes between 3 and 5 years to enroll enough participants in a cancer clinical trial to make the results scientifically legitimate and statistically meaningful. Also, cure rates for many childhood cancers are approaching 80 percent, in part because almost all children with cancer are either enrolled in clinical trials or treated according to protocols developed through clinical trials.

To increase participation in clinical trials, last month the President directed NCI to fully implement a new system to make it easier for physicians to enroll patients in clinical trials. Under the directive, NCI will complete this simplified system for breast, colon and prostate cancers by next spring and expedite the system for other cancers as well. This new system will ensure that physicians are informed about cutting-edge cancer clinical trials and will allow them to enroll patients on the spot. This effort will give tens of thousands of cancer patients improved access to cancer clinical trials.

The Administration has also asked Congress to pass legislation that would allow coverage of cancer clinical trials for Medicare beneficiaries. Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. Older Americans, however, frequently cannot participate in cutting-edge cancer clinical trials because Medicare does not pay for experimental treatments. This legislation would give older Americans access to cutting edge treatments.

Eliminating Racial and Health Disparities. The President has also proposed a comprehensive race and health initiative designed to eliminate racial health disparities in six critical health areas, including cancer. This effort includes \$450 million over five years to test innovative approaches. To learn more about that includes a grant program for new community-based approaches to address disparities. Successful approaches identified in these projects will be applied throughout all new programs and initiatives at the Department of Health and Human Services. The President has also proposed \$300 million to build on successful programs that have proven effective at addressing these disparities, including the breast cancer screening and treatment program at the Indian Health Service.

Office of Cancer Survivorship. On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. There now are more than 8 million cancer survivors of which about 2 million American women are breast

cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects, factors that predispose survivors of cancer, second malignancies, reproductive problems following cancer treatment, and their unique insurance and employment issues. In August 1998, NCI committed \$15 million over the next five years to cancer survivorship grants that will be overseen by this office. These grants support top-of-the-line research on issues faced by long-term cancer survivors.

Cancer Information Service (CIS). In its 26th year, the National Cancer Institute's Cancer Information Service is a national information and education network, providing the latest, most accurate cancer information for patients, the public, and health professionals. Approximately 25 percent of all CIS calls are related to breast cancer. Specifically, trained staff provide the latest scientific information in understandable language, and will offer the location of the caller's nearest FDA certified mammography facility. With staff available to answer questions in English and Spanish, the CIS responds to about 600,000 phone calls annually through its toll-free number (1-800-4CANCER).

Ensuring Rights for Breast Cancer Patients. The Clinton Administration has urged Congress to pass a strong, enforceable Patients' Bill of Rights to protect the rights of all health care consumers and their families and to assure that the health care system is fair and responsive to consumers' needs. Among the patient protections proposed by the President's Advisory Commission last year, there are special protections for breast cancer patients: guaranteed access to specialists, which would allow cancer patients to have direct access to their oncologists without having to see a primary care physician for a referral; and transitional care, which would allow patients to continue with an oncologist for a period of time, even if their insurance changes or if the doctor leaves or is terminated from a managed care plan. President Clinton has already taken steps to apply these patient protections to all federal health care programs and plans that serve 85 million Americans, including Medicare, Medicaid, and the Federal Employees Health Benefits program.

Privacy of Genetic Information and Breast Cancer. President Clinton has also supported bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage or to set premiums. The Administration has also asked Congress to pass legislation that prevents employers from discriminating on the basis of genetic information. In many diseases, such as breast cancer, scientists are beginning to identify genetic alterations that may place a woman at increased risk. Women who test positive may increase cancer detection efforts, may elect to have preventive surgery, or may join a cancer prevention research study. However, genetic information may be used by insurance companies and others to discriminate and stigmatize individuals and groups of people. In fact, studies show that one of the leading reasons women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.

Access to Important Medical Procedures. The Congress has just passed and the President will soon sign into law, new protections to assure that women whose health plan covers mastectomies also cover breast reconstructive surgery for those women who chose it.

The President has also endorsed bipartisan legislation that ensures that women are not forced out of the hospital before they are ready because of pressure from their health plan. DHHS also sent a letter to all Medicare managed care plans making it clear that they may not set time limits for inpatient hospital treatment or requirements for outpatient treatment, and that rather a woman and her doctor should make decisions about what is medically necessary.

Department of Veterans Affairs. Department of Veterans Affairs (VA) is an active partner with many other federal, state, and local organizations to meet the health care needs of women veterans. The VA is also one of the largest breast health service providers in our nation.

NEW APPROACHES IN ADDRESSING THE DISEASE

The Administration has responded by forming unprecedented collaborations within the federal government and forging public-private partnerships to reach all communities, particularly populations that are underserved.

National Action Plan on Breast Cancer

Under President Clinton's direction and under the leadership of DHHS Secretary Donna Shalala, the National Action Plan on Breast Cancer (NAPBC) was developed in 1993 to spearhead the national response to breast cancer and foster cooperation and communication with experts inside and outside government. The NAPBC is co-chaired by Wanda K. Jones, Dr.P.H., Deputy Assistant Secretary for Health (Women's Health) and Fran Visco, Esq., President of the National Breast Cancer Coalition.

The plan has identified the following six priority areas: biological resources, etiology, hereditary susceptibility, clinical trials, consumer involvement and information dissemination. Six working groups were formed to identify and implement specific initiatives within these priority areas. Through its six working groups, the NAPBC has played a pivotal role in catalyzing national efforts, including activities of governmental and non-governmental organizations, agencies, and individuals in the fight against breast cancer.

Accomplishments of the NAPBC include:

Building Partnerships: One-Time Grants. In September 1995, the NAPBC awarded over \$9 million in one-time grants for 99 innovative research and outreach projects, with a special emphasis on the development of public-private partnerships targeted in the six original priority areas. These grants focused on the broad topic areas with the NAPBC working groups including, biological resources, etiology, hereditary susceptibility, public education, clinical trials and consumer involvement.

Raising Awareness about Health Insurance and Workplace Discrimination. The NAPBC played a pivotal role raising awareness on the basis of an individual's genetic predisposition to disease by developing recommendations for federal and state policies. Both sets of recommendations were published in the medical journal *Science* in October 1995 and March 1997 respectively. The Administration has developed a set of principles based on these recommendations and, in the summer of 1997, the President called upon Congress to pass legislation that would prohibit discrimination against individuals predisposed to the disease.

Linking Women to Breast Cancer Information. In October 1996, President Clinton launched the NAPBC Internet Web site (<http://www.napbc.org>). The web site serves as a gateway to information on breast cancer research, prevention, detection, and treatment. The number of hits on this site was last reported to average around 40,000 hits per month.

The NAPBC web site provides answers on frequently asked questions about breast cancer, as well as information on the NAPBC, breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences, publications, and government and private resources.

Bridging the Gap Initiative Pilot Project. A pilot project designed and implemented in which five community-based organizations across the nation are finding innovative ways to link informationally-underserved women with breast cancer information through new technology such as the Internet and WebTV. The five existing sites included Bowling Green, Kentucky; Boston, Massachusetts; Little Rock, Arkansas; San Francisco, California; and Anchorage, Alaska.

Involving Consumers. A survey was conducted to assess the extent of consumer involvement in activities in areas such as breast cancer research, service delivery, education and outreach, and public policy. The ultimate goal is to identify and implement ways to bridge the gaps between the current status and potential status of consumer involvement.

Overcoming Barriers to Participation in Clinical Trials. An extensive literature search was conducted to reveal barriers to participation in clinical trials and identify potential means of reducing those barriers. This information is now being analyzed and will be compiled into a critical review of the literature that will be submitted for publication early next year.

Developing "Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals." This outline serves as a framework for high-quality, customized education and training for health care professionals on the implications of genetic testing for breast cancer susceptibility.

Developing "Genetic Testing for Breast Cancer Risk: It's Your Choice." This video was developed and over 30,000 copies were distributed to medical practitioners, cancer centers and breast cancer organizations. The video addresses the pros and cons as well as psychosocial issues involved in genetic testing to assist consumers in making informed choices about genetic testing.

Developed a Breast Cancer Comprehensive Questionnaire. This questionnaire was developed and focus-group tested in order to understand the causes of this disease. Six etiologic areas -- addressing environmental exposures, sociodemographic factors, occupational exposures, medical history, lifestyle, and diet -- and long and short versions of a core questionnaire provide a standardized set of questions, for use by all researchers on risk factors linked to breast cancer.

Publishing. Papers were published on "Hormones, Hormone Metabolism, Environment, and Breast Cancer" in a supplement to the journal, *Environmental Health Perspectives*, in April 1997.

Publishing Proceedings. Three papers summarizing the November 1997 “Workshop on Physical Activity and Breast Cancer” were published in a supplement to the medical journal, *Cancer*, on August 1, 1998.

Conducting Focus Groups. Telephone focus groups were conducted in the Fall 1997 in order to design a plan for a marketing campaign, intended to demystify breast cancer clinical trials, promote awareness, and encourage women to learn about and enroll in such trials. The design of a plan for the marketing plan is expected to be completed in early 1999, at which time partner organizations will be sought to implement its components.

Advancing Research. Through public and private partners, a network of tissue banks was designed and implemented to assist researchers needing biological materials for breast and other cancer research studies. This network can be accessed through the NAPBC Web site.

Creating Guidelines. Guidelines were developed for Institutional Review Boards (IRBs) and others. A model patient consent form, and a patient fact sheet on donating tissue samples for research were also produced.

Federal Coordinating Committee on Breast Cancer

Under the Clinton Administration, all federal agencies have mobilized and joined in the battle against breast cancer through establishment of the Federal Coordinating Committee on Breast Cancer (FCCBC). The FCCBC was formed at the direction of the Secretary in response to the Secretary’s 1993 Conference on Breast Cancer as a liaison group to the National Action Plan on Breast Cancer. It is comprised of representatives from all DHHS agencies, and other departments across the federal government including the Department of Defense, Department of State, Veterans Affairs, Environmental Protection Agency, Department of Labor, and the Department of Housing and Urban Development. The group fosters focuses attention on the disease across agencies, collaboration and cooperation in crosscutting initiatives, and reduces unnecessary duplication of efforts. The FCCBC has developed an Internet-accessible inventory of all government breast cancer activities.

FCCBC Supplement Grant Program. In September 1997, the FCCBC provided supplemental funding for a diverse portfolio of grants that increase knowledge of the causes of breast cancer, improve early detection, prevention and treatment of the disease, and bring lifesaving outreach and education programs to many medically underserved women across the nation.

The program awarded \$2.7 million to fund 22 innovative projects, with 50 percent of funding directed to programs which address the needs of underserved populations. Emphasizing interagency collaborations, the Supplemental Grant Program’s highlights include:

- A research project supported by the Agency for Health Care Policy and Research to better

understand the frequency of “drive-through” mastectomies in the era of managed care.

- An Indian Health Service project to expand the training and support of community health aides in the delivery of breast cancer early detection services to Alaska Native women in rural Alaskan villages.
- A project supported by the Health Resources and Services Administration to expand breast cancer services to Hispanic farm workers.
- A research project conducted by the National Institute of Environmental Health Sciences that will provide the foundation for a novel approach to identifying environmental chemicals with the potential to cause breast cancer.
- A National Cancer Institute project that is collecting in-depth survey information to evaluate the impact of a no-cost cancer screening program for low income, African-American women.
- The development of a database sponsored by the Health Care Financing Administration to measure the impact of breast cancer screening interventions for Hispanic Medicare beneficiaries.
- A Centers for Disease Control and Prevention research study to investigate a common variation of the protein p53, which appears to be a susceptibility factor for breast cancer. The study defines the link between this variant and different environmental and occupational exposures. The study may assist in determining why breast cancer in African-Americans and Hispanics often differs from Caucasians.
- A study by the Food and Drug Administration to reduce toxicity and improve the effectiveness of a chemotherapy drug, amino glutethimide, and a standard treatment of choice for cancer patients who no longer respond to tamoxifen.
- A Department of Agriculture outreach project to underserved women in Northern Appalachia to educate them about breast health and the possible preventative benefits of proper nutrition.
- A Department of Energy project to develop imaging technology to validate positive mammograms and thereby help reduce unnecessary biopsies.

FCCBC Partnering Workshop. In September 1998, the FCCBC convened a workshop entitled “Partnering to Improve Outcomes: Opportunities for Collaboration in Government Breast Cancer Programs.” The workshop highlighted federal activities related to breast cancer and encouraged the formation of new partnerships while strengthening existing interagency collaborations in breast cancer research, policy, services, and public health. The closing session

of the workshop outlined barriers to and facilitators of federal partnerships throughout the conference.

Other Collaborations

Federal Multi-Agency Consortium on Imaging to Improve Women's Health. In July 1994, the Public Health Service's Office on Women's Health, in collaboration with NCI, began an initiative to examine technologies currently under exploration for improving breast imaging. The Federal Multi-Agency Consortium on Imaging to Improve Women's Health is exploring the applications of technologies from other fields to improve the early detection and diagnosis of illnesses and conditions affecting women.

The Department of Health and Human Services has been working with the Department of Defense, the Central Intelligence Agency, National Aeronautics and Space Agency, and other public and private entities to enhance the ability to detect breast cancer at its earliest stages and to explore opportunities in telemedicine.

In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection and treatment at its earliest stages. In October 1996, DHHS awarded \$1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community—originally used for missile guidance and target recognition—to improve the early detection of breast cancer.

In October 1996, the Food and Drug Administration (FDA) sponsored a conference "The Transfer of Defense, Intelligence, Space and Energy Technologies to the Early Detection and Control of Cancers in Women," in an effort to facilitate such public/private partnerships.

National Mammography Campaign. The Health Care Financing Administration and the National Cancer Institute have entered into an inter-agency agreement to develop, implement, and promote a short term joint health promotion campaign targeting Medicare beneficiaries. The purpose of the campaign is to increase awareness of the importance of the expanded Medicare benefit and regularly scheduled mammography screening among women ages 65 and older.

As part of the agreement, NCI has developed mammography publications to target older women. The new publications include a poster and bookmark featuring an older woman and the Medicare message, as well as a large-print, easy-to-read brochure. All materials will include information on Medicare's expanded benefit and will be printed in English and Spanish.

Centers for Disease Control and Prevention's Public/Private Partnerships. Partnerships are critical to the CDC's cancer control efforts. A successful national program to control breast and cervical cancers, such as the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), depends on the involvement of a variety of committed partners and national organizations. CDC collaborates with state and local governments, health care professionals and

organizations, social service and voluntary organizations, and academia.

Through these critical partnerships, CDC assists private and public nonprofit organizations in the following program areas:

- Developing, implementing, and evaluating national and community-based interventions for cancer prevention and early detection;
- Testing new methods and replicating proven strategies to educate their constituents about breast and cervical cancers; and,
- Increasing access to breast and cervical cancer screening among underserved women.

CDC and Partners Helping Underserved Women. In October 1993, a unique public-private partnership was established among CDC, Avon Products Inc., the YWCA of the U.S.A., the National Alliance of Breast Cancer Organizations (NABCO), and the National Cancer Institute. The partnership seeks to educate women about breast health and to improve access to early detection services. Avon's Breast Cancer Awareness Crusade has raised more than \$25 million for breast cancer programs nationwide through the sale of its Breast Cancer Awareness pink ribbon products.

Since 1993, about 300 community-based programs in 49 states and Puerto Rico have received funding, from Avon's Crusade through the YWCA of the U.S.A. and NABCO, to educate women about breast cancer and to provide underserved women with access to early detection services. Earlier this year, all funding of community-based programs was consolidated under the Breast Health Access Fund administered by NABCO.

CDC and Partners Assisting At-Risk Populations. Partnerships that focus their prevention efforts on those at greater risk are essential for understanding and alleviating the disparities that exist. Deaths due to breast cancer are decreasing among white women, but not as steadily among African-American women. Both mammography and Pap tests are underutilized by women who are members of racial and ethnic minority groups, have less than a high school education, are older, or live below the poverty level.

To address these differences in the burden of cancer and in the use of cancer prevention services, CDC funds a strong and effective network of partners that are well-positioned in the communities at risk including:

- The U.S. Conference of Mayors' Research and Education Foundation
- The National Center for Farmworkers Health, Inc.
- The American Social Health Association
- The Association of Asian Pacific Community Health Organizations
- The National Hispanic Council on Aging
- The Baylor College of Medicine "Salud en Accion Program"
- The Institute for the Advancement of Social Work Research

- The Mautner Project for Lesbians with Cancer
- The National Asian Women's Health Organization
- The National Association of Community Health Centers
- The National Education Association Health Information Network
- The National Caucus and Center on Black Aged, Inc.
- The Witness Project
- The World Education

These partners have developed projects that focus on specific at-risk populations and cover a wide range of prevention and research activities. For example, many projects are involved with developing low literacy, bilingual, and culturally appropriate educational campaigns. These prevention techniques and research efforts result in increasing knowledge and awareness of breast and/or cervical cancer and promoting screening for early detection in communities around the nation.

CHALLENGES AND NEW FRONTIERS

While continuing to work toward the ultimate goal of eradicating breast cancer, the Clinton Administration is striving to meet new challenges in its ongoing campaign against this deadly disease:

1. We must ensure adequate and sustained support for research. Only research can unlock tomorrow's medical discoveries and treatments.
2. We can only defeat breast cancer if researchers and scientists continue to work together, across agency lines, departmental walls, and the public-private divide.
3. We must work to increase participation in cancer clinical trials to assure that breast cancer patients have access to cutting-edge research and to help speed up discoveries.
4. We must continue to work to ensure that advances and breakthroughs translate into high quality care for breast cancer patients. We have heard too many stories about breast cancer patients who could not see the needed specialist or who had critical treatment denied or delayed until it was too late. We must work to enact protections that breast cancer patients need and deserve.
5. As we crack the genetic code, it should be used to improve treatment, not increase discrimination. No person should have their health care or their job put at risk because they are genetically at risk for cancer.
6. We must continue efforts to expedite new cutting edge treatments for breast cancer, while maintaining our commitment to quality and public health.
7. We must renew our scientific efforts to discover the cause of racial disparities in breast cancer rates between white women and women of color in order to close the gaps. This will help ensure that all women, regardless of race or ethnicity, benefit from our progress against breast cancer.
8. We must improve early detection so that more women catch breast cancer at its earliest and most treatable stages.
9. We must learn more about the environmental factors that cause breast cancer; and
10. We must find ways to send young women clear messages about the importance of a healthy lifestyle to prevent breast cancer, and other diseases, before they start.

To address the devastating disease of breast cancer in the new millennium will require that we strengthen our partnerships across the government and within the private sector to move forward an agenda that will eventually lead to the eradication of this devastating disease. In the first six months of 1999 we will join together consumers, policymakers, researchers and advocacy organizations for a day of dialogue on breast cancer. We will reflect upon all that has been accomplished to conquer this disease over the past five years, including progress that has been made in breast cancer research, policies, services, and health outcomes, and chart the course for addressing the disease over the next five years.