

~~Some~~ somewhere should be in ~~the~~ President Clinton

background here should focus on importance of mammography

showed continued commitment to ~~the~~ ^{to} ~~few~~ breast cancer by reauth MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 1998 this program.

In 1992, the Mammography Quality Standards Act (MSQA) was created in response to the growing incidence of breast cancer and its associated mortality rates. It established national quality standards for mammography facilities and an accreditation and inspection program to ensure that these standards are met. A May 10, 1998 GAO study recently reported that MSQA has had a positive effect on facilities' adherence to accepted quality assurance standards and improved the quality of the diagnostic techniques used, which will increase early detection of breast cancer and potentially save the lives of thousands of women. ^{specific incident in GAO of women not getting quality mammograms}

^{does GAO give any #s about how many women have been served? or any stats demonstrating improvements} The Mammography Quality Standards Reauthorization Act of 1998 builds on the success of the original Act, expanding current law to provide additional patient protections to women receiving mammography services. The Reauthorization Act ~~requires that~~ ^{improvements on this critical program, by assuring} makes important

Medical centers notify women directly and in laymen's terms about the results of their mammograms.

Presently, women whose physicians request that they undergo breast cancer screening do not have to be notified of the results. Only physicians and self-referred women must be notified directly. Requiring medical centers to notify women directly about the results of their mammograms ^{will ensure that} ensures that women will receive potentially life saving information in a timely and responsible manner.

^{This new provision of} ~~The Secretary of Health and Human Services~~ require facilities that fall significantly below Federal quality standards to warn patients about their record of poor service. Patients have the right to know about the quality of care they will potentially receive. If facilities that do not meet Federal quality standards fail to notify their patients of this fact, they will be subject to a civil money penalty of up to \$10,000. ^{if this new reauthorization}

In addition, the Reauthorization Act provides additional flexibility for those facilities that have proven themselves to be exemplary in their delivery of mammography services. Under this new expansion of current law,

- **The FDA will establish a demonstration program exempting facilities with exceptionally high quality standards from the annual Federal inspection.** This demonstration program will allow the Federal government to focus its quality assurance efforts on those facilities that will potentially fall below established clinical standards, thereby increasing the effectiveness of our present monitoring efforts.

^{this concept should be the lead - the fact that it improve efficiency - not exempting} I know that there needs to be some fluff about how important breast cancer is to the President, etc. ^{The fluff should be} if you can help me with language, I'll put it in.

that we are ~~requiring~~ showing solid support for this
great successful program by reauthorizing
it.



Assistant Secretary for Health
Surgeon General
Washington, D.C. 20201

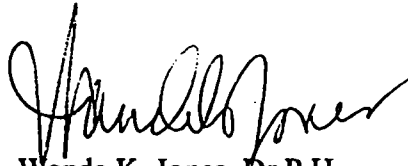
DATE: October 14, 1998

TO: Chief of Staff
Through: ES _____
ASH/SG _____

FROM: Deputy Assistant Secretary for Health (Women's Health)

SUBJECT: Department's Breast Cancer Accomplishments Report 1993-1998 - ACTION

A revised final report detailing the accomplishments the Administration has made in the area of breast cancer over the past five years is attached for your review. The report is expected to be released at a White House Breast Cancer event on Wednesday, October 21, in recognition of Breast Cancer Awareness Month.



Wanda K. Jones, Dr.P.H.

Attachment

**Breast Cancer: Five Years of Accomplishments in a Dedicated Fight and Commitment to
Eradicate the Disease
Executive Summary
(October 13, 1998)**

Despite recent declines in mortality rates, breast cancer remains the second leading cause of cancer deaths among American women; the disease will claim nearly half a million lives this decade. In addition, the lifetime risk of developing breast cancer is one in every eight women, up from one in every twenty women just two decades ago.

this is different
Faced with these statistics, the Clinton Administration has responded by significantly ~~by~~ increasing funding for research, prevention and treatment. Health and Human Service (HHS) discretionary spending on breast cancer increased from approximately \$274 million in FY 1993 to over \$400 million today. The Centers for Disease Control and Prevention (CDC) increased its resources devoted to breast cancer from approximately \$42 million in FY 1993 to \$84 million in FY 1998. And to undertake vital research, the National Institutes of Health (NIH) increased breast cancer funding from \$237 million in FY 1993 to an estimated \$433 million in FY 1998, to President Clinton's budget request of \$458 million in FY 1999.

As evidenced by the funding, this Administration is waging America's crusade against breast cancer on many fronts through HHS. Spearheading the effort is the National Action Plan on Breast Cancer (NAPBC), developed at the direction of President Clinton under the leadership of HHS Secretary Donna Shalala. The NAPBC is helping to coordinate the national response to breast cancer by fostering cooperation and communication among experts inside and outside government. It has also awarded over \$9 million in grants for 99 research and outreach projects. To foster collaborations among breast cancer programs within the federal government, the Federal Coordinating Committee on Breast Cancer was established as a liaison to the NAPBC; since 1997, it has also awarded nearly \$3 million to fund research projects.

In the battle against breast cancer, early detection is the most important weapon; moreover, it is often the only difference between a woman becoming a survivor or a statistic. As of January 1st, 1998, due to a proposal by the President, Medicare is helping to pay for annual mammograms for all beneficiaries 40 and over. And thanks to the FDA's Mammography Quality Standard 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. The Agency for Health Care Policy and Research (AHCPR) has also developed a clinical practices guide with information on mammography standards and recommendations for women.

Because older, black and low income women have the highest breast cancer mortality rates, the CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to uninsured, low-income, elderly, minority and Native American women nationwide; over the past six years, it has provide screening tests to over 1.7 million women. The CDC has also established partnerships with state and local governments, health care organizations, universities and even the Avon corporation to develop, implement and evaluate community-based interventions for cancer prevention and detection, especially for underserved women. To assist one particularly underserved community, the Substance Abuse and Mental Health Services Administration is helping women with mental and addictive disorders prevent and detect breast cancer, while the First Lady is leading a mammography awareness campaign aimed at women over 65.

While continuing to battle breast cancer with early detection, ~~it is~~ scientific research ~~that~~ is opening new windows on prevention and new doors to treatment. As part of NIH's Women's Health Initiative, the largest set of clinical trials, ever, on the causes and prevention of breast cancer is being conducted. And the Agency for Health Care Policy and Research (AHCPR) is currently funding a five year study which will examine alternative treatments for early stage breast cancer in the elderly.

Promising news came in late 1994 when a breast cancer susceptibility gene (BRCA1), that may account for 5 to 10 percent of breast cancer cases, was identified. To further such work, in 1996 President Clinton announced 30 million for a new fund for research into the genetic basis of breast cancer.

Additionally, the National Cancer Institute's landmark Breast Cancer Prevention Trial found that women at high-risk for breast cancer could reduce the risk by taking the drug tamoxifen. Recent studies have suggested that Herceptin may be beneficial for some patients with breast cancer that has spread to other parts of the body, while Taxol, if used with chemotherapy, may be beneficial if cancer has spread beyond the lymph nodes.

In 1996, President Clinton 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 renewal and approval, and it has recently approved several new devices. 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.

With all of these advances in prevention, detection and treatment, a new need arose: Dealing with the well-being of cancer survivors. In 1996, President Clinton established the Office of Cancer Survivorship to support research in this area. That same year, HHS established six National Centers of Excellence in Women's Health to serve models for improving the health

care of American women across the life span. As of September 1998, the National Centers of Excellence ^{is are 18} ~~have expanded to eighteen~~, six of which will specialize on the health of minority women.

Even with all of these accomplishments, the Clinton Administration continues to explore new frontiers in breast cancer prevention, detection and treatment. HHS has been working with other public and private agencies to find ways in which imaging technologies from other fields, especially the computer technology used to improve spy satellites, may advance the early detection of breast cancer. Inter-departmental efforts are also underway to develop a Mobile Breast Cancer Center that will generate and transmit a patient's digital mammogram to a breast screening center. HHS' Office on Women's Health has established a committee to investigate how environmental factors may contribute to breast cancer, and a collaborative effort at NIH is studying the cancer risk in the northeast and mid-Atlantic regions of the country.

Taken together, all of these current efforts and future endeavors may one day help remove breast cancer from the medical books and consign it to the history books.

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.

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. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.

In 1998, approximately 180,300 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.

• Declining Mortality Rate

Death rates from the disease are highest among older, African-American, and low-income women. (With early detection and proper treatment, however, the chances of surviving breast cancer are improving.) Between 1982 and 1987, breast cancer incidence for women increased about 4 percent per year, but has recently leveled off. *do we know why? Is this attributable to prevention?*

what are the rate changes? Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. The death rate for women with breast cancer has declined 4.6 percent between 1991 and 1995. The greatest reductions in death rates were among younger women (9.3 percent) and white women (6.6 percent), with more modest reductions among women age 65 and older (2.8 percent) and African Americans (1.6 percent). *how much higher?*

A study in the medical journal *Cancer* (July 1998) attributes the decrease or leveling off in breast cancer incidence and mortality to a trend toward progressively earlier diagnosis 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 50-69, 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 50-64, and 45 percent of women age 65 and older reported not having had a mammogram during the past two years.

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.

For 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.

- Although trends in early diagnosis are encouraging, breast cancer continues to threaten too many women's lives.

- ***Increased Funding***

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

Cancer research is vital to understanding of how to prevent, detect, and treat breast cancer. The Clinton Administration has responded by investing in breast cancer research at the National Institutes of Health (NIH) – increasing funding from \$237 million in FY 1993, to an estimated \$433 million in FY 1998, and to President Clinton's budget request of \$458 million in FY 1999.

- The Department of Health and Human Services (HHS) discretionary funding for breast cancer research, prevention, detection, and treatment has nearly doubled in the years since 1993 – from approximately \$283 million in FY 1993 to nearly \$550 million today.

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.

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 further explore the genetic basis of breast cancer and the most effective methods of treating those genetically pre-disposed to the disease.

↑ this is in common

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 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.

• 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 specifically special populations that are underserved.

•
National Action Plan on Breast Cancer. Under President Clinton's direction and under the leadership of HHS' 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.

Coordinated by HHS' Office of Women's Health and funded through the National Cancer Institute, the plan identifies 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, and coordinating activities of government and non-governmental organizations, agencies, and individuals in the fight against breast cancer.

Accomplishments include:

- ***Building Partnerships: One-time Grants.*** In September 1995, 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.
- ***Linking Women to Breast Cancer Information.*** In October 1996, President Clinton launched the NAPBC Internet Web site (<http://www.napbc.org>). The web site, developed by a public/private partnership and coordinated by HHS' Office of Women's Health, serves as a gateway to information on breast cancer research, prevention, detection, and treatment.

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.* Designed and implemented a pilot project 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.
- *Involving Consumers.* Conducted a survey 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.* Conducted an extensive literature search 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 is will be submitted for publication later this year.
- *Developed "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.
- *Raising Awareness about Health Insurance and Workplace Discrimination.* The NAPBC played a pivotal role on 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 (??).
- *Developed "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 Breast Cancer Comprehensive Questionnaire.* This questionnaire was developed and focus-group tested in order to the understand the causes of this disease. Six grouping -- consisting of 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.
- *Publications.* Papers published on "Hormones, Hormone Metabolism, Environment, and Breast Cancer" in a supplement to the journal, *Environmental Health Perspectives*. (??)

- *Published Proceedings.* The November 1997 "Workshop on Physical Activity and Breast Cancer" proceedings were published in a supplement to the medical journal, *Cancer*.(??)
- *Conducted Focus Groups.* Focus groups done (where? when?) in order to design a plan for a marketing campaign, designed to demystify breast cancer clinical trials, promote awareness, and encourage women to learn about and enroll in such trials.
- *Actions to Advance Research.* Designed and implemented, through public and private partners, a network of tissue banks to assist researchers needing biological materials for breast and other cancer research studies. This network can be accessed through the NAPBC Web site.
- *Created Guidelines.* Developed guidelines for Institutional Review Boards (IRBs) and others, a model patient consent form, and a patient fact sheet on donating tissue samples for research.

Federal Coordinating Committee on Breast Cancer(FCCBC). 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 fosters collaboration and cooperation in crosscutting initiatives, and ensures against unnecessary duplication of efforts. FCCBC has developed an Internet-accessible inventory of all government breast cancer activities. Additionally, the Federal Coordinating Committee on Breast Cancer is a liaison group with to the National Action Plan on Breast Cancer..

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 (AHCPR) to better understand the frequency of "drive-through" mastectomies in the era of managed care.
- An Indian Health Service (IHS) project to expand the training and support of community health aides in the delivery of breast cancer early detection services to Native American women in rural Alaskan villages.
- A project supported by the Health Resources and Services Administration (HRSA) to expand breast cancer services to Hispanic farm workers.

- A research project conducted by the National Institute of Environmental Health Sciences (NIEHS) 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 (HCFA) to measure the impact of breast cancer screening interventions for Hispanic Medicare beneficiaries.
- A Centers for Disease Control and Prevention (CDC) 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 (FDA) to reduce toxicity and improve the effectiveness of a chemotherapy drug, amino glutethimide, used to treat breast cancer patients and a standard treatment choice for patients who no longer respond to tamoxifen.
- A Department of Energy supported 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.

Federal MultiAgency Efforts

Federal Multi-Agency Consortium on Imaging to Improve Women's Health. In July 1994, the Office of 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 CIA, NASA, 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, 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.

(INSERT OTHER AGENCIES' CONTRIBUTIONS HERE)

More recently, 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.

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 and women living in rural and remote areas in particular.

Breast Cancer Surveillance Consortium. Established in October 1994 by NCI, the Breast Cancer Surveillance Consortium is comprised of eight/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 natural history of breast cancer.

By the year 2000, it is estimated that the Consortium’s database, with data collected from eight/nine participating sites across the country, will contain information on nearly 3.2 million mammograms and over 24,000 cases of breast cancer. This data will allow researchers to study

the effect of mammography on the many facets of breast cancer, such as how the biological characteristics of a breast tumor may affect screening performance. The data will also enable researchers to compare mammography screening practices among different regions of the country.

National 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 Centers of Excellence program, with facilities located at academic institutions in different areas of the country, unites women's health research, medical training, clinical care, public health education, community outreach, and the promotion of women in academic medicine around a common mission—to improve the health status of diverse women across the life span.

With less than \$3.5 million to date in funding from the U.S. Public Health Service's Office on Women's Health, the Centers have leveraged more than \$41 million in additional funds to promote the advancement of women's health. Six more centers were established in the 1997 and an additional six centers with a special emphasis on the health of minority women were announced in September 1998.

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 evaluation national, 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

→ design and effects of this program

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 in 1998, all funding of community-based programs has been 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 sponsors the 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 are focused 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.

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. These discoveries are leading to more refined technologies for detecting and diagnosing breast cancer, better supportive care and improved outcomes for patients during and after treatment, and ultimately, for preventing the disease together.

The Administration's increased efforts against this deadly disease has 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.

- *Advances in Prevention*

Research on how cancer develops has shown that cancer invariably involves altered genes and gene function. Studies in cancer genetics are 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.

Discovery of BRCA1 and BRCA2 Genes Linked to Breast Cancer. A 1994 study on women with a history of breast cancer, conducted by the National Institute of Environmental Health Sciences (NIEHS), the University of Utah, and Myriad Genetics, revealed two different breast cancer susceptibility genes, BRCA1 and BRCA2, which increase a woman's risk for developing breast cancer. Scientists have found that alterations in these two important genes are associated with most inherited breast cancers.

Researchers have also 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, early detection and treatment strategies.

In October 1996, President Clinton announced \$30 million in new 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. Through this collaborative effort between the Department of Defense and the National Institutes of Health, the Administration hopes to move rapidly toward identifying high-risk women and eventually preventing breast cancer before it strikes.

Should we discuss funding increase?

Additionally, the NIEHS is funding research on the development of transgenic mice with BRCA1 and BRCA2 mutated genes to study the effects of irradiation and environmental agents on breast cancer development.

Breast Cancer Prevention Trial (BCPT). Earlier this year, the Breast Cancer Prevention Trial, a national clinical trial sponsored by the NCI, tested tamoxifen -- a drug agent used for the past two decades to treat the reoccurrence of breast cancer -- as a breast cancer prevention agent. The results were unveiled eighteen months early because the drug was shown to reduce the incidence of breast cancer by 49 percent in women at high risk of the disease.

The BCPT proved for the first time that it is possible to reduce the short term incidence of breast cancer in women at greater than average risk of breast cancer. In September 1998, a Food and Drug Administration (FDA) advisory committee recommended tamoxifen for the use of short-term breast cancer incidence. The NCI is now developing an education program to help physicians and patients decide who should consider taking tamoxifen.

Clinical Trials and Prevention of Breast Cancer. Currently, 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. 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. A second trial, which includes over 27,000 women, will evaluate the effectiveness of hormone replacement therapy in preventing heart disease, and breast cancer will be carefully monitored as a potential adverse outcome.

Finally, the initiative will test whether supplements of calcium and vitamin D will prevent 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 Initiative are expected after 2005.

Environmental Factors and Breast Cancer. In August 1994, HHS' Office of 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 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, estrogenic-like chemicals, such as DDT, DDE, and other pesticides as well as PCBs.

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 PCB's (called congeners may be more estrogenic, making them pathogens 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 Detection*

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 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. Radiation therapy systems have been approved for treatment.

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 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 our 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.

↳ so far this has identified
xx genes (we announced
this at the cancer
march)
if we challenged scientists to use it
to provide
funding

Advances in Treatment

provided
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 other options for treatment are Zoladex (gosereline acetate implant), Arimidex (anastrozole), Taxotere (docetaxel), Xeloda (capecitabine), Femara (letrozole), Fareston (toremifene citrate), and Aredia (pamidronate disodium), and Herceptin. *Can't we say something collective here about these drugs. what they are doing - change new paper*
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 humanized 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 25-30 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.

•
FDA's Fast Track for Review and Approval of Cancer Drugs. Since 1996(??), the Food Drug and Administration (FDA) has accelerated the review and approval of new drugs and expanded patients' access to promising therapies not yet approved in the United States. For example, promising medications approved in other countries or found to shrink tumors to a greater extent than current therapies will be made available in the U.S. to treat patients with advanced breast cancer.

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.

- ***Further Research Steps to a Cure***

- Longer-term follow up on the Breast Cancer Prevention Trial and results from other confirmatory trials are needed before Taxol or similar drugs are ready for women to use routinely. 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, diagnose 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 epidemiological, prevention, and therapy trials;
- Ensure investigator access to necessary technology;
- Enhance infrastructure at academic health centers;
- Modifications of existing mechanisms to promote translational, prevention, and therapy trials;
- Improve communications efforts and incorporate patient-focused outcome;
- Research in basic behavioral change, decision making, and communication;
- Recruitment, training, and retention of translational investigators;
- Enhanced communications among investigators in various disciplines;

- Reassessment of funding strategies to target innovation and accommodate longitudinal studies; and,
- Streamline consent process for clinical research.

IMPROVEMENTS AND COMMITMENTS

• *Improved Efforts*

The Clinton Administration has worked to educate and to improve access to mammography screenings among all women specifically 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 preventive procedures to detect diseases on January 1, 1998. The expanded benefits include coverage to help pay for annual mammograms for all beneficiaries age 40 and over. Under the expanded benefits, Medicare waives the Part B deductible for screening mammograms. Additionally, a one-time baseline mammogram for women 35-39; and expanded pap smear to include both a pelvic exam and a breast exam every three years for most women are now available to Medicare beneficiaries.

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 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. *also Horizon campaign right? and worked in partnership w/*

Cancer Information Service (CIS). In its 26th year, the National Cancer Institute's Cancer Information Survey 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. *public/private community*

Specifically, trained staff provide the latest scientific information in understandable language, and will provide 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).

last Friday
Mammography Quality Standards Act (MQSA). On October (??) 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 immediately.

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 are available by calling the NCI's Cancer Information Service at 1-800-4-CANCER.

is fighting
Ensuring Rights for Breast Cancer Patients. *By asking Congress to pass a strong* With the Patients' Bill of Rights, the Clinton Administration has ~~proposed~~ to protect the rights of all health care consumers and their families by assuring the health care system is fair and responsive to ~~consumers'~~ *their* needs. ~~Among the~~ *include* patient protections proposed by the President's Advisory Commission last year, there are special concerns 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 the managed care plan. President Clinton continues to urge Congress to pass a comprehensive Patients' Bill of Rights and has already ~~applied~~ *taken steps* these patients' protections to ~~all~~ federal health care programs and plans.

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, set premiums, or to distribute confidential 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 reasons women do not get genetic testing for breast cancer is because they fear the information will be used to discriminate against them.

And ~~Medicare~~ cover of clinical trials for Medicare beneficiaries

→ ~~but too few~~ & enrolled in clinical

use have also supported legislation to prevent employers from using genetic info. to discriminate

Improvements in Reaching Special Populations

Mammography Awareness 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 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 screening tests to more than 1.7 million medically underserved women since its inception. The NBCCEDP is able to screen 12-15 percent of the eligible population for these cancers.

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 and mammography services and counseling on risks for breast cancer.

Reaching Out to Older Americans. In the context of an expanding older-aged segment of the U.S. population, the National Institute on Aging (NIA)'s, Geriatrics Program, has supported a variety of breast cancer related activities. The burden of malignant breast tumors for the 65+ age group is illustrated by a cancer mortality rate of 58.2 percent in the latest five-year period (1990-94). In FY 1997, the National Institute on Aging awarded over \$4.6 million in support of breast cancer research.

→ what does this \$ do - we should make this sound more imp

CHALLENGES AND NEW FRONTIERS

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

- ***Increasing Quality of Life***

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. Today, more than 8 million Americans are cancer survivors, about 2 million American women are breast cancer survivors.

On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. This 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. On September 26, 1998, President Clinton announced that \$15 million will be committed over the next five years to cancer survivorship grants. Overseen by this office, these grants will support top-of-the-line research on issues faced by long-term cancer survivors.

- ***Progress on Educating Women and Decreasing Racial Disparities***

Early detection remains our most powerful weapon in the war against breast cancer; overall, ninety-three percent of breast cancer cases are successfully treated when detected early. While more women are getting mammograms, a third of women age 50-64, and an even higher percentage of women over 65, still report that they have not had a mammogram during the past two years.

Our dual challenge is to ensure that all women understand the importance of early detection and prevention, and that they have access to the services and information they need. This is especially important for minority women. While the breast cancer death rate declined 6.6 percent between 1991 and 1995 for white women, it only declined 1.6 percent for minority women. We must continue to explore innovative ways to provide minority and other underserved populations with access to mammography screenings.

- ***Fighting Genetic Discrimination***

In a study released in October 1997, 4 out of 10 Americans said they worry that they will lose their jobs if their employers find out they have cancer. But Americans also worry about what may happen if someone finds out they are at risk for cancer. Women who have the gene for breast cancer may not get tested or seek treatment because they fear losing their health insurance or other discrimination.

Our challenge is to continue to work for legislation that will protect the privacy of genetic, and all medical, information, so ensure that our health care records will always be used to heal us and not reveal us.

include describing the administrative initiative which targets as cancer the one of health care.

- *Scientific Advancement: Research into Causes and Treatments*

As we continue to harness the power of science in our race for a cure, we are faced with three challenges:

First, we can only defeat breast cancer if researchers and scientists continue to work together, across agency lines, departmental walls, and the private-public divide.

Second, we must ensure adequate and sustained support for research; only research can unlock tomorrow's medical discoveries and treatments.

Third, we must renew our scientific efforts to discover the cause of racial disparities in breast cancer rates between white women and women of color and to close the gaps. This will help ensure that all women, regardless of race or ethnicity, benefit from our progress against breast cancer.

- *Educate the Next Generation of Women*

Learning about breast cancer can never start too early. We cannot wait until a young woman enters adulthood, because a woman's behavior when she is young may increase her risk of breast cancer later in life. For example, recent studies have indicated that smoking and excessive alcohol consumption many increase a woman's chance of getting breast cancer, especially if she begins these risky behaviors as an adolescent.

Our challenge is to 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.

NEW FRONTIERS

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.

This day of dialogue will enable us to face head-on the challenges that lie before us and move forward towards eventual eradication of a disease which adversely affects countless women and the families that love them.

GAO

Testimony

Before the Subcommittee on Health and the Environment,
Committee on Commerce, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Friday, May 8, 1998

MAMMOGRAPHY QUALITY STANDARDS ACT

X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown

Statement of Marsha Lillie-Blanton, Associate Director
Health Services Quality and Public Health Issues
Health, Education, and Human Services Division



Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the findings of our work over the last several years examining the impact of the Mammography Quality Standards Act (MQSA). Quality mammography services are a key tool in the early detection of breast cancer, significantly increasing the possibility of survival for the estimated 180,000 women who are diagnosed with this devastating disease each year. MQSA was enacted in 1992 in response to the growing incidence of breast cancer and its associated mortality rates. MQSA established minimum national quality standards for the nation's approximately 10,000 mammography facilities, as well as an accreditation and inspection program to help ensure that these standards are met.

The act directed us to study the impact of MQSA's standards on (1) the quality of mammography services, (2) early detection of breast cancer, and (3) women's access to mammography services. Today, I will focus on our findings on these issues, which are drawn from our final report issued last October.¹

In summary, we found that the overall impact of MQSA on mammography services has been positive, in that it has increased mammography facilities' adherence to accepted quality assurance standards and improved the quality of X-ray images. The impact on early detection of breast cancer is less clear. Improving the quality of mammography images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. However, neither data nor research methodologies are now in place to clearly establish these links. Progress is being made to remedy these problems so that improvements in cancer outcomes can be measured. Regarding concerns that the additional burden of MQSA quality assurance standards could result in facilities deciding to close rather than to upgrade, we found no indication that MQSA has caused access problems.

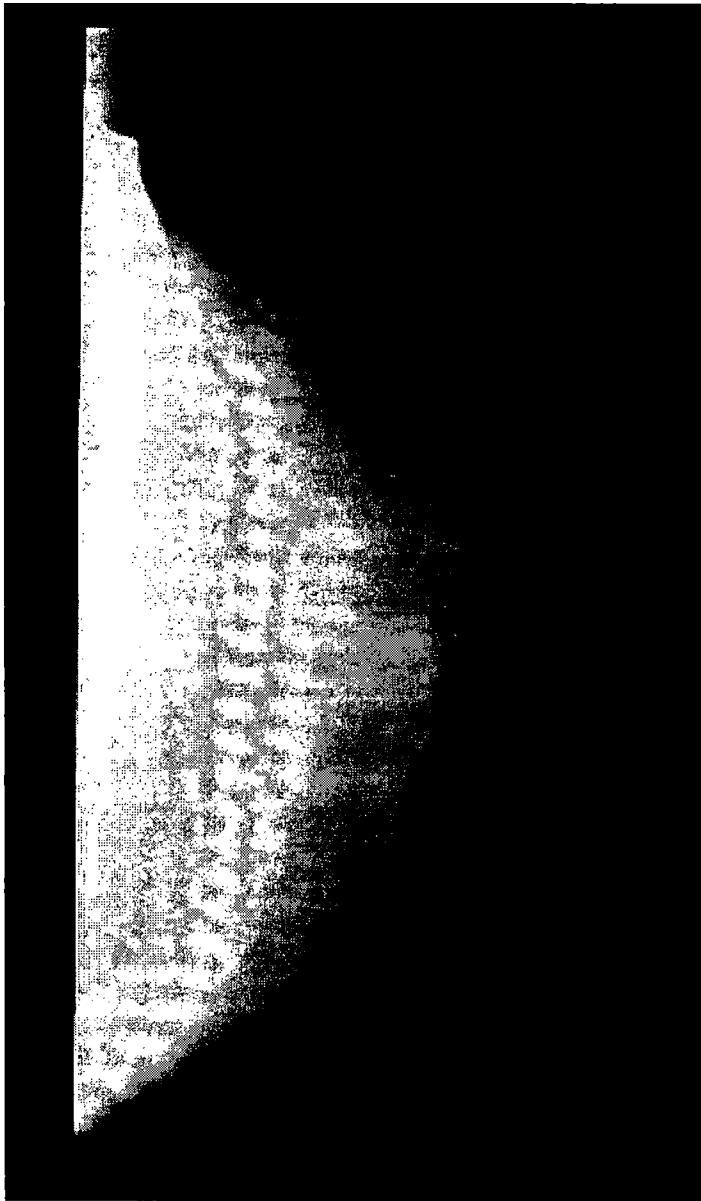
Background

According to the Centers for Disease Control and Prevention, in 1995, almost 60 percent of women over the age of 50 reported having received a mammogram in the past year. The value of mammography in reducing mortality is directly tied to its ability to detect cancer at its earliest stages. Mammography is capable of detecting tumors much smaller than those detected by other means. However, it is one of the most technically

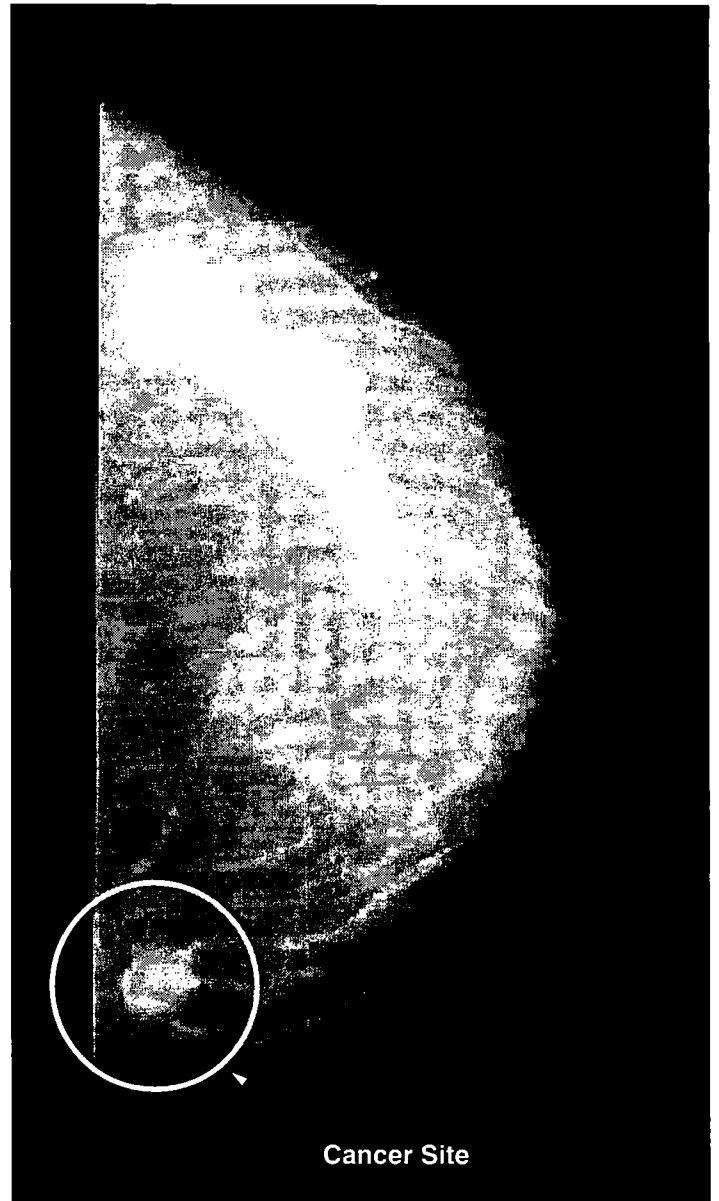
¹Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes (GAO/HEHS-98-11, Oct. 21, 1997).

challenging radiological procedures, and ensuring the quality of the image and its interpretation is important in detecting potential tumors. Figure 1 illustrates this point. It shows two mammograms of the same patient who had a cancerous breast tumor. As you can see, the picture on the left is not clear enough to permit detection of the cancer site that is visible in the picture on the right.

Figure 1: Low- and High-Quality Mammography Images of the Same Patient



Tumor Not Visible



Tumor Visible

A mammogram that is of poor quality or incorrectly interpreted can have considerable diagnostic consequences. If the mammogram is incorrectly seen as indicating cancer (that is, a positive test result), a woman may need to endure unnecessary and costly follow-up procedures. A mammogram that is interpreted as normal when an abnormality is actually present could result in the missed diagnosis of early lesions and delayed treatment, which could cost a woman's life.

MQSA contained a number of provisions designed to ensure the quality of the image and its interpretation. Among other things, MQSA provided that

- the Food and Drug Administration (FDA) establish quality standards for mammography equipment, personnel, and practices;
- all mammography facilities, regardless of location or setting, be accredited by an FDA-approved accrediting body once every 3 years and obtain a certificate from FDA in order to provide mammography services after October 1, 1994; and
- all mammography facilities have an annual evaluation by a qualified medical physicist and an annual inspection by FDA-approved inspectors that includes a test of image quality.

MQSA Has Had a Positive Effect on the Quality of Mammography Services

MQSA's quality standards and the related accreditation process have had a substantial effect on improving the quality of services. FDA substantially based its standards on an accreditation program developed by the American College of Radiology (ACR), a private, nonprofit professional association of radiologists. When MQSA initially took effect, many mammography units did not meet the standards. For example, between October 1, 1994, and August 1, 1995, about 2,600 (35 percent) of the mammography units that sought ACR accreditation (the main accrediting body used by FDA) initially failed to meet accreditation requirements. While almost all of these units were eventually granted full accreditation, they first had to demonstrate that they had improved their quality assurance activities. The accreditation process continues to result in more facilities meeting quality assurance standards. For example, the percentage of facilities that obtained ACR accreditation on the first attempt increased from 66 percent in 1995 to 82 percent in 1997.

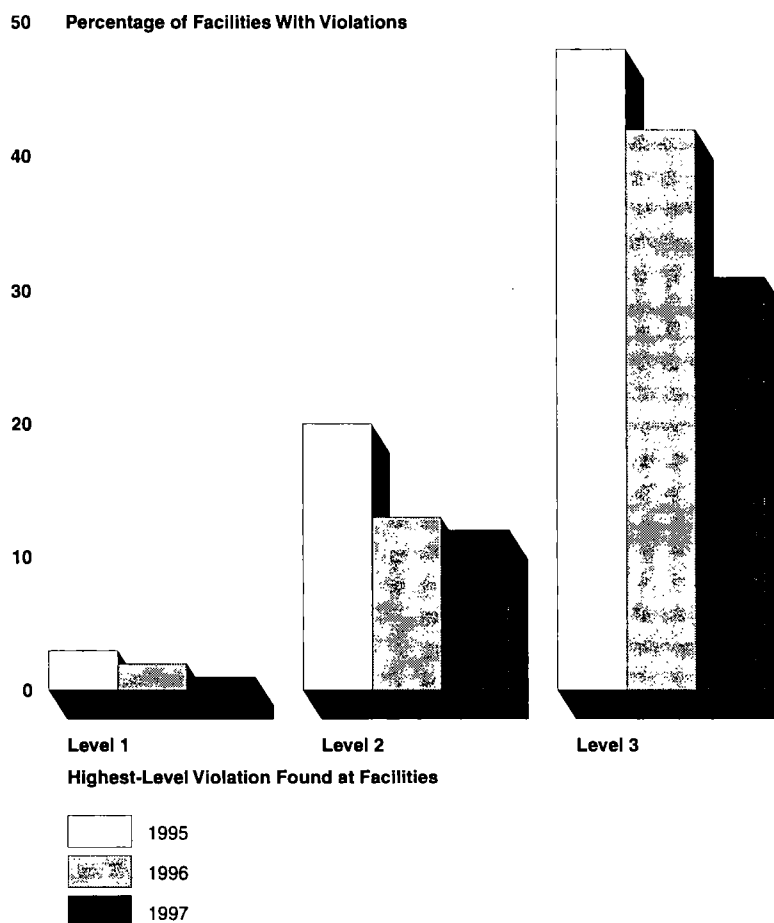
MQSA's inspection requirement gives FDA another means to ensure that facilities comply with standards on a day-to-day operating level. While accreditation is generally based on a review of written application materials, annual inspections are conducted on site, which allows

inspectors to verify information provided during the accreditation process. In January 1997 we reported on some initial problems with FDA's inspection program, such as inconsistent approaches in conducting inspections and reporting results, as well as weaknesses in follow-up systems to ensure that facilities were correcting deficiencies in a timely manner.² FDA has taken the actions that we recommended in our report to remedy these operational problems.

As FDA entered its third year of annual inspections, inspection results continued to show improvement in facility compliance with MQSA quality standards. As figure 2 shows, the percentage of facilities found to have violations dropped in every violation category during the first 3 years of the inspection program.

²FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance Is Growing (GAO/HEHS-97-25, Jan. 27, 1997).

**Figure 2: Comparison of
Mammography Facilities' Inspection
Results, Fiscal Years 1995-97**



Level 1 violations are those that can have the most detrimental effect on the quality of mammography services—for example, a facility's having personnel who do not meet FDA's minimum qualification standards. Level 2 violations are considered less significant—for example, a facility's not having an evaluation of equipment by a medical physicist during the past 14 months. FDA considers both level 1 and level 2 violations to be significant violations for which it requires the facility to submit written plans for corrective actions. From fiscal year 1995 to fiscal year 1997, the proportion of inspected facilities whose highest-level violation was a level

1 dropped from 3 percent to 1 percent, and the proportion whose highest-level violation was a level 2 dropped from 20 percent to 12 percent.

Level 3 violations are more minor in nature—for example, a facility's not having the required documentation of a quality control test—and do not require a written response. Most facilities with violations had only level 3 violations; these numbers also dropped during the 3-year period. Consistent with the decrease in the number of violations, the proportion of facilities with no violations at all nearly doubled, from about 30 percent in 1995 to about 55 percent in 1997.

While these inspection results relate to the quality of mammography services in general, one particular aspect of inspections can be tied more directly to the quality of the image itself. The quality of the image is tested through a “phantom image test” involving an X ray of a plastic block that contains 16 test objects to determine how many of the objects are visible on the resulting image produced by the facility's mammography equipment.³ Because FDA was already conducting some phantom image testing before MQSA, it is possible to make general comparisons of image quality before and after the law took effect. In 1992, before the law was implemented, 11 percent of the facilities failed the test. Since 1995, the failure rate has been about 2 percent.

Data and Methodology Problems Prevent Measuring MQSA's Impact on Saving Lives

Although MQSA can be linked to improved quality of mammography images, it is difficult to say to what extent it has helped to improve mammography interpretation or increase the frequency of early detection of cancer which has been shown to save lives. Researchers face several methodological challenges in clearly demonstrating these links.

The first problem is that criteria have not been established to measure how well images are being interpreted by radiologists. Some experts have suggested that some type of peer review or proficiency test would help improve accuracy, but FDA and others have argued that such measures are too difficult and costly to implement and that each facility should instead set up a system to monitor the performance of its interpreting physicians.

The second problem is the overall lack of sufficient clinical data to assess MQSA's contribution to mammography performance and resulting cancer outcomes. For example, while various regional, state, and local cancer

³The plastic block, which represents an average-sized compressed breast, contains a wax insert that holds 16 test objects—6 fibrous structures (fibers), 5 embedded microcalcifications (speck groups), and 5 different-sized tumor-like masses that simulate growths that could be cancerous.

registries collect clinical data on breast cancer cases, including stage and tumor size, the data do not indicate whether the cancer was detected by mammography.

A third and overarching problem is that no clear consensus exists on appropriate performance and outcome measures for mammography. Experts we talked with pointed out the following areas of analytical and definitional complications.

- Researchers do not agree on how to decide when a mammogram is a false negative. For example, under a 12-month follow-up scenario, if a mammogram is interpreted as negative and during the 12 months after the mammogram a cancer is detected, then the negative mammogram is considered a false negative. Some researchers believe the follow-up period should be as little as 7 months, while others believe it should be a year or more. The number of false negatives identified will be affected by the length of the follow-up period that is used.
- Because the ultimate goal of mammography is to reduce breast cancer mortality, some studies have used mortality reduction as a measure of mammography effectiveness. However, because women with breast cancer generally survive longer than 5 years, measuring changes in mortality reduction requires a long follow-up time. Because MQSA has been in effect for only a few years, not enough time has elapsed to permit use of mortality reduction as a measure for assessing MQSA's effect on cancer outcomes.
- As an alternative to mortality reduction rates, some researchers have used the early-stage cancer detection rate as an intermediate measure of the effectiveness of mammography.⁴ But using this rate to measure the effectiveness of mammography, also poses methodological difficulties. The most controversial problem concerns whether or not cases of carcinoma in situ (CIS) should be included when measuring mammography effectiveness. While CIS is considered the earliest stage of breast cancer, some experts view CIS as a very slow-growing, noninvasive tumor. They contend that including CIS cases as early-stage cancer overstates the benefit of mammography in reducing mortality. Others argue that some CIS tumors can grow quickly and develop into serious, even fatal, disease and that, therefore, CIS cases should be considered early-stage cancer.

While these methodological problems are formidable, they do not appear to be insurmountable, and, in fact, progress is being made toward

⁴The most widely used approach to categorizing cancers involves the use of staging classifications, with the size of the tumor being one of the most important factors in determining the stage of the cancer.

resolution. As authorized by MQSA, the National Cancer Institute in 1994 established the Breast Cancer Surveillance Consortium, which consists of nine federally funded research projects at sites in most of the major geographical regions of the United States. These projects collect data from affiliated area mammography practices and link mammography data to cancer registry data. The Consortium's goal is to ensure that the data collected can be analyzed to address issues relating to mammography performance and cancer outcomes. The Consortium has spent considerable time developing a consensus on which data elements to collect in order to obtain consistent and reliable data, and it is also working to develop a consensus of common definitions for measurement. By the year 2000, the Consortium expects to have sufficient data to analyze mammography performance and cancer outcomes. Consortium efforts have the potential to greatly strengthen the quality of information about the impact of mammography on improving cancer outcomes. However, they are unlikely to provide substantial information about MQSA's specific effect because data are not available for a pre- and post-MQSA comparison.

MQSA Has Not Limited Access

When MQSA was passed, the Congress was concerned that access to mammography services might be limited because many providers might choose to drop mammography services rather than upgrade facility operations to comply with the standards. Our analysis of data collected by FDA shows that of the approximately 10,000 facilities offering mammography before MQSA, about 4 percent, or 404 facilities, closed during the 12 months preceding MQSA's October 1994 implementation. Data for December 1994 to March 1997 showed a net loss of 163 mammography facilities.

We found no evidence, however, that these closures adversely affected access to mammography services. For example, almost all of the closed facilities were located within 25 miles of another certified mammography facility. Further, state health officials from those states with the greatest numbers of closures generally told us that many of the closed facilities were either low-volume providers that did not generate enough revenue to cover the costs of meeting MQSA requirements or poor-quality providers that could not meet accreditation requirements. Officials in several states said that a sizable number of the facilities identified as closed—more than 40 percent—continued to provide services in some form. For example, some facilities continued to provide services by merging with another facility or consolidating their equipment from satellite clinics. Others

contracted with mobile service providers to continue serving their patients.

Conclusions

As the Congress considers reauthorization of MQSA, two points are clear. First, overall, MQSA has had a positive impact on the quality of mammography services and no adverse effect on women's ability to obtain access to mammography. We believe it is reasonable to attribute a large part of the quality improvement to MQSA processes that enforced accreditation standards that were not previously met by many facilities and to FDA's annual inspection process, which provides a valuable, systematic means of helping ensure that these higher standards are maintained.

Second, quantifying MQSA's effect on the accuracy of mammogram interpretation and on the improvement of cancer outcomes is much more problematic. Although data collection efforts now under way will probably make it easier to monitor the quality of image interpretation and the effects of mammography on cancer outcomes in the future, the absence of pre-MQSA data means that analysts may not be able to fully measure how the act itself has affected these two areas.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of the Subcommittee may have.

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Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown (Testimony, 05/08/98, GAO/T-HEHS-98-164).

Pursuant to a congressional request, GAO discussed the findings of its work over the last several years examining the impact of the Mammography Quality Standards Act (MQSA), focusing on: (1) the quality of mammography services; (2) early detection of breast cancer; and (3) women's access to mammography services.

GAO noted that: (1) it found that the overall impact of MQSA on mammography services has been positive, in that it has increased mammography facilities' adherence to accepted quality assurance standards and improved the quality of X-ray images; (2) the impact on early detection of breast cancer is less clear; (3) improving the quality of mammography images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer; (4) however, neither data nor research methodologies are now in place to clearly establish these links; (5) progress is being made to remedy these problems so that improvements in cancer outcomes can be measured; and (6) regarding concerns that the additional burden of MQSA quality assurance standards could result in facilities deciding to close rather than to upgrade, GAO found no indication that MQSA has caused access problems.

----- Indexing Terms -----

REPORTNUM: T-HEHS-98-164
TITLE: Mammography Quality Standards Act: X-ray Quality Improved,
Access Unaffected, but Impact on Health Outcomes
Unknown
DATE: 05/08/98
SUBJECT: Breast cancer
Disease detection or diagnosis
Women
Medical equipment
Health care facilities
Inspection
Quality control

Abstracts of GAO Reports and Testimony, FY98

T-HEHS-98-164, May 8, 1998 (10 pages). Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown, by Marsha Lillie-Blanton, Associate Director, Health Services Quality and Public Health Issues, before the Health and Environment Subcommittee, House Committee on Commerce. [\[Text\]](#) [\[PDF\]](#)

The overall impact of the Mammography Quality Standards Act on mammography services has been positive, increasing the adherence of mammography facilities to accepted quality assurance standards and improving the quality of X-ray images. The impact on early detection of breast cancer is less clear. Improving the quality of mammography images should lead to more accurate interpretation by doctors and, therefore, to more early detection of breast cancer. However, neither data nor research methodologies are now in place to clearly establish these links. Progress is being made to address these problems so that improvements in cancer outcomes can be measured. Regarding concerns that the additional burden of the act's quality assurance standards could lead facilities to close rather than to upgrade, GAO found no indication that the act has caused access problems.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

October 6, 1998

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 4382 - Mammography Quality Standards Reauthorization Act of 1998
Sponsors - Rep. Bliley (R) VA and 23 others

Last Day for Action

October 13, 1998 - Tuesday

Purpose

Reauthorizes appropriations for and amends programs for the inspection and certification of mammography facilities.

Agency Recommendations

Office of Management and Budget	Approval
Department of Health and Human Services (HHS)	Approval
Department of Veterans Affairs	Approval
Office of Personnel Management	No objection (Informally)
Department of Defense	No objection (Informally)
Department of Justice	No objection (Informally)

Discussion

The Mammography Quality Standards Act of 1992 (MQSA) requires all mammography facilities to be certified by the Federal Government. The MQSA established national quality standards for mammography, including requirements that facilities (1) employ only qualified physicians to interpret mammograms, (2) have a quality assurance program, and (3) be accredited by an approved accreditation body and inspected annually by the Food and Drug Administration (FDA).

H.R. 4382 would reauthorize appropriations for the MQSA through FY 2002 and amend the Act's programs for the inspection and certification of mammography facilities. In particular, H.R. 4382 would reauthorize appropriations of such sums as may be necessary for: (1) mammography facility certification activities that are not supported by user fees (e.g., administration of mammography facilities, consumer education, and mammography standards); and (2) breast cancer screening surveillance research grants to determine the cost and effectiveness of screening programs in reducing breast cancer mortality.

In addition, H.R. 4382 would expand current law to:

- Require medical centers to notify women directly and in laymen's terms about the results of their mammograms. (Under current law, doctors and self-referred women must be notified of the results. Women whose doctors request that they undergo breast cancer screening do not have to be notified.)
- Establish a demonstration program under which FDA would be allowed to waive the annual MQSA inspection for facilities with exceptionally high standards.
- Authorize the Secretary of HHS to require facilities that fall significantly below MQSA standards to warn potential patients about their record of poor service. H.R. 4382 would subject facilities failing to notify a patient of their poor service record as required by the Secretary of HHS to a civil money penalty of up to \$10,000.

Pay-As-You-Go Scoring

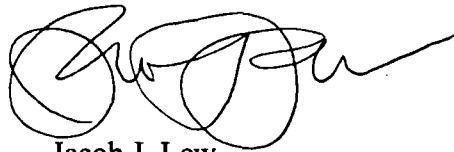
H.R. 4382 could increase receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. This Office estimates that the pay-as-you-go effect of H.R. 4382 would be less than \$500,000 annually.

Conclusion and Recommendations

HHS strongly recommends approval of H.R. 4382. In its enrolled bill views letter, the Department states that H.R. 4382 "would continue to ensure that mammography facilities are accredited and certified, and inspected annually."

The Department of Veterans Affairs (VA), which has medical facilities that must adhere to the MQSA guidelines, also recommends approval of H.R. 4382. In its views letter, VA notes that the bill's provisions would "further the Administration's efforts to provide patients with clear information regarding their test results, access to their medical records, and information concerning the caliber and quality of the medical facilities providing them services."

We join HHS and VA in recommending approval of H.R. 4382, which passed the Senate by voice vote and the House by a vote of 400-1.

A handwritten signature in black ink, appearing to read "Jacob J. Lew", with a stylized, cursive script.

Jacob J. Lew
Director

Enclosures

Date: 10/19

FAX



Health Division



Office of Management and Budget
Executive Office of the President
Washington, D.C. 20503

To: Sarah B.

Fax:

Phone:

From: Bob Donnelly

Number of Pages (not including cover): 6

Subject: Mastectomy provision

SARAH

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Please call if there are any problems with this transmission:

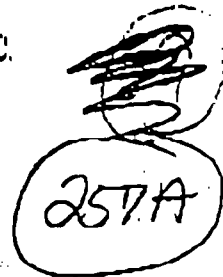
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1 **TITLE ~~IX~~—WOMEN'S HEALTH**
2 **AND CANCER RIGHTS**

3 **SEC. 9 01. SHORT TITLE.**

4 This title may be cited as the "Women's Health and
5 Cancer Rights Act of 1998".

6 **SEC. 9 02. AMENDMENTS TO THE EMPLOYEE RETIRE-**
7 **MENT INCOME SECURITY ACT OF 1974.**

8 (a) IN GENERAL.—Subpart B of part 7 of subtitle
9 B of title I of the Employee Retirement Income Security
10 Act of 1974 (29 U.S.C. 1185 et seq.) is amended by add-
11 ing at the end the following new section:

12 **"SEC. 713. REQUIRED COVERAGE FOR RECONSTRUCTIVE**
13 **SURGERY FOLLOWING MASTECTOMIES.**

14 "(a) RECONSTRUCTIVE SURGERY.—A group health
15 plan, and a health insurance issuer providing health insur-
16 ance coverage in connection with a group health plan, that
17 provides medical and surgical benefits with respect to a
18 mastectomy shall ensure that, in a case in which a mastec-
19 tomy patient elects breast reconstruction, coverage is pro-
20 vided for—

21 "(1) all stages of reconstruction of the breast
22 on which the mastectomy has been performed;

23 "(2) surgery and reconstruction of the other
24 breast to produce a symmetrical appearance; and

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1 “(3) the costs of prostheses and complications
2 of mastectomy including lymphedemas;
3 in the manner determined by the attending physician and
4 the patient to be medically appropriate. Such coverage
5 may be subject to annual deductibles and coinsurance pro-
6 visions as may be deemed appropriate and as are consist-
7 ent with those established for other benefits under the
8 plan or coverage. Written notice of the availability of such
9 coverage shall be delivered to the participant upon enroll-
10 ment and annually thereafter.

11 “(b) NOTICE.—A group health plan, and a health in-
12 surance issuer providing health insurance coverage in con-
13 nection with a group health plan shall provide notice to
14 each participant and beneficiary under such plan regard-
15 ing the coverage required by this section in accordance
16 with regulations promulgated by the Secretary. Such no-
17 tice shall be in writing and prominently positioned in any
18 literature or correspondence made available or distributed
19 by the plan or issuer and shall be transmitted—

20 “(1) in the next mailing made by the plan or
21 issuer to the participant or beneficiary;

22 “(2) as part of any yearly informational packet
23 sent to the participant or beneficiary; or

24 “(3) not later than January 1, 1999;

25 whichever is earlier.

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1 “(c) PROHIBITIONS.—A group health plan, and a
2 health insurance issuer offering group health insurance
3 coverage in connection with a group health plan, may
4 not—

5 “(1) deny to a patient eligibility, or continued
6 eligibility, to enroll or to renew coverage under the
7 terms of the plan, solely for the purpose of avoiding
8 the requirements of this section; and

9 “(2) penalize or otherwise reduce or limit the
10 reimbursement of an attending provider, or provide
11 incentives (monetary or otherwise) to an attending
12 provider, to induce such provider to provide care to
13 an individual participant or beneficiary in a manner
14 inconsistent with this section.

15 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed to prevent a group health plan or
17 a health insurance issuer offering group health insurance
18 coverage from negotiating the level and type of reimburse-
19 ment with a provider for care provided in accordance with
20 this section.

21 “(e) PREEMPTION, RELATION TO STATE LAWS.—

22 “(1) IN GENERAL.—Nothing in this section
23 shall be construed to preempt any State law in effect
24 on the date of enactment of this section with respect
25 to health insurance coverage that requires coverage

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1 of at least the coverage of reconstructive breast sur-
2 gery otherwise required under this section.

3 "(2) ERISA.—Nothing in this section shall be
4 construed to affect or modify the provisions of sec-
5 tion 514 with respect to group health plans."

6 (b) CLERICAL AMENDMENT.—The table of contents
7 in section 1 of the Employee Retirement Income Security
8 Act of 1974 (29 U.S.C. 1001 note) is amended by insert-
9 ing after the item relating to section 712 the following
10 new item:

"Sec. 713. Required coverage reconstructive surgery following mastectomies."

11 (c) EFFECTIVE DATES.—

12 (1) IN GENERAL.—The amendments made by
13 this section shall apply with respect to plan years be-
14 ginning on or after the date of enactment of this
15 Act.

16 (2) SPECIAL RULE FOR COLLECTIVE BARGAIN-
17 ING AGREEMENTS.—In the case of a group health
18 plan maintained pursuant to 1 or more collective
19 bargaining agreements between employee representa-
20 tives and 1 or more employers, any plan amendment
21 made pursuant to a collective bargaining agreement
22 relating to the plan which amends the plan solely to
23 conform to any requirement added by this section
24 shall not be treated as a termination of such collec-
25 tive bargaining agreement.

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1 SEC. 9 03. AMENDMENTS TO THE PUBLIC HEALTH SERV.

2 ICE ACT.

3 (a) GROUP MARKET.—Subpart 2 of part A of title
4 XXVII of the Public Health Service Act (42 U.S.C.
5 300gg-4 et seq.) is amended by adding at the end the fol-
6 lowing new section:

7 "SEC. 2706. REQUIRED COVERAGE FOR RECONSTRUCTIVE
8 SURGERY FOLLOWING MASTECTOMIES.

9 "The provisions of section 713 of the Employee Re-
10 tirement Income Security Act of 1974 shall apply to group
11 health plans, and health insurance issuers providing health
12 insurance coverage in connection with group health plans,
13 as if included in this subpart."

14 (b) INDIVIDUAL MARKET.—Subpart 3 of part B of
15 title XXVII of the Public Health Service Act (42 U.S.C.
16 300gg-51 et seq.) is amended by adding at the end the
17 following new section:

18 "SEC. 2752. REQUIRED COVERAGE FOR RECONSTRUCTIVE
19 SURGERY FOLLOWING MASTECTOMIES.

20 "The provisions of section 2706 shall apply to health
21 insurance coverage offered by a health insurance issuer
22 in the individual market in the same manner as they apply
23 to health insurance coverage offered by a health insurance
24 issuer in connection with a group health plan in the small
25 or large group market."

26 (c) EFFECTIVE DATES.—

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~~8~~
(1) GROUP PLANS.—

(A) IN GENERAL.—The amendment made by subsection (a) shall apply to group health plans for plan years beginning on or after the date of enactment of this Act.

(B) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by the amendment made by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(2) INDIVIDUAL PLANS.—The amendment made by subsection (b) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the date of enactment of this Act.

CLINTON ADMINISTRATION ANNOUNCES HISTORIC INCREASE IN FUNDING FOR CANCER RESEARCH, THE LARGEST BREAST CANCER CLINICAL TRIAL EVER, AND OTHER NEW STEPS TO FIGHT BREAST CANCER

October 21, 1998

Today, in honor of breast cancer awareness month, First Lady Hillary Rodham Clinton announced: the largest increase ever at the National Cancer Institute (NCI); the largest preventive clinical trial in history for breast cancer drugs; and a new expanded mammography outreach campaign. Marking the fifth anniversary of the Clinton Administration's groundbreaking National Action Plan on Breast Cancer, the First Lady also unveiled a landmark five-year report from the Federal Coordinating Committee on Breast Cancer charting the extraordinary progress in breast cancer. The First Lady:

Announced Record Funding Increases for the National Cancer Institute. As part of the recent budget agreement, Congress has passed a significant down-payment on the President's multi-year proposed funding for the National Institutes of Health. Today, the First Lady announced that the National Cancer Institute will receive a total budget of \$XX will enable NCI to undertake critical new research activities, including: exploring new efforts to pinpoint who is a risk for cancer, developing new interventions to prevent, detect, diagnose and treat cancer, and to enhance survivorship from cancer; and bringing research discoveries to consumers and to medical practice. (*Kind of boring -- Anything we can say about breast cancer here*). This builds on historic increases in breast cancer at the NCI [\$x to \$x].

Announced Largest Breast Cancer Clinical [drug?] Trial Ever That May Have Great New Potential For Women With Breast Cancer. The First Lady also announced a new clinical trial to study tamoxifen, a breast cancer prevention drug, to raloxifene, which researchers believe will also prevent the disease, but with fewer side effects. The unique STAR trial will consist of 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 ongoing trial at NIH that is examining the relationship between diet and disease.

Launched New Awareness Campaign To Help Ensure Women Get Recommended Mammograms. The First Lady also unveiled a new expanded promotion campaign, including public service announcements, outreach and promotional efforts, and intensified campaigns in six cities, run by HHS to encourage women ages 65 years and older to get a regularly scheduled mammogram screenings. This year's campaign will emphasize the new mammography Medicare benefit that the President proposed and signed into law last year makes regular mammograms more affordable. HHS is also expanding outreach efforts to special populations -- low-income and African American 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 free mammogram screenings and launch public service announcements in key cities targeted to minority communities while the Food and Drug Administration has developed and distributed educational materials to underserved communities around the country.

Unveiled Landmark Report in Honor of Five-Year Anniversary of National Action Plan on Breast Cancer (NAPBC). The First Lady also announced a new report from the Federal Coordinating Committee on Breast Cancer highlighting the accomplishments in breast cancer over the past five years, since the Administration launched the NAPBC. This report underscores critical progress since the Administration has started including:

- A significant investment in research--reaching [\$595 -- from Visco] million in 1998 that has led to historic advances in breast cancer, such as the identification of new breast cancer genes, and new promising new treatments, such as taxol and hereceptin;
- 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; and 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 rates and care among minority women; and
- Innovative interagency and public-private partnerships that have made remarkable strides, such as applying the latest in defense and space technology to better detect cancerous tissues and develop less intrusive surgeries for patients.

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 included 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 this kind of 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 the health plans and employers from discriminating against individuals on the basis of 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.

Note: If Congress passes Jane Henney as expected than we should highlight the first woman and first oncologist of the FDA.



FAX TRANSMITTAL

To: Sarah Bianchi
Fax: 456-5557
From: Joanne Howes and Sara Chenault
Date: October 21, 1998
Re:

Number of pages (including cover sheet):

BHAccount#:

Comments: Per your request, attached is the draft of the revised NBCC Clinton Administration Breast Cancer Report Card. Please feel free to call us with any questions.

*If there is a problem with this transmission,
please call 202-530-2900.*

1818 N Street, NW • Suite 450 • Washington, D.C. 20036 202-530-2900 fax: 202-530-2901
250 West 57th Street Suite 2217 New York, NY 10107 212-245-8735 fax: 212-245-8738

The Clinton Administration Breast Cancer Report Card

NBCC Issues	Excellent	Good	Fair	Poor
Research				
Increase Federal Funds for Breast Cancer Research	✓			
DoD Breast Cancer Research Program	✓			
Breast Cancer Research at the NIH and NCI	✓			
Access				
Health Care Reform		✓*		
Mammography Awareness, Insurance Coverage and Quality	✓			
FDA Approval of Cancer Drugs		✓		
Genetic Discrimination	✓			
Clinical Trial Coverage	✓			
Influence				
Incorporation of Consumer Advocates	✓			
Public/Private Partnerships	✓			

*Although the Clinton Administration has made many positive steps toward health care reform, their lack of support for the Breast and Cervical Cancer Treatment Act of 1998 (S. 2017/H.R. 3779), which would ensure breast cancer treatment for low-income women diagnosed with breast cancer through the federal Centers for Disease Control Breast and Cervical Cancer Early Detection Program, is a major disappointment.

Breast Cancer, 480< Government study to seek safe breast-cancer prevention

By LAURA MECKLER=
Associated Press Writer=

WASHINGTON (AP) In the largest breast cancer study ever, government researchers are embarking next year on a multiyear project designed to find a safe drug to prevent the disease.

Tamoxifen, already widely used as a breast cancer treatment, is thought possibly to reduce in certain women the risk of getting breast cancer. But it comes with dangerous side effects, including an increased risk of uterine cancer.

The new National Cancer Institute study will compare tamoxifen with the osteoporosis drug raloxifen to see if raloxifen will do as good a job of preventing breast cancer, with fewer side effects.

President Clinton announced the study Wednesday in a White House ceremony.

"We all owe it to ourselves and our future to make a sustained commitment to research that, once and for all, can win this war," Clinton said.

"I want you to know that I believe that we are within reach of genuine cures and genuine prevention strategies of stunning impact."

The study will include more than 20,000 postmenopausal women who have an increased risk of breast cancer. Each will get either tamoxifen or raloxifen. Researchers from 193 institutions are participating, including sites in almost every state, and through partnerships the trial will be conducted at about 400 individual sites.

"It will be the most significant clinical trial to date," Donna Shalala, the secretary of Health and Human Services, said.

Shalala also touted the administration's work to fight breast cancer, including increased research funding and prevention efforts. She credited collaboration between scientists, policy-makers and advocates for the progress.

The budget Congress approved before adjourning Wednesday allows an 11 percent increase in money for breast cancer research, Shalala said, part of increased funding for all of the National Institutes of Health. And she unveiled new efforts to encourage older, low-income black and Hispanic women to get mammogram screenings.

Breast cancer will strike an estimated 178,000 U.S. women this year, killing about 43,500.

The Food and Drug Administration has not yet approved the prevention study, which will begin next year. The first results are not expected until 2006 or 2007.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

Phone: (202)690-7850

Fax: (202)690-5673

To: Sarah B.Fax: 456-5557 Phone: _____Date: _____ Total number of pages sent: 3

Comments:

Here's AP story on breast cancer.

Vicki Rivas-Vazquez

An earlier study of raloxifene found the drug reduces breast cancer risk by about two-thirds. But researchers are not confident in the results, because they came from a study of osteoporosis patients and were not long-term.

A National Cancer Institute study found that tamoxifen cuts the chances of breast cancer by 45 percent in certain women. But it can cause potentially life-threatening side effects, including uterine cancer and blood clots, with women over 50 particularly vulnerable.
APWR-10-21-98 1715EDT

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