



FAX Transmission

**U.S. Department of Health and Human Services
Office of the Secretary**

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TO: Sarah Bianchi

FAX: 5557

PHONE:

FROM: Ellen Dahl

Office of the Assistant Secretary for Public Affairs

Phone: (202) 690-7578

Fax: (202) 690-5673

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COMMENTS:

Talking Points for Press Briefing On Breast Cancer Awareness Month Event
October 21, 1998

- Good morning, I would like to introduce Dr. Susan Wood, of the Office of Women's Health, and from the National Cancer Institute, Dr. Jeff Abrams and Dr. Leslie Ford.
- When I took office, the President and I vowed to make fighting breast cancer a top priority. Five years ago this month, the nation's leading breast cancer advocates sent a petition with over 6 million signatures calling for a national action plan to fight this deadly disease. I am here today to say with pride that the President, the Vice President, and I have answered the call and are committed to keeping breast cancer a top priority.
- I'd like to recognize the 5th anniversary of the National Action Plan on Breast Cancer and that we are releasing a report today highlighting that we have made significant progress.
- In 1994, a breast cancer susceptibility gene (BRCA1) was identified, that may account for 5 to 10 percent of breast cancer cases. To further such work, in 1996 President Clinton announced \$30 million for a new fund for research into the genetic basis of breast cancer.
- In 1996, President Clinton and I announced a new FDA initiative to improve women's access to promising new cancer therapies. The FDA has put cancer drugs on a fast track for review and approval, and it has recently approved several new devices and diagnostic tools. These include serum tumor markers, assays to measure certain proteins in breast cancer tissues, an advanced ultrasound system to be used in conjunction with mammography, and a new computer based system to improve the reading of mammograms.
- As of January 1, 1998, due to a proposal by the President, Medicare is helping to pay for annual mammograms for all beneficiaries 40 and over. Under this new benefit, Medicare waives the Part B deductible for screening mammograms
- Also, thanks to the FDA's Mammography Quality Standards Act, women are now assured greater safety and accuracy in their mammograms. Furthermore, to enhance our understanding of screening practices and effectiveness, the Breast Cancer Surveillance Consortium is gathering information on 3.2 million mammograms. AHCPR has also developed a clinical practices guide with information on mammography standards and recommendations for women. (The President signed the reauthorization on October 9, 1998.)
- Today I am pleased to announce three new actions that build on this history of progress. First, plans are underway for the most ambitious clinical trial to date to reduce women's risk of breast cancer, pending approval by the FDA. If approved, the trial will open early next year in 400 sites across the United States, with approximately, 20,000 women taking part.

- Second, the clinical trial, "Study of Tamoxifen and Raloxifene" (STAR) will evaluate the benefits and risks of the drug raloxifene in reducing the risk of breast cancer among women who have not had the disease. The study builds on the success of the recent Breast Cancer Prevention Trial, which demonstrated the effectiveness of the drug tamoxifen in reducing the risk of developing breast cancer.
- As part of the recent budget agreement, and the record funding for the National Institutes of Health, the National Cancer Institute has received a total budget of \$2.9 billion, which is a 15% increase over last year's funding level -- *the largest budget in the history of NCI*. For breast cancer alone, NCI will receive a total budget of \$388 million in FY 1999, which is a 11.5% increase over last year's funding level.
- Third, I am pleased to announce new efforts to encourage mammography screening among special populations, especially older, low income and minority women, who tend to have the highest breast cancer mortality rates. HCFA will join with the NCI to aim new efforts at five states with high concentrations of older women, and earlier this month, HCFA launched a multi-city mammography project to focus on educating minority Medicare beneficiaries about the importance of regular mammogram screenings.
- All of these efforts, build on Vice President Gore's announcement in January of this year on the Administration's new cancer initiative, which includes an historic \$4.7 billion increase in spending in cancer-wide research at NIH, a 65 percent increase over the next five years. (NIH estimates that in 2003, total cancer research spending will be \$4.85 billion.) This year's total NIH budget for cancer research is \$3.4 million, a 15% increase over last year's level.
- We need to continue to get the message out that 93 percent of breast cancer cases are successfully treated when detected early. Regular mammograms can reduce the chance of death from breast cancer by one-third or more. Despite the potential benefits, 33 percent of women ages 50-64, and 45 percent of women age 65 and older, report not receiving a mammogram during the past two years. Breast cancer is the second leading cause of cancer deaths among American women. This year alone, another 180,000 cases of breast cancer will be diagnosed, and some 43,500 women will die from the disease.
- This has been a great victory for women and it couldn't have been done without the hard work and commitment by such people as Fran Visco, of the National Action Plan on Breast Cancer, and the members of the Federal Coordinating Committee on Breast Cancer. And here at HHS, I'd like to recognize the successful efforts and innovative partnership by the Office of Women's Health and the National Cancer Institute.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Contacts: HHS Press Office (202) 690-6343
NCI Press Office (301) 496-6641
FDA Press Office (301) 827-6242

BREAST CANCER: NEW EFFORTS UNDERWAY

Overview: Breast cancer is the most commonly diagnosed cancer of women and the second leading cause of cancer deaths among American women. Regular mammography and clinical breast exams are essential for early detection of breast cancer. For women age 50-69, having regular mammograms can reduce the chance of death from breast cancer by one-third or more. During the most recent five-year period, mortality rates among white women declined for all decades of ages between 30 and 79, and for all decades of ages among black women from 30 to 69. A July 1998 article in the journal Cancer attributes the decrease to a trend toward progressively earlier diagnosis of breast cancer. According to the study, the number of patients diagnosed with the earliest stages of breast cancer increased from 42 percent in 1985 to 46 percent in 1995. Despite these numbers, 33 percent of women ages 50-64, and 54 percent of women age 65 and older reported not receiving a mammogram during the past two years.

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. HHS Secretary Donna E. Shalala convened a conference in December 1993 to establish a National Action Plan on Breast Cancer. The national plan, which is being carried out today by the public, private and volunteer sectors, is a key element of the Administration's commitment to fighting breast cancer.

At the same time, spending on breast cancer research at HHS' National Institutes of Health has increased from \$283 million in FY 1993 to nearly \$550 million in FY 1998. President Clinton's FY 1999 budget is expected to include an estimated \$605 million for breast cancer spending at the Department of Health and Human Services.

In 1995, First Lady Hillary Rodham Clinton launched a campaign urging older women to obtain mammograms, and, in particular, to promote use of Medicare coverage for mammography. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screening.

In addition, President Clinton proposed, and Congress adopted, the expansion of Medicare coverage to help pay for annual mammograms for all Medicare beneficiaries age 40 and over. This new benefit became available on January 1, 1998.

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Background: More Women Can Survive Breast Cancer

- A woman's chances of getting breast cancer change with age: by age 40, one of 217 women will face breast cancer; by age 70, one of 14 will be diagnosed with the disease. Although death rates from breast cancer declined 4.6 percent between 1991 and 1995, breast cancer accounts for 31 percent of all cancers diagnosed among women.
- Approximately 180,000 new cases of breast cancer are estimated for 1998, and about 43,500 women are expected to die from breast cancer. Epidemiologic 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. Between 1982 and 1987, breast cancer incidence for women increased about 4 percent per year, but recently has leveled off. Death rates from the disease are highest among older, black, and low-income women.
- With proper early detection and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. The greatest reductions in death rates were among younger women (7.6 percent) and white women (5.3 percent), with more modest reductions among African Americans (1.6 percent).
- During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

HHS discretionary funding for breast cancer research, early detection, diagnosis, prevention and treatment has increased from approximately \$283 million in FY 1993 to nearly \$550 million in FY 1998. Cancer research is vital to our understanding of how to prevent, detect and treat breast cancer. The Clinton Administration has invested in breast cancer research at the National Institutes of Health by increasing funding from \$237 million in FY 1993, to \$433 million in FY 1998. Total NIH breast cancer research funding in FY 99 is expected to be an estimated \$480 million, an 11 percent increase over last year. NCI funding for breast cancer in FY 1999 is expected to be \$388 million, an increase of 11.5 percent from FY 1998.

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

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HHS Action To Combat Breast Cancer

Under President Clinton, a wide array of activities are underway and new initiatives have been launched:

New Mammography Benefit

President Clinton proposed, and Congress adopted, the expansion of Medicare coverage which will help pay for annual screening mammograms for all Medicare beneficiaries age 40 and over. Under this new benefit, which became available January 1, 1998, Medicare will waive the Part B deductible for screening mammograms.

Mammography Awareness and Education Programs

In October 1998, to mark Breast Cancer Awareness Month, the Health Care Financing Administration (HCFA) and NCI joined together to increase awareness among older women of the importance of regular mammograms and Medicare's coverage of annual screenings. The new efforts focus on high concentration areas of older women. In addition, HCFA is offering mammogram screenings and/or airing a series of public service announcements geared toward older African American and Hispanic American women in the following cities: Atlanta, Chicago, Cleveland, Los Angeles, Philadelphia, San Antonio, and Washington, D.C.

Mammography Quality Standards

Congress passed the Mammography Quality Standards Act (MQSA) in 1992 to ensure that all women have access to high quality mammography services. Under the final rules of the Mammography Quality Standards Act (MQSA), published in October 1997, the FDA sets high standards for mammography facilities and certifies those which meet the standards. The roughly 10,000 mammography facilities nationwide accredited by the FDA must meet quality standards for equipment and personnel, and are inspected annually. President Clinton recently signed legislation reauthorizing the Mammography Quality Standards Act.

These regulations spell out the details for requiring facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled interpreting 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 any follow-up testing or treatment can begin immediately. The names and locations of Food and Drug Administration (FDA) certified mammography facilities are available by calling the Cancer Information Service at 1-800-4-CANCER. In addition, the FDA has included a list of all FDA certified mammography facilities in the United States on its internet home page. The address is <http://www.fda.gov/cdrh/faclist.html>.

National Action Plan on Breast Cancer

HHS' Office on Women's Health coordinates the *National Action Plan on Breast Cancer*. This first-ever national plan was developed in 1993 under Secretary Shalala's leadership. The Plan has awarded over \$9 million in grants for 99 innovative research and outreach projects, with a special emphasis on the development of public-private partnerships targeted in the six priority areas:

- *The Information Action Council Working Group* is working to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other

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information technologies.

- *The Etiology Working Group* is focusing on efforts to expand the scope and breadth of biomedical, epidemiological and behavioral research on breast cancer. The group has identified four priority areas: chemicals and hormones, viruses, radiation and electromagnetic fields, and lifestyle factors.
- *The National Biological Resources Banks Working Group (NAPBC)* has focused on the development of a national mechanism and standard for obtaining and storing tissue for multiple areas of breast cancer research. The NAPBC has awarded funds to establish a national biological resources bank and is now conducting a survey of tissue banks throughout the country to identify and determine the accessibility of all available biological resources.
- *The Working Group to Ensure Consumer Involvement* has defined several specific activities to help ensure consumer involvement at all levels in the development of national research, education, and service delivery programs related to breast cancer.
- *The Clinical Trial Accessibility Working Group* has identified a series of initiatives to address four types of barriers to participation in clinical trials, including barriers associated with the informed consent process, patient and physician misperceptions about clinical trials, lack of information about the availability of trials, and cost.
- *The Working Group on Heredity Susceptibility* is evaluating the ethical, legal and policy issues of individuals carrying breast cancer susceptibility genes.

On October 27, 1996, President Clinton launched the National Action Plan on Breast Cancer (NAPBC) Internet web site. The web site, developed by a public/private partnership and coordinated by the Department of Health and Human Services Office on Women's Health, is designed to serve as a gateway to information on breast cancer research, treatment, and prevention. The 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. The web site address is: <http://www.napbc.org>.

Federal Coordinating Committee on Breast Cancer

In 1994, Secretary Shalala formed the Federal Coordinating Committee on Breast Cancer to coordinate and enhance federal efforts on breast cancer. The group brings together experts from HHS, the Departments of Defense and Veterans Affairs, the Department of Energy, the Environmental Protection Agency, and the Department of Agriculture to address a variety of breast cancer issues. These innovative interagency and public-private partnerships have yielded studies on prevention and treatment drugs such as tamoxifen and herceptin and applied the latest in technology from the Department of Defense and NASA to better detect cancerous tissues and develop less intrusive surgeries for patients.

On October 21, 1998, the Secretary submitted a five year progress report entitled "Breast Cancer: A Report on the Fight to Prevent, Treat and Cure the Disease." This report highlighted the Federal Coordinating Committee's work as well as the National Action Plan on Breast Cancer's successes.

Herceptin

On September 25, 1998, FDA approved Herceptin, the first genetically-engineered antibody therapy for

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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.

Breast Cancer Prevention Trial

As part of a large North American study conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP) with support from the National Cancer Institute (NCI), over 13,000 women volunteered to take tamoxifen or an inactive pill to see if the drug would help prevent new cases of breast cancer. On April 6, 1998, NCI announced that there were 45 percent fewer cases of breast cancer reported in the women in the trial who took the drug versus those on the inactive pill. The study highlighted the fact that while a reduction in new cases is significant, there are risks associated with tamoxifen that must be carefully weighed against the benefits of breast cancer reduction. When the trial results were published in September 1988, the reduction in incidence was found to be 49 percent. In addition, NSABP and NCI are developing information for individual decision making that will help women at increased risk of breast cancer consult with their health care providers about whether or not to begin tamoxifen therapy.

Study of Tamoxifen and Raloxifene (STAR Trial)

On October 21, 1998, the First Lady and Secretary Shalala announced the largest-ever trial to reduce the incidence of breast cancer is scheduled to open at an estimated 400 sites across the United States and Canada early in 1999, pending approval by the Food and Drug Administration. The Study of Tamoxifen and Raloxifene, or STAR, will include 22,000 postmenopausal women at increased risk of breast cancer. STAR will build on the success of the NSABP by determining whether raloxifene, a drug similar to tamoxifen, is also effective in reducing the incidence of breast cancer in women who have not had the disease. Raloxifene was recently approved by the Food and Drug Administration as an osteoporosis prevention drug for postmenopausal women.

Women's Health Initiative

In 1992, National Institutes of Health (NIH) launched the Women's Health Initiative (WHI), which includes one of the largest set of clinical trials ever conducted on the causes and prevention of breast cancer. It is testing whether a diet low in fat and high in fruits, vegetables, grains, and cereals will prevent breast cancer in the almost 49,000 women who enrolled in the study.

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Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

Breast cancer research has been expanded at the National Institutes of Health. Promising news came late in 1994 when a team of investigators at the University of Utah, Myriad Genetics, and the National Institute of Environmental Health Sciences (NIEHS) identified a breast cancer susceptibility gene (BRCA1) that may account for 5-10 percent of the breast cancers diagnosed each year. The discovery of a second, entirely different breast cancer susceptibility gene, BRCA2, has helped us understand even more about the genetics of breast cancer. Most recently researchers discovered a particular variant of the BRCA1 susceptibility gene in Jewish women of eastern European descent (Ashkenazi Jews). While only 5-10 percent of all breast cancers are the result of an inherited anomaly, these findings hold promise for the development of new prevention and treatment strategies.

Other breast cancer research includes psychosocial research, which looks at how to enhance the quality of life in women with breast cancer, and the Breast Cancer Prevention Trial, which is studying ways in which to prevent breast cancer.

On October 27, 1996, President Clinton announced \$30 million in new funding for research into the genetic basis of breast cancer through a collaborative initiative between the Department of Defense and the National Institutes of Health.

Privacy of Genetic Information and Breast Cancer

President Clinton has supported bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage, set premiums, or to distribute confidential information. In many diseases, such as breast cancer, we 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 testing also can be used by insurance companies and others to discriminate and stigmatize individuals and groups of people. In fact, studies show that one of the reasons women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.

National Breast and Cervical Cancer Early Detection Program

CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. Resources devoted to breast cancer screening services have grown from an estimated \$43 million in FY 1993 to \$85 million in FY 1998. The program, which has been operating in an increasing number of states over the past six years, has provided more than 1.3 million screening tests to medically underserved women. Currently, the program provides funding for all 50 states, five territories, the District of Columbia, and 15 American Indian/Alaska Native organizations.

Breast Cancer Among the Elderly

The Agency for Health Care Policy and Research (AHCPR) is currently funding a five-year Patient Outcomes Research Team study on the care, costs, and outcomes of early stage breast cancer. The study will examine three alternative treatments for early stage breast cancer in the elderly: modified radical mastectomy, breast-conserving surgery with radiotherapy, and breast-conserving surgery without radiotherapy. The project will look at quality and cost-effectiveness in these projects and will develop clear recommendations for treating early stage breast cancer in the elderly.

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New Frontiers In Breast Cancer Early Detection

The Department of Health and Human Services has been working with the Department of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer. In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection as well. In October, 1996, HHS 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.

Centers of Excellence

On October 1, 1996, the Department of Health and Human Services established six National Centers of Excellence in Women's Health to serve as national models for improving the health care of American women. The new Centers of Excellence program, with facilities located at academic institutions in different areas of the country, will integrate health care services, research programs, public education and health care professional training. HHS' Office of Women's Health now supports 18 Centers of Excellence.

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, AHCPR in October 1994 developed a Clinical Practice Guideline--*Quality Determinants of Mammography*--with separate versions for mammography providers, health care professionals, and consumers. The guidelines detail the roles and responsibilities of each health care professional involved in mammography services, and include information and recommendations for women.

Mammography for Women with Addictive and Mental Disorders

Women who are in need or who receive substance abuse or mental health services often lack appropriate primary health care, including breast cancer education, detection, 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, delivering primary health care services to women who often are medically underserved. These services include education on breast self-examination and mammography services, and counseling on risks for breast cancer.

Environmental Factors and Breast Cancer

HHS' Office on Women's Health has 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.

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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. The Office of Cancer Survivorship supports research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

For the first time this year, the National Cancer Institute began including consumer advocates as full voting members of the peer review groups that judge the worth of grant applications. This year the National Cancer Institute also formed a Director's Consumer Liaison Group, a formal committee of 15 cancer survivors who directly advise the NCI director and bring the patient's perspective to bear on the full range of NCI activities. By next year, NCI will fully integrate patients and advocates into activities such as reviewing grant proposals, and planning policy.

Vice President Gore also announced on September 26, 1998, that NCI is funding \$15 million in new cancer survivorship grants to fund top-of-the-line research to examine cancer's impact on survivors and their families.

In March 1996, FDA also initiated a program to educate and recruit cancer patients and their advocates to participate in meetings of FDA advisory committees - groups of outside experts that advise FDA on cancer-related therapies. More than two dozen cancer patients or their advocates have made important contributions to the advisory committees that review cancer-related therapies.

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- With proper early detection and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. The greatest reductions in death rates were among younger women (7.6 percent) and white women (5.3 percent), with more modest reductions among African Americans (1.6 percent).
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On October 27, 1996, President Clinton launched the National Action Plan on Breast Cancer (NAPBC) Internet web site. The web site, developed by a public/private partnership and coordinated by the Department of Health and Human Services Office on Women's Health, is designed to serve as a gateway to information on breast cancer research, treatment, and prevention. The 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. The web site address is: <http://www.napbc.org>.

Federal Coordinating Committee on Breast Cancer

In 1994, Secretary Shalala formed the Federal Coordinating Committee on Breast Cancer to coordinate and enhance federal efforts on breast cancer. The group brings together experts from HHS, the Departments of Defense and Veterans Affairs, the Department of Energy, the Environmental Protection Agency, and the Department of Agriculture to address a variety of breast cancer issues. These innovative interagency and public-private partnerships have yielded studies on prevention and treatment drugs such as tamoxifen and herceptin and applied the latest in technology from the Department of Defense and NASA to better detect cancerous tissues and develop less intrusive surgeries for patients.

On October 21, 1998, the Secretary submitted a five year progress report entitled "Breast Cancer: A Report on the Fight to Prevent, Treat and Cure the Disease." This report highlighted the Federal Coordinating Committee's work as well as the National Action Plan on Breast Cancer's successes.

Herceptin

On September 25, 1998, FDA approved Herceptin, the first genetically-engineered antibody therapy for

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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.

Breast Cancer Prevention Trial

As part of a large North American study conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP) with support from the National Cancer Institute (NCI), over 13,000 women volunteered to take tamoxifen or an inactive pill to see if the drug would help prevent new cases of breast cancer. On April 6, 1998, NCI announced that there were 45 percent fewer cases of breast cancer reported in the women in the trial who took the drug versus those on the inactive pill. The study highlighted the fact that while a reduction in new cases is significant, there are risks associated with tamoxifen that must be carefully weighed against the benefits of breast cancer reduction. When the trial results were published in September 1988, the reduction in incidence was found to be 49 percent. In addition, NSABP and NCI are developing information for individual decision making that will help women at increased risk of breast cancer consult with their health care providers about whether or not to begin tamoxifen therapy.

Study of Tamoxifen and Raloxifene (STAR Trial)

On October 21, 1998, the First Lady and Secretary Shalala announced the largest-ever trial to reduce the incidence of breast cancer is scheduled to open at an estimated 400 sites across the United States and Canada early in 1999, pending approval by the Food and Drug Administration. The Study of Tamoxifen and Raloxifene, or STAR, will include 22,000 postmenopausal women at increased risk of breast cancer. STAR will build on the success of the NSABP by determining whether raloxifene, a drug similar to tamoxifen, is also effective in reducing the incidence of breast cancer in women who have not had the disease. Raloxifene was recently approved by the Food and Drug Administration as an osteoporosis prevention drug for postmenopausal women.

Women's Health Initiative

In 1992, National Institutes of Health (NIH) launched the Women's Health Initiative (WHI), which includes one of the largest set of clinical trials ever conducted on the causes and prevention of breast cancer. It is testing whether a diet low in fat and high in fruits, vegetables, grains, and cereals will prevent breast cancer in the almost 49,000 women who enrolled in the study.

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Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

Breast cancer research has been expanded at the National Institutes of Health. Promising news came late in 1994 when a team of investigators at the University of Utah, Myriad Genetics, and the National Institute of Environmental Health Sciences (NIEHS) identified a breast cancer susceptibility gene (BRCA1) that may account for 5-10 percent of the breast cancers diagnosed each year. The discovery of a second, entirely different breast cancer susceptibility gene, BRCA2, has helped us understand even more about the genetics of breast cancer. Most recently researchers discovered a particular variant of the BRCA1 susceptibility gene in Jewish women of eastern European descent (Ashkenazi Jews). While only 5-10 percent of all breast cancers are the result of an inherited anomaly, these findings hold promise for the development of new prevention and treatment strategies.

Other breast cancer research includes psychosocial research, which looks at how to enhance the quality of life in women with breast cancer, and the Breast Cancer Prevention Trial, which is studying ways in which to prevent breast cancer.

On October 27, 1996, President Clinton announced \$30 million in new funding for research into the genetic basis of breast cancer through a collaborative initiative between the Department of Defense and the National Institutes of Health.

Privacy of Genetic Information and Breast Cancer

President Clinton has supported bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage, set premiums, or to distribute confidential information. In many diseases, such as breast cancer, we 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 testing also can be used by insurance companies and others to discriminate and stigmatize individuals and groups of people. In fact, studies show that one of the reasons women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.

National Breast and Cervical Cancer Early Detection Program

CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. Resources devoted to breast cancer screening services have grown from an estimated \$43 million in FY 1993 to \$85 million in FY 1998. The program, which has been operating in an increasing number of states over the past six years, has provided more than 1.3 million screening tests to medically underserved women. Currently, the program provides funding for all 50 states, five territories, the District of Columbia, and 15 American Indian/Alaska Native organizations.

Breast Cancer Among the Elderly

The Agency for Health Care Policy and Research (AHCPR) is currently funding a five-year Patient Outcomes Research Team study on the care, costs, and outcomes of early stage breast cancer. The study will examine three alternative treatments for early stage breast cancer in the elderly: modified radical mastectomy, breast-conserving surgery with radiotherapy, and breast-conserving surgery without radiotherapy. The project will look at quality and cost-effectiveness in these projects and will develop clear recommendations for treating early stage breast cancer in the elderly.

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New Frontiers In Breast Cancer Early Detection

The Department of Health and Human Services has been working with the Department of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer. In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection as well. In October, 1996, HHS 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.

Centers of Excellence

On October 1, 1996, the Department of Health and Human Services established six National Centers of Excellence in Women's Health to serve as national models for improving the health care of American women. The new Centers of Excellence program, with facilities located at academic institutions in different areas of the country, will integrate health care services, research programs, public education and health care professional training. HHS' Office of Women's Health now supports 18 Centers of Excellence.

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, AHCPR in October 1994 developed a Clinical Practice Guideline--*Quality Determinants of Mammography*--with separate versions for mammography providers, health care professionals, and consumers. The guidelines detail the roles and responsibilities of each health care professional involved in mammography services, and include information and recommendations for women.

Mammography for Women with Addictive and Mental Disorders

Women who are in need or who receive substance abuse or mental health services often lack appropriate primary health care, including breast cancer education, detection, 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, delivering primary health care services to women who often are medically underserved. These services include education on breast self-examination and mammography services, and counseling on risks for breast cancer.

Environmental Factors and Breast Cancer

HHS' Office on Women's Health has 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.

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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. The Office of Cancer Survivorship supports research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

For the first time this year, the National Cancer Institute began including consumer advocates as full voting members of the peer review groups that judge the worth of grant applications. This year the National Cancer Institute also formed a Director's Consumer Liaison Group, a formal committee of 15 cancer survivors who directly advise the NCI director and bring the patient's perspective to bear on the full range of NCI activities. By next year, NCI will fully integrate patients and advocates into activities such as reviewing grant proposals, and planning policy.

Vice President Gore also announced on September 26, 1998, that NCI is funding \$15 million in new cancer survivorship grants to fund top-of-the-line research to examine cancer's impact on survivors and their families.

In March 1996, FDA also initiated a program to educate and recruit cancer patients and their advocates to participate in meetings of FDA advisory committees - groups of outside experts that advise FDA on cancer-related therapies. More than two dozen cancer patients or their advocates have made important contributions to the advisory committees that review cancer-related therapies.

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**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 mamunograms 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>).