

See mammography
folder too.

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E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

16-Oct-1996 08:57am

TO: Jennifer L. Klein
TO: Nicole R. Rabner

FROM: Pauline M. Abernathy
 National Economic Council

SUBJECT: FYI latest HHS breast cancer funding numbers

FYI.

HHS funding for breast cancer in FY97 is \$531 million, up from \$476 million in FY96. The FY97 level is \$16 milion above our request, but we were still requesting a significant increase, so I think we can now say we have "doubled" funding since FY93 (\$271 m).

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

October 18, 1996

Contact: HHS Press Office
(202) 690-6343
Office on Women's Health
(202) 690-7650

BREAST CANCER: NEW EFFORTS UNDERWAY

Overview: Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. There is no proven way to prevent breast cancer, so early detection, through mammography and clinical breast exams, and treatment are essential.

For women age 50-69, having regular mammograms can reduce the chance of death from breast cancer by one third or more. Despite these numbers, nearly half of women age 50 and older have not had a mammogram in the past two years, while only 37 percent of women age 65 and older have a mammogram every two years.

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

At the same time, federal spending on breast cancer has been significantly increased since 1993.

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

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Background: More Women Can Survive Breast Cancer

- 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 1995 alone, approximately 182,000 new cases of breast cancer were diagnosed in women and 46,000 died from the disease. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- Death rates from the disease are highest among older, black, and low-income women. During the last 20 years, death rates from breast cancer for women over 65 increased by 35 percent for black women and 11 percent for white women. Mortality rates vary widely among racial and ethnic groups in the United States. Hispanic, Chinese, Filipino and Japanese women have annual rates at or below 15 per 100,000 women, while black, white and Native Hawaiian women have rates above 25 per 100,000 women.
- With proper screening and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. During the most recent 5-year period of available data (1989 to 1993), the age-adjusted breast cancer mortality rates fell approximately 6 percent among white women and rose about 1 percent among black women. By comparison, from 1980 to 1989, rates increased 3 percent among white women and 16 percent among black women.
- During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

HHS funding for breast cancer research, prevention and treatment has increased from approximately \$273 million in FY 1993 to an estimated \$531 million in FY 1997. As the Centers for Disease

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Control and Prevention (CDC) are working to increase access for all women to mammography screening and follow up services, the resources devoted to breast cancer services have increased from \$42 million in FY 1993, to \$81 million in FY 1997. Cancer research is vital to our understanding of how to prevent, detect and treat breast cancer. The Clinton Administration has invested in breast cancer research at the National Institutes of Health by increasing funding from \$229 million in FY 1993, to \$420 million in FY 1997. HHS also helps provide treatment for breast cancer through the Medicare and Medicaid programs and through the Indian Health Service.

HHS Action To Combat Breast Cancer

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

National Action Plan on Breast Cancer

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

- The Information Action Council Working Group is working to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other information technologies.
- The Etiology Working Group is focusing on efforts to expand the scope and breadth of biomedical, epidemiological and behavioral research on breast cancer. The group has identified four priority areas: chemicals and hormones, viruses, radiation and electromagnetic fields, and lifestyle factors.
- The National Biological Resources Banks Working Group (NAPBC) has focused on the development of a national mechanism and standard for obtaining and storing tissue for multiple areas of breast cancer research. The NAPBC has awarded funds to establish a national biological resources bank and is now conducting a survey of tissue banks throughout the country to identify and determine the accessibility of all available biological resources.

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- *The Working Group to Ensure Consumer Involvement* has defined several specific activities to help ensure consumer involvement at all levels in the development of national research, education, and service delivery programs related to breast cancer.
- *The Clinical Trial Accessibility Working Group* has identified a series of initiatives to address four types of barriers to participation in clinical trials, including barriers associated with the informed consent process, patient and physician misperceptions about clinical trials, lack of information about the availability of trials, and cost.
- *The Working Group on Heredity Susceptibility* is evaluating the ethical, legal and policy issues of individuals carrying breast cancer susceptibility genes.

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

National Breast and Cervical Cancer Early Detection Program

The CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nation-wide. The program, which has been operating in an increasing number of states over the past six years, has provided screening tests to almost one million medically underserved women. In October, 1996, the program went nationwide, with funding for all 50 states.

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Breast Cancer Among the Elderly

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

New Frontiers In Breast Cancer Early Detection

The Department of Health and Human Services has been working with the Department of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer. In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection as well. In October, 1996, HHS awarded \$1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community -- originally used for missile guidance and target recognition -- to improve the early detection of breast cancer.

Centers of Excellence

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

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, the AHCPR in October 1994, developed a Clinical Practice Guideline--Quality Determinants of Mammography--with separate versions for mammography providers, health care professionals, and consumers. The guidelines define the areas of responsibility for each member of the health care team delivering mammograms, including women themselves.

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Mammography Standards

New regulations were put in place in 1992 to ensure that all women have access to high quality mammography services. The roughly 10,000 mammography facilities nationwide accredited by the FDA must meet quality standards for equipment and personnel, and are inspected annually.

These regulations spell out the details for requiring facilities to hire capable technicians, use quality equipment that produces clear images, and employ skilled radiologists to interpret the results. The rules also require that doctors and patients be fully and quickly informed of results so that any follow-up testing or treatment can begin immediately. The names and locations of FDA certified mammography facilities are available by calling the Cancer Information Service at 1-800-4-CANCER.

Environmental Factors and Breast Cancer

HHS' Office on Women's Health has established a Federal Interagency Coordinating Committee on the Environment and Women's Health that focuses on how home, work, atmospheric pollutants, exogenous hormones, drugs, and other environmental factors may contribute to the risk of breast cancer and other disorders.

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Attn: Jennifer Klein

Here's the information about the clinical trials on breast cancer imaging.

Jacci Duncan, 202/401-9545

Clinical Trials

The U.S. Public Health Service's Office on Women's Health, in a unique collaboration with the CIA, has 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.

Over the last two years, the Public Health Service's Office on Women's Health, within the Department of Health and Human Services, has been exploring how our national investments in defense, space and intelligence technologies can be used to improve breast cancer detection techniques. Research results from this initiative indicated there was a strong potential for adapting the high-tech imaging capabilities of the CIA and the Department of Defense -- estimated to be some 10 years ahead of medical imaging, to improve the early detection and diagnosis of breast cancer.

Clinical trials mark a turning point in the progress of transferring imaging technologies from other fields to improve breast cancer detection. The trials mean we can now start applying what we've learned at the research bench to the clinical setting, with the hope of finding breast cancer at an earlier stage when there is the greatest hope for effective treatment and better survival.

Contact:

Susan Blumenthal, M.D., M.P.A., Deputy Assistant Secretary for Women's Health
U.S. Public Health Service's Office on Women's Health

THE U.S. PUBLIC HEALTH SERVICE'S OFFICE ON WOMEN'S HEALTH LAUNCHES "CENTERS OF EXCELLENCE IN WOMEN'S HEALTH"

The U.S. Public Health Service's Office on Women's Health, within the Department of Health and Human Services, has announced the establishment of six National Centers of Excellence in Women's Health to serve as national models for improving the health care of American women.

The National Centers of Excellence in Women's Health, located at academic institutions in different areas of the country, will serve as demonstrations and models which can be evaluated and duplicated throughout the nation. The Centers will integrate health care services, research programs, public education and health care professional training, as well as forge links with health care services in the community.

"The National Centers of Excellence in Women's Health will be innovative models of one-stop shopping for women's health care, and at the same time they will provide an integrated research agenda, and community and professional leadership for women's health," said Susan J. Blumenthal, M.D., M.P.A., Deputy Assistant Secretary for Women's Health and Assistant Surgeon General.

The Centers represent a public-private partnership between HHS and the academic institutions. The U.S. Public Health Service's Office on Women's Health is providing \$1 million to support the centers.

Women served by the National Centers of Excellence in Women's Health will have all of their health care needs met in one place by having access to comprehensive services and resources. In addition, the centers will develop a multidisciplinary research agenda across medical specialties; focus medical education on gender differences in the causes, treatment and prevention of disease; and use new information technologies to bring cutting edge women's health information to the public.

and health care providers. The Centers will also develop leadership strategies to foster recruitment, retention and promotion of women in academic medicine.

"Until six years ago, women's health was seriously neglected in research, health care service delivery, and public and health care professional education," Dr. Blumenthal said. "Since 1990, a new national focus on women's health, reflected in numerous initiatives in the public and private sectors, is brightening the prospects for a healthier future for American women. The purpose of the National Centers of Excellence is to facilitate this progress through increased knowledge, improved treatment and prevention of diseases in women. "The Centers of Excellence will provide the following women's health resources and services:

- An integrated one-stop shopping center for the delivery of clinical health care services to women.
- Emphasis on preventive care.
- Emphasis on psychosocial issues in health.
- A research agenda on women's health issues.
- Strategies to promote women's participation in clinical research trials.
- Coordination and linkage between clinical services in academic centers and surrounding communities.
- Educational programs and materials for the general public and health care professionals on women's health, using new cutting edge information technologies and telemedicine approaches.
- The integration of a women's health curriculum into medical school education.
- A leadership plan to foster the recruitment, retention and promotion of women in academic medical careers.
- Networking within the community to form alliances with business groups, consumer groups, scientific organizations and public policy leaders.

The U.S. Public Health Service's Office on Women's Health is the focal point for women's health within the Department of Health and Human Services, providing national leadership in advancing women's health in public policy, research, service delivery and education. The Office acts as a catalyst for developing new national and regional initiatives to improve women's health in the United States and internationally.

September 24, 1996

MEMORANDUM TO MELANNE VERVEER
JENNIFER KLEIN
NANCY ANN MIN
LYNN HOGAN

FROM: BARBARA WOOLLEY

RE: NATIONAL BREAST CANCER COALITION POLICY PLATFORM

Thought you might be interested in the National Breast Cancer Coalition Breast Cancer Policy Platform.

The National Breast Cancer Coalition believes that the following policies must be implemented in order to continue to make progress against breast cancer and ultimately, to eradicate the disease.

- ONE The United States Congress must appropriate \$2.6 billion for high quality, peer-reviewed breast cancer research, by the year 2000.
- TWO The United States Congress and the President of the United States must continue support for the Department of Defense peer-reviewed breast cancer research program, under the strategies recommended by the Institute of Medicine.
- THREE The United States Congress and the President of the United States must commit to continued, increasing appropriations for biomedical research through the National Institutes of Health and the National Cancer Institute and implement or expand programs to fund quality, peer-reviewed breast cancer research through all appropriate agencies and departments, such as the Environmental Protection Agency and the Veterans Administration.
- FOUR The President of the United States and the United States Congress must expand the federal commitment to eradicating breast cancer through increased outreach and education programs and the regulation and provision of treatment and other services, in all agencies and departments, including the Environmental Protection Agency, the Center for Disease Control, the Health Care Financing Administration, the Department of Education, the Department of Defense and the Veterans Administration.
- FIVE The President of the United States should continue support for a national action plan on breast cancer that is a public/private partnership, under the leadership of the National Breast Cancer Coalition.
- SIX The laws, regulations and policies of the United States must mandate universal access to high quality health care.
- SEVEN All women of appropriate age should have access to high quality, screening mammography at appropriate intervals.
- EIGHT Discrimination in the provision of health insurance or employment based on pre-existing conditions or predisposition to disease must be eliminated.
- NINE Third party payment of all costs, including all medically necessary care, incurred by participation in approved clinical trials and investigational studies must be mandated.
- TEN The laws of the United States and regulations of all federal and state agencies and departments that impact breast cancer, must mandate the inclusion of representative consumers in all decision making.

January, 1996

National Breast Cancer Coalition Breast Cancer Policy Platform Statement of Endorsement

I, _____ do endorse and
(position/candidate for)

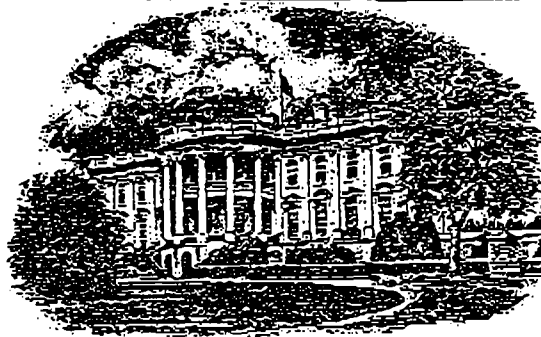
pledge my support for the National Breast Cancer Coalition's Breast Cancer Policy Platform.

Signature _____ Date _____

Representing _____

FAX COVER**Health and Personnel Division**

Executive Office of the President
Office of Management and Budget
OEOP, Room 262
Washington, D.C. 20503

**DATE:** _____**TO:** _____*Jennifer Klein***AGENCY:** _____**FAX NO:** _____*6-2878***FROM:****Nancy-Ann Min****Associate Director for Health and Personnel****Phone Number (202) 395-5178****Fax number (202) 395-9119****Number of pages (including cover)** 2**COMMENTS:**

*call if you have questions or need
additional information*

- Sarah B.

President Clinton's Commitment to Breast Cancer Research

*Since the President took office, National Institutes of Health funding for breast cancer research has increased from \$229 million to \$410 million, a 79% increase over four years.

*Department of Defense breast cancer research funding moved from \$206 million in Fiscal Year 1993 to \$0 in the Fiscal Year 1997 budget.

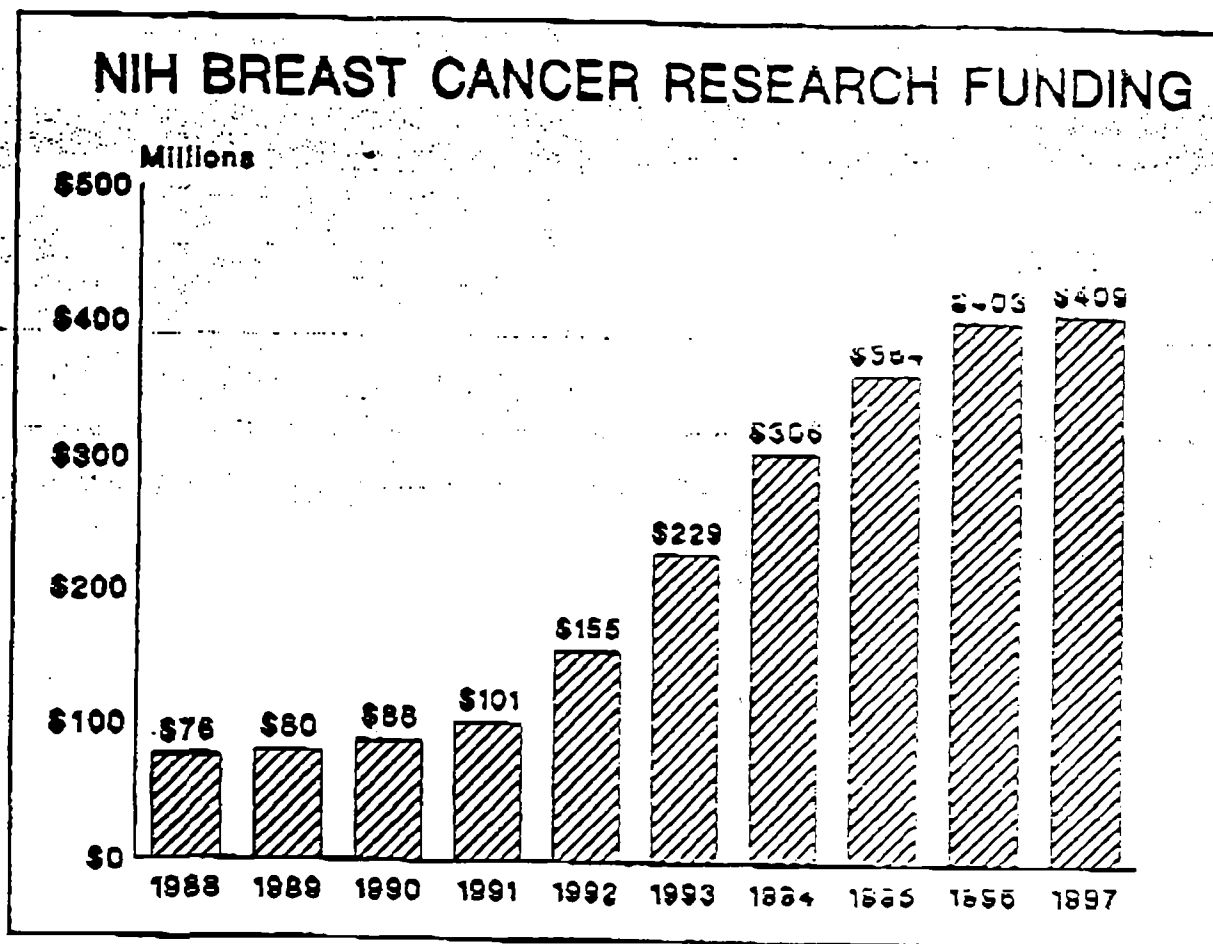
*Total Federal breast cancer research rose from \$436 million in 1993 to \$478 million in 1996, an increase of \$42 million.

*Total Federal breast cancer research moved from \$436 million in FY 1993 to \$410 million in FY 1997, a decline of \$26 million.

Federal Breast Cancer Research Funding

YEAR	National Institutes of Health	Department of Defense	Total Federal Spending
FY 1993	\$229 million	\$207 million	\$436 million
FY 1996	\$403 million	\$ 75 million	\$478 million
FY 1997	\$410 million	\$ 0	\$410 million

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NATIONAL INSTITUTES OF HEALTH

Breast Cancer Spending/Action Plan

QUESTION:

What is included in the 1997 NIH request for breast cancer research? What is the status of the National Action Plan on Breast Cancer (NAPBC)?

ANSWER:

► **BUDGET:** NIH will devote \$409 M to breast cancer research and education in 1997, a \$6.3 M (+1.6%) increase over 1996, and a \$181 M (+79%) increase over 1993. This includes maintaining the \$20 M within the NCI budget to support the Secretary's National Breast Cancer Action Plan. [See note next page on spending changes.]

► **"ACTION PLAN" ACTIVITIES:**

- In the 18 months since the Secretary's Conference to Establish a National Action Plan on Breast Cancer (NAPBC), a public/private partnership has been created to meet the objectives outlined by this Conference.
- Six priority areas were identified and Working Groups for each have been formed to implement the Plan's goals:
 - Hereditary susceptibility.
 - National biological resources banks.
 - Etiology.
 - Clinical trials accessibility.
 - Ensuring consumer involvement.
 - Information action council.
- Efforts to implement the NAPBC have been focused primarily around a combination of grants for innovative breast cancer research and outreach projects, and workshops. Recent major activities include:
 - Awarded \$9.2 M for innovative projects to 95 grantees in September 1995, out of 610 applications reviewed.
 - Convened a workshop on Genetic Information and Health Insurance and produced a list of recommendations for publication in Science magazine.
 - Convened a workshop on Hormones, Hormone Metabolism, and Breast Cancer, which identified potential new areas for research.
 - Awarded a contract to conduct a survey on biological resources accessibility and to establish a national database of tissue sources.
 - Compiled an inventory of breast cancer-related information on the Internet.

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ADDITIONAL INFORMATION:

- ▶ **NOTE: SPENDING CHANGE:** Following its review in 1995 of breast cancer research proposals, NIH is now projecting lower spending levels in breast cancer research. According to NIH, fewer high quality research grant proposals were received than expected, and as a result, 1995 spending totaled \$364 M compared to the planned \$377 M. NIH now projects breast cancer spending in 1996 to be \$403 M, instead of the \$426 M plan of a year ago.
- ▶ **Incidence:** Breast cancer affects one of every eight women in the U.S., and represents 32% of all cancers in women.
- ▶ **Progress:** Much progress is being made in our battle against breast cancer:
 - Three genes linked to hereditary breast cancer have been discovered in the last two years.
 - Breast cancer screening rates are the highest in history;
 - Breast cancer mortality has begun to decline - down 5% since 1989, the largest short-term decline in 40 years - thanks to advances in chemotherapy, hormonal treatments, and access to and use of screening mammography.
 - Clinical trials using tamoxifen have decreased breast cancer recurrence by as much as 50%.
- ▶ **Breast Cancer Awareness Campaign:** The National Cancer Institute and the U. S. Postal Service are joining forces to spread the word about breast cancer. The Postal Service will issue 100 million Breast Cancer Awareness stamps this year as the centerpiece of a nationwide awareness campaign from its post offices across the country. NCI's Cancer Information Service toll-free number (1-800-4-CANCER) will appear on the border of each sheet of stamps as the source for information on breast cancer.
- ▶ **CDC Breast/Cervical Cancer Prevention:** For 1997, CDC expects to spend \$125 M for breast and cervical cancer prevention, the same level as in 1996, and a 75% increase over 1993. Beginning in 1996, the CDC Breast and Cervical Cancer Early Detection Program will be implemented in all 50 States and 9 Indian tribes or tribal organizations.
- ▶ **National Action Plan on Breast Cancer:**
 - In October 1993, President Clinton was presented with a petition signed by 2.6 million people calling for the establishment of a strategy to end the breast cancer epidemic.

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- On December 14-15, 1993, 300 individuals attended the Secretary's Conference to Establish a National Action Plan on Breast Cancer (NAPBC), including many of the country's leading experts in breast cancer research, education and health policy.
- "The Proceedings of the Secretary's Conference to Establish a National Action Plan on Breast Cancer" provided a framework and plan for activities.
- This is not a Federal plan, but a national operational strategy, promoting partnerships among public, private and non-profit sectors to solve problems and coordinate actions related to breast cancer.
- Many of the activities called for in the NAPBC will be carried out directly by or through partnerships with private industry; Federal, State, and community health organizations; consumer groups; researchers; health professionals; the media; advocacy groups; and voluntary organizations.
- Dr. Susan J. Blumenthal, Deputy Assistant Secretary for Women's Health; and Frances Visco, President of the National Breast Cancer Coalition, are NAPBC co-chairs.
- PHS's Office of Women's Health will coordinate the Plan's implementation.

NIH Breast Cancer Spending
(Dollars in millions)

	1995	1996	1997	Change	% Chg
NCI.....	\$308.7	\$336.8	\$341.0	+54.2	+1.3%
NHLBI.....	1.3	1.3	1.4	+0.1	+4.0%
NIDDK.....	17.9	18.6	18.8	+0.2	+1.1%
NIGMS.....	10.9	14.7	14.9	+0.2	+1.2%
NICHD.....	5.4	5.7	5.8	+0.1	+1.8%
NEI.....	0.7	0.7	0.8	+0.1	+1.6%
NIHHS.....	5.0	8.5	9.6	+1.1	+13.5%
NIA.....	1.7	2.6	2.6	+0.0	+1.6%
NIMH.....	1.0	1.3	1.2	-0.1	-2.9%
NIAAA.....	0.8	0.9	0.9	..	..
NINR.....	2.5	2.6	2.7	+0.1	+1.9%
NCRR.....	1.1	1.2	1.2	..	..
NCHGR.....	6.8	8.2	8.5	+0.3	+3.2%
FIC.....	0.1	0.1	0.1	..	..
Total, NIH..	\$363.9*	\$403.2*	\$409.5	+56.3	+1.6%

* Last year's spending plan was \$377.1 M in 1995 and \$426.2 M in 1996.

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NATIONAL ACTION PLAN ON BREAST CANCER

QUESTION: Senator Specter wrote to you on May 24 regarding Senate report language directing that NCI designate \$14.5 million for implementation of the National Action Plan on Breast Cancer. What is the status of this funding?

ANSWER: I am committed to continuing to expand our efforts in breast cancer research and to fully implementing the National Action Plan. Thus far, we have spent \$5.0 million in FY 1996 for continuation funding of research grants and related management costs.

We are currently programming the remaining \$9.5 million to be used for new research grants and further planning and related activities. The Director of the National Cancer Institute has advised me that there are sufficient quality research proposals which address the priorities in the Plan and will result in us spending at least \$14.5 million this year.

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT
SURGEON GENERAL
(RESEARCH AND DEVELOPMENT)
ROOM 3E368, PENTAGON

(703) 695-5615
Fax: (703) 695-8691

FAX TRANSMISSION COVER SHEET

Date: April 12, 1996
To: JENNIFER KLEIN
Fax: 202-456-2878
Re: Breast Cancer Research Funding
Sender: LTC TERRY RAUCH

YOU SHOULD RECEIVE 2 PAGE(S), INCLUDING THIS COVER SHEET. IF
YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL (703) 695-5615.

**BREAST CANCER FUNDING PROFILE
(\$M)**

	<u>REQUEST</u>	<u>APPROPRIATION</u>	<u>CONGRESSIONAL</u>
			<u>ADD</u>
FY 92	0	25.0	25.0
FY 93	0	210.0	210.0
FY 94	0	30.0	30.0
FY 95	0	150.0	150.0

NATIONAL CANCER INSTITUTE

PLANNING, EVALUATION, AND ANALYSIS BRANCH
OFFICE OF PROGRAM OPERATIONS AND PLANNING

DATE: 4-22-96

TO: Jennifer Klein

FAX NO. 202-456-2878

FROM: Anne Middleswarth

Building 31, Room 11A21

National Cancer Institute, Bethesda, MD 20892

FAX NO. 301-402-1225 TELEPHONE NO. 301-496-5515

Cover Sheet + 7 Page(s) Transmitted

ADDITIONAL COMMENTS:

Here's breast cancer information as requested.

April 22, 1996

NOTE TO JENNIFER KLEIN RE NCI BREAST CANCER INFORMATION

In response to your request to Ed Sondik, here is information about selected research and other activities related to breast cancer that are supported by the National Cancer Institute. Feel free to contact me if you have questions about the material or would like more information.

There are numerous NCI Fact Sheets on breast cancer topics that are accessible through Worldwide Web. You can type the address <http://www.nih.gov/> to get to the NIH Home Page. Then click on Health Information, then click on NIH Gopher Cancernet Menu. Fact Sheets are one of the choices on the Cancernet Menu. (We can send you fact sheets, too, if the computer route doesn't work for you.)

Hope this is helpful.

Anne Middleswarth

Anne Middleswarth
Planning, Evaluation and Analysis Branch
Office of the Director, NCI
(301) 496-5515

NATIONAL CANCER INSTITUTE BREAST CANCER RESEARCH

Breast cancer is the second leading cause of cancer death in women, and comprises about 30 percent of all female cancer cases with 184,300 new cases and 44,300 deaths estimated for 1996. NCI-supported breast cancer research activities include basic research and investigations to improve prevention, early detection and diagnostic technology, treatment, rehabilitation, and community outreach. Selected NCI breast cancer data and research activities follow.

Incidence Data: White women have the highest incidence rates of all racial/ethnic groups at 112.8 per 100,000 women. Hawaiian women are next with a rate of 105.6, followed by black women with a rate of 97.3 per 100,000. Since 1973, there has been a 24% increase in incidence (all races), but it appears that the increase leveled off after 1987. The increase is largely due to increased incidence in women age 50 and over.

Mortality Data: Breast cancer mortality in all American women declined from 27.5 per 100,000 to 25.9 per 100,000 between 1988 and 1993; the decrease was most prominent among younger women. Racial differences in the rates exist. For all ages combined, mortality rates for black women are higher than those for white women (31.3 compared to 26.6 per 100,000). In the period from 1989 to 1993, breast cancer mortality decreased about 6% for white women, but did not decline for black women. Research is underway to understand these and other ethnic differences and to determine how risk factors, access to screening and early detection, treatment and medical follow-up, and supportive care influence cancer rates.

Hereditary Breast Cancer: Researchers, supported in part by NCI, cloned and sequenced BRCA1, a breast and ovarian cancer susceptibility gene on chromosome 17. In high-risk families, women who carry mutations in BRCA1 have an 80-90 percent lifetime risk of breast cancer, and a 40-50 percent risk of ovarian cancer. Another breast cancer susceptibility gene, BRCA2, has been mapped to chromosome 13; mutations in this gene do not appear to increase risk of ovarian cancer.

NCI-supported scientists, in collaboration with researchers from the National Center for Human Genome Research (NCHGR) and the extramural community, have identified a specific BRCA1 mutation (185delAG) in nearly 1 percent of blood samples collected from women of Ashkenazi (Eastern European) Jewish descent. This is the first evidence that an alteration in the BRCA1 gene is present not only in families at high risk for breast cancer, but in a subgroup of the general population. This mutation may account for as much as 16 percent of breast and 39 percent of ovarian cancers in Ashkenazi Jewish women age 50 and under.

NCI is funding a new "snapshot" study in the Washington, D.C. metropolitan area to estimate the risk of breast and ovarian cancer associated with the 185delAG deletion in Ashkenazi Jews, outside of high risk families, by collecting blood samples and information on the personal and family medical histories of study participants.

To facilitate research on genetic predisposition to cancer and to address information and education needs of the public and health care providers regarding gene mutations and cancer, NCI is forming a **Cancer Genetics Network**. This national infrastructure will allow wide access to genetic testing for cancer predisposition and supply information to individuals who seek and receive testing, health care providers, and researchers. As envisioned, this network will be wide-ranging yet highly interconnected to facilitate access to genetic testing, aid research efforts, and make educational materials and other information relevant to cancer genetics readily available.

In conjunction with the NCHGR, the National Institute for Nursing Research, and the National Institute of Mental Health, NCI is funding a **Cancer Genetics Studies Consortium** to conduct multidisciplinary research to examine the psychosocial and clinical impact of using testing for genetic alterations in families with heritable breast, ovarian, and colon cancer. Objectives of this research effort include:

- identifying individuals who are most likely to benefit from genetic counseling for heritable cancer risks; and
- determining the best ways to educate people who are considering genetic tests for cancer risk assessment and how to counsel those who are tested.

NCI supports a network of organizations that comprise a **Cooperative Family Registry for Breast Cancer (CFRBC)**. The purpose of the registry is to collect pedigree information, epidemiologic and clinical data, and biological specimens (such as blood and tissue samples) from patients with a family history of breast cancer in order to provide resources for epidemiologic and interdisciplinary studies. The registry also will help identify women at high risk for breast cancer who might benefit from new preventive and therapeutic strategies.

Screening Mammography Rates: Data from the 1992 National Health Interview Survey show that 36 percent of women in the United States had screening mammography in the year preceding the survey. 68 percent of women reported yes when asked had they ever been screened with mammography. These rates show an increase from 1989 when only 17 percent of women had a mammogram within the previous year and 38 percent had ever had a mammogram.

Research on Screening: Research shows that regular screening mammography significantly reduces the death rate from breast cancer in women over the age of 50. Trials performed over the past 30 years to determine whether regular screening mammography can save lives do not answer definitively the question of the value of screening mammography in younger women. There is no question that mammography is often able to detect breast cancer in women under the age of 50, but the extent to which finding those cancers will translate into saved lives is uncertain.

NCI has provided partial support for a study in the United Kingdom which is looking at the efficacy of screening in women 40-49. At a meeting in March 1996, researchers re-examined the data from Swedish studies regarding the mortality benefit of screening mammography in women ages 40-49. NCI hopes that further analysis of these promising data, some of which have not

been published, along with NCI's own meta-analysis of past studies will determine the benefit of screening mammography in these women.

Although regular screening with mammography is known to reduce breast cancer deaths among women aged 50 and over, many in this age group do not get mammograms on a regular schedule. Researchers are testing ways to reach this population through behavioral strategies such as telephone counseling, tailored print communications, and programs through community organizations. These efforts focus especially on lower income, older, and minority women.

NCI continues to support research to develop **imaging technologies** with greater sensitivity and specificity than conventional mammography such as digital mammography, computer-aided diagnosis, magnetic resonance imaging, nuclear medicine, digital ultrasound, PET imaging, and optical imaging.

The **Mammography Quality Standards Act**, which became effective October 1, 1994, and the **quality mammography guidelines** published by the Agency for Health Care Policy and Research help ensure that mammography in the U.S. is of high quality. The Mammography Quality Standards Act (enforced by the Food and Drug Administration) requires facilities that offer mammography to meet certain requirements for equipment, staff expertise, and quality control procedures and to be certified. The guidelines tell women what to look for in the facility where they get a mammogram, including examination, interpretation, and reporting procedures. All FDA-certified facilities are listed in NCI's Physician Data Query (PDQ) system and are available through the Cancer Information Service, reached at 1-800-4-CANCER.

Breast Cancer Prevention Trial (BCPT): The BCPT is studying the ability of tamoxifen to prevent breast cancer in women at high risk, and includes women with ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS), conditions that may precede development of invasive breast cancer. About 280 centers are participating in this study which will accrue 16,000 women to a randomized trial. Participants take either tamoxifen or a placebo daily for five years. Neither the participants nor their physicians know which pills they are assigned. As of the end of January 1996, 11,837 women have been randomized to the trial. The informed consent includes all known information about tamoxifen-associated risks, and has been updated to include new information.

Adverse Effects of Tamoxifen Use: Since clinical trials have shown that tamoxifen can increase the risk of endometrial cancer, NCI advises women to report any unusual vaginal bleeding while taking tamoxifen, and recommends an annual examination by a gynecologist. A board of scientists convened by the International Agency for Research on Cancer (IARC) reviewed published reports on the potential cancer risk of tamoxifen and determined that "there is conclusive evidence that tamoxifen reduces the risk of contralateral breast cancers" in women with breast cancer, and that there is evidence for an increased risk of endometrial cancer in women receiving tamoxifen. They also report that there is a lack of evidence in humans that tamoxifen increases the risk for other cancers.

Treatment: Validating promising breast cancer therapies in clinical trials is a high priority for NCI. When a trend becomes apparent in these trials, NCI advises investigators and physicians to modify or stop their trials or treatment regimens. In November 1995, NCI distributed a clinical announcement to 22,000 oncologists nationwide recommending that physicians limit **tamoxifen use in the treatment of early breast cancer** to 5 years. This followed a decision by the National Surgical Adjuvant Breast and Bowel Project (NSABP) to stop a clinical trial in which investigators found no additional benefit for women being treated for breast cancer who took tamoxifen for more than five years. A Scottish trial found that women who stopped taking tamoxifen after 5 years had a lower rate of breast cancer recurrence than the group receiving treatment for more than 5 years. NCI stresses that, for women with early stage breast cancer, treatment with tamoxifen confers a proven survival benefit when given as an adjuvant (additional) therapy for up to five years following breast cancer surgery.

Research is underway to define the **predictive value of newly identified markers** such as genes or gene products. We are finding that the absence or presence of certain proteins can indicate that a tumor is more likely to recur or to be more aggressive. Learning to read these molecular signs will enable us to tailor treatments to individuals. For example, women whose breast cancers express high levels of the oncogene c-erbB-2 appear to experience more aggressive tumor development, and higher treatment intensity may be more effective than low intensity treatment.

Studies suggest that the chance of cure for women with advanced breast cancer or with adverse prognostic indicators may be increased by a higher dose of chemotherapy, but this may be toxic to the patient's bone marrow, thereby increasing the likelihood of infections. **Autologous bone marrow transplantation (ABMT)** can reduce this complication. NCI is sponsoring randomized clinical trials to determine if high-dose chemotherapy with ABMT increases survival in women with advanced or poor prognosis breast cancer.

Expanded Access to Clinical Trials: NCI and the Department of Defense (DoD) recently signed an interagency agreement that allows patients who are beneficiaries of TRICARE/CHAMPUS, the DoD's health program, to participate in NCI-sponsored treatment clinical trials. The DoD provides health services to about 8.3 million beneficiaries (most are members of the armed forces and their families). The new agreement gives these individuals access to NCI-sponsored clinical trials that test promising treatments for cancer in medical centers around the country. It builds on a DoD demonstration project that provided CHAMPUS reimbursement for eligible beneficiaries to receive high dose chemotherapy with stem cell rescue for breast cancer under NCI-approved trials.

NCI and DoD will evaluate the success of the new program, looking specifically at patient enrollment and cost of care. Patients will enjoy the benefits of receiving protocol-level care, and research will benefit with the increased enrollment of patients to clinical trials. This project may serve as a model for future partnerships with groups such as the Health Care Financing Administration, managed care companies, and self-insured corporations.

Research on Causes of Breast Cancer: NCI supports basic and population-based research to identify environmental and genetic factors contributing to breast cancer incidence and mortality. For example, in collaboration with the National Institute of Environmental Health Sciences, NCI is conducting the **Long Island Breast Cancer Study Project (LIBCSP)** to evaluate the contribution of various environmental and occupational factors to the etiology of breast cancer, and to develop a geographic system to evaluate current and past exposures. Current projects funded at New York area universities and cancer centers are studying a variety of compounds including organochlorines, polycyclic aromatic hydrocarbons, estrogen metabolites, genetic factors, and electromagnetic field (EMF) exposures, and are collecting tissue samples and data about family history to elucidate connections between environmental factors and breast cancer.

Research in other parts of the United States may help clarify the genetic, hormonal, and/or environmental influences on breast cancer. **The Northeast/Mid-Atlantic Study** is examining the role of various environmental exposures along with other possible risk factors to better understand the causes of breast cancer in the northeastern United States, an area of high incidence and mortality.

A recently published study of **geographic patterns of breast cancer** reported that mortality rates were much more uniform throughout the United States when regional differences in the percentage of women with known breast cancer risk factors due to personal and family history were taken into account, and the Northeast no longer had a particularly high breast cancer mortality rate. However, not all of the geographic variation in breast cancer mortality could be explained.

In 1995, NCI began a study of the risk of breast cancer associated with **DDT exposure** in African Americans from Triana, Alabama, where the population was heavily exposed to pesticides found in fish caught in contaminated waterways. In 1996, a small feasibility study will investigate the association between breast cancer risk and DDT exposure in India where this agent continues to be used in agriculture.

Research Programs Dedicated to Breast Cancer: NCI supports six **Specialized Programs of Research Excellence (SPORes)** for breast cancer. A key focus of the SPORes is to move research results from the laboratory to the clinic and other human settings and to send clinical observations to the laboratory to help understand the biology of human disease. The SPORes also maintain tissue resources that are available to researchers and offer career development and training for cancer scientists. Interdisciplinary research at SPORes is expected to lead to reductions in cancer incidence and mortality. One SPORes is combining molecular, epidemiologic, and public health research approaches to reduce breast cancer incidence and mortality in rural African American populations.

Outreach and Information Dissemination: NCI's Cancer Information Service (CIS) provides accurate, up-to-date cancer information to patients and their families, the public, and health care professionals in all 50 states through 19 offices located at NCI-funded Cancer Centers and other

health care institutions. By dialing 1-800-4-CANCER, callers are automatically connected, free of charge, to the office serving their region. The CIS answers more inquiries about breast cancer than any other cancer site. It supports state and local breast cancer education efforts and is a partner to organizations that want to sponsor media campaigns, screening programs, and other related community actions.

The Centers for Disease Control and Prevention (CDC) is supporting outreach coordinators at four CIS offices to bring more women into low-cost breast and cervical cancer screening programs (also supported by CDC) in four states. Linking the CIS offices and the CDC screening programs should benefit both parties and the communities they serve.

The United States Postal Service will issue a **Breast Cancer Awareness Stamp** on June 15. NCI's CIS toll-free number will appear on the border of each sheet of stamps as the source for breast cancer information. In addition, educational materials will be available at post offices across the country, and a video on breast cancer produced by LIFETIME television will be shown in more than 2,000 post office lobbies. NCI helped develop resources and media products for the information campaign. **ENCORE^{plus}**, a program of the YWCA of the U.S.A., the American Cancer Society, and several breast cancer groups will join with the Postal Service to provide breast health information forums and mammography screenings at selected post offices and other community locations.

DHHS Secretary's National Action Plan on Breast Cancer (NAPBC): NCI is a key partner in the NAPBC, a transgovernment and private sector collaboration to reduce the burden of breast cancer. The DHHS Office on Women's Health coordinates implementation of the Action Plan.

NCI Breast Cancer Funding

FY 1995	FY 1996
<u>Actual</u>	<u>Estimate</u>
\$309 Million	\$337 Million

4/22/96

NARAL Promoting Reproductive Choices

FAX COVER SHEET

DATE:

1/19/96

TO:

Jen Klein

456-1715

OFFICE:

FROM:

Karen Guss

PHONE:

973 3013

THIS IS PAGE ONE OF 3 TOTAL PAGES

COMMENTS:

JK-

I predict~~ed~~ that HRC will get some mail on this subject so I thought I'd pass on these clips to you.

Sorry I haven't been able to call - all hell is breaking loose - I haven't stopped working since I got back. (True, I had lots of time off this month, so I can't complain). Anyway, one of these days I'll get both a job and a life.

Can you have lunch w/ me and (engaged?) Molly next week? I hope I get to see you before our big Alm-Aley date! - KG

Breast-Cancer Gene Study Advances; Official Wants to Restrict Use of Test

By MICHAEL WALDHOLZ

Staff Reporter of THE WALL STREET JOURNAL

The head of the U.S. human genome project said a new genetic test detecting a gene that causes breast cancer should be restricted to certain medical-research centers at this time.

Francis Collins, director of the National Center for Human Genome Research, said he expects that new research to be released today will spur many women to seek the test. But he said he is against the widespread screening for the gene outside of selective research institutions. Two gene-testing companies are hoping to sell the breast-cancer-gene test to the public outside of research centers.

"Right now, the many risks associated with the test exceed its benefits," he said. "Many questions need to be answered by researchers before it makes sense to recommend the test for most women."

In late 1994, following an intense worldwide scientific race, scientists found that a defect to a gene called BRCA1 causes an inherited form of breast cancer that accounts for about 5% or so of all breast-cancer cases. Immediately, several research teams began random testing of women with breast cancer to determine if their disease was caused by the inherited gene defect.

In studies released by two of those research groups that are being published in today's *New England Journal of Medicine*, researchers found that breast cancer among a good portion of women under age 40 is likely to be caused by inheriting the defective gene. In two separate reports, the researchers said that between 10% and 20% of breast cancer among young women is due to inheriting the flawed gene. The finding is striking because none of these women had known of a family history of breast cancer.

"We definitely need to move ahead cautiously [with testing young women]," said Dr. Daniel Haber, a researcher at Massachusetts General Hospital who directed one of the studies. "But we need to figure out how to test many women who are unknowingly at risk."

Dr. Haber said young women with breast cancer found to carry the gene defect should be closely monitored because they are at high risk for developing another bout of breast cancer or ovarian cancer, which is also caused by the gene. Moreover, the test can help alert the women's close female relatives who may also be at risk of developing the cancers.

But in a commentary accompanying release of the two studies, Dr. Collins said the gene test is still highly experimental. He urged that women get screened only at a handful of medical centers where scientists and genetic counselors are studying how best to use the test information.

Dr. Collins said he and others are worried that women and doctors will mis-

interpret complicated results of the test. For example, doctors aren't certain how best to treat a woman who has the gene. He also is concerned that women without the gene will be given a false sense of security because they still have the same 1-in-12 risk of getting breast cancer.

In the Massachusetts General study, the researchers tested young Jewish women who had breast cancer before age 40. Late last year, scientists found that one specific type of flaw in the gene accounted for about 1% of all breast cancers among women with an Eastern European Jewish heritage. In the new study, the Massachusetts General researchers led by Dr. Haber found that eight of 39 young Jewish women with breast cancer carried the gene mutation. None of the women previously suspected they had a family history of the disease.

In a separate report from the Fred Hutchinson Cancer Research Center in Seattle, scientists said they found gene defects in six of 80 women under age 35 with breast cancer who also had no family history of the disease. Taken together, the studies suggest there are many women at risk of carrying the gene who are unaware they have a family risk of developing breast cancer.

This week, OncorMed Inc., a genetics-testing company in Gaithersburg, Md., announced that it is making available to doctors its own BRCA1 test. The company has provided the test to research centers since the middle of last year but will now provide it to independent doctors and their patients who agree to meet certain guidelines. Another company, Myriad Genetics Inc. of Salt Lake City, hopes to also offer the test later this year.

WSS
1-18-96
BIO

Gene Linked to Early Breast Cancer

Associated Press

BOSTON, Jan. 17—A single bad gene appears to cause a significant share of breast cancer in young women, especially Jews, in whom it may trigger more than a quarter of all cases under age 40.

A whirlwind of research over the past two years has pinpointed a gene that is often to blame when breast cancer clearly runs in families.

Now, two new studies show for the first time that this same gene is frequently the cause whenever the disease strikes women in their twenties and thirties, even if there is no strong pattern of breast cancer among the victim's close relatives.

"This is an important finding," said Richard Klausner, director of the Na-

tional Cancer Institute. "It takes genetic susceptibility the next step—from individuals who are members of preselected families with a history of cancer—and now looks at all young women."

The younger women are when they get breast cancer, the more likely it is that the disease is caused by a mutation in the recently discovered gene, called BRCA1.

The discovery of the importance of BRCA1 does nothing to steer doctors toward better treatments, although that may someday happen. It raises the possibility of getting a jump on the disease by testing women for the faulty gene, if researchers are able to develop effective methods of preventing breast cancer. However, since such methods have not yet been iden-

tified, genetics experts are recommending that, for now, testing for mutations in the gene should be done only as part of research.

When it works properly, the BRCA1 gene helps prevent cancer.

Last September, researchers reported that 1 percent of American Ashkenazi Jews, whose families came from Central and Eastern Europe, carry one particular defect in their BRCA1 gene. The new work suggests this mutation accounts for a significant fraction of breast cancer cases in young Jewish women.

Two studies on BRCA1 in a total of 498 young breast cancer patients were conducted at Massachusetts General Hospital in Boston and the Fred Hutchinson Cancer Research Center in Seattle. Both studies are in

Thursday's issue of the New England Journal of Medicine.

Francis Collins, head of the National Center for Human Genome Research, wrote in an editorial in the journal that the reports suggest that in women under 30, the genetic defect is responsible for 38 percent of breast cancer among Jews and 8 percent among non-Jews. Under age 40, it causes 27 percent of cases among Jews and 5 percent among non-Jews.

The American Cancer Society estimates breast cancer will kill 44,300 U.S. women this year, more than any other form of cancer except lung cancer. However, the disease is rare among the young. Before age 30, breast cancer strikes 17 in every 1 million women.

The National Cancer Institute is coordinating a study of Ashkenazi Jews in the Washington area to determine the prevalence of the mutation and its relation to breast and ovary cancer.

1.13.96
AS
W7

Fax Transmittal

Office of the Director National Cancer Institute

Date: 3-16-95
To: Jennifer Klein
Fax No. 202-456-2878

From: Dr. Sondik

Bldg. 31; Room 11A48
National Cancer Institute, Bethesda, Maryland 20892

Fax No. 301-402-0338 Telephone No. 496-5615
or
Fax No. 301-496-6005

Cover Sheet Plus / Pages Transmitted

Additional Comments:

NATIONAL
CANCER
INSTITUTE

It is critical that we safeguard the welfare of the thousands of patients and participants in NSABP and other clinical studies and do everything possible to ensure the proper execution and oversight of the studies in progress. The NCI has worked closely with the University of Pittsburgh and the NSABP to resolve the problems that were uncovered last spring and to restore seriously eroded confidence in clinical trials.

As a result, new leadership is in place, and the NSABP has been restructured in a manner that separates its headquarters and operating center from its statistical center, emphasizing the importance of quality control and auditing procedures. *Enrollment in* ~~Access to~~ NSABP studies has

reopened, and there is every reason to expect that this work will go forward with the precision and integrity that the public, the scientific community, and the Government expect and deserve.

The NCI intends to continue its support of the critically important NSABP research agenda. As the work moves forward, it is essential to build on the successes of the past as well as learn from the failures. Every action will be taken to maintain support for clinical trials, a vital component of the National Cancer Program.

Thank you for your interest and your expression of concern.

11-1 2878



Susan J. Blumenthal, M.D., M.P.A.
Deputy Assistant Secretary for Health
(Women's Health)
Assistant Surgeon General

Office on Women's Health
U. S. Public Health Service
Hubert Humphrey Bldg, Rm. 730-B
200 Independence Avenue, SW
Washington, DC 20201

Date: 3/9/95

To: Jennifer Klein

Organization/Office: _____

Fax: 456-2878

Telephone: _____

Subject: _____

From: Susan J. Blumenthal

Telephone: (202) 690-7650

Fax: (202) 401-4005

No. of Pages (including cover): _____

PLEASE NOTE:

Here's a suggested reply letter —
Let me know if you need anything else —
Susan Blumenthal

Speak with me about
it depending on who
will be signing the
letter → given
there's a
lawsuit pending between Pillsbury + NCI!

Dear :

Thank you for your letter to _____, regarding the National Surgical Adjuvant Breast and Bowel Project (NSABP). We understand your concerns, and we want to assure you that the pioneering contributions made by the NSABP and Dr. Bernard Fisher to breast cancer research are recognized and appreciated.

You are probably aware of the finding of scientific fraud at St. Luc Hospital in Montreal, the subsequent investigation by the Office of Research Integrity (ORI), and widespread concern about NSABP's delay in notifying journals, the press, and the public about this incident. You also may be aware that, in addition, NSABP did not promptly provide to the National Cancer Institute (NCI) information in their possession regarding an episode of possible misconduct and data manipulation at yet another hospital (St. Mary's) in Montreal, even in the face of the report from ORI on the St. Luc case. In addition, serious management problems occurred at NSABP, including failure to properly oversee audit and quality control activities, as well as issues related to proper informed consent procedures.

03/09/95 13:14

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DR BLUMENTHAL

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03/08/95 18:37

☎ 301 402 0338

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It is critical that we safeguard the welfare of the thousands of patients and participants in NSABP and other clinical studies and do everything possible to ensure the proper execution and oversight of the studies in progress. The National Cancer Institute (NCI) has worked closely with both the University of Pittsburgh and the NSABP to resolve the problems that were uncovered last spring and to restore seriously eroded public confidence in clinical trials. As a result, new leadership is in place, and the NSABP has been restructured to strengthen internal data quality control. Accrual to NSABP studies has reopened, and there is every reason to expect that this organization's important work will go forward with the precision and integrity that the scientific community, and the American public expect and deserve.

The NCI fully intends to continue supporting the critically important NSABP research agenda. As the work moves forward, it is essential to build on the successes of the past as well as learn from the failures. Every action will be taken to maintain support for clinical trials, a vital component of the National Cancer Program.

Thank you for your interest and your expression of concern.

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Fax No. 301-402-0338 Telephone No. 496-5615
or
~~Fax No. 301-496-6005~~

Cover Sheet Plus 10 Pages Transmitted

Additional Comments:

NATIONAL
CANCER
INSTITUTE

Edward J. Sondik, Ph.D.
Acting Director
National Cancer Institute

NSABP
March 13, 1995

2

- o Thank you. I appreciate the opportunity to speak with you. As of March 1st I began to serve as Acting Director of the NCI. As many of you know, for the last year I served as NCI's Acting Deputy Director, and prior to that I served for several years as the Deputy Director of the Division of Cancer Prevention and Control and the Associate Director of the Surveillance Program.
- o For us at NCI the next several months will be a challenge with our changes in leadership, with the intramural program and streamlining reviews underway, and, perhaps most important, with the focus on reducing the budget deficit, but it is a challenge I look forward to. Today, however, I am here to talk about NSABP.
- o Let me begin with a brief report from the NCI Surveillance, Epidemiology and End Results (SEER) Program that relates to NSABP.

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- o Our mortality statistics tell us that deaths from breast cancer declined by over 5 percent from 1989 to 1992. This is the largest sustained decrease since 1950. The changes are due, we believe, to a combination of advances in therapy and screening programs--and I emphasize *therapy*--as well as a possible change in risk factors. Clearly the NSABP research contribution deserves great credit.
- o We see declines in mortality in all age groups, but most dramatically in the age group 30 and 39 years of age. Indeed, for these young women the decline amounts to about nine percent since 1989 and almost 18 percent since 1987. It is especially important to note that not only have lives been saved, but they have been saved with improvements in surgery that offer a better quality of life.
- o I must hasten to add, however, this decline was only seen among whites while African American women experienced a 2 percent increase in death rate. In fact, African-Americans have higher incidence and death rates for cancer overall. We need to find the causes of these differentials, and increase minority accrual to clinical trials to ensure that all Americans benefit from research.

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- o It is impossible to study such improvements and not see the value and importance of clinical trials and specifically the value and importance of the NSABP.
- o All of us have been through a devastating year.
- o The NSABP is central to NCI's commitment to reduce death and suffering from cancer. If I leave any doubt when I fly out of San Diego that NSABP is of fundamental importance to the NCI, then I have failed. Breast cancer is the second leading cause of death in American women. Colorectal cancer is the second leading cause of cancer death. NCI has a deep commitment to this research and to clinical trials. I would venture to say that seldom has a nation had such agreement on a problem to be solved. The public wants progress, the Congress wants progress and the scientists and clinicians want progress, particularly about breast cancer.

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- o The recent gene discoveries pose, in turn, major challenges for future research and development, for progress in screening and treatment, for stratification in clinical trials and for counseling. On the other hand, never has science and the day-to-day process of science had such visibility. We must be sure we without shelter and without shadow, and translate the results of research to the public as expeditiously as possible.
- o But now we are emerging from this awful year for the clinical trials community in general and for NSABP specifically.
- o With the publication of papers on the audit process and on the reanalysis we will have set the scientific record straight so that the public and the profession can be fully informed about the comparable efficacy of lumpectomy and mastectomy.
- o I am optimistic that we are now in a strong position to once again focus on clinical research. Let me be as emphatic and clear as I can be: I am here to reaffirm NCI's continuing commitment to the NSABP and to its history and achievements. We are here to look to the future of NSABP and breast and colorectal cancer treatment and prevention clinical trials.

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- o That we are all here today is due to the hard work of many people. I want to thank, even more strongly, I want to *commend* Ronald Herberman and Norman Wolmark. Ron Herberman deserves thanks from all of us for his role as Interim Chairman of the NSABP during a period of unprecedented public and scientific scrutiny. His work helped to maintain the continuity of NSABP clinical trials. I believe we share relief and optimism as accrual to NSABP studies continues.

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- o And we at NCI wish Dr. Wolmark well as he assumes the Chairmanship of this Group and we will stand by to assist him and we congratulate him on his appointment.
- o We want to acknowledge the exceptional cooperation of this Cooperative Group in carrying out the B-06 audit. In addition to reaffirming the results of B-06 clinical trials, it demonstrated the quality of the clinical research that had been conducted by the NSABP over many years.
- o And, I want to thank and commend the NSABP staff for their commitment and dedication over this most difficult of periods. I had the chance to meet just some of them last year and was most impressed then--and since--with their achievements.
- o In addition, on behalf of the NCI and the NIH, I am pleased that Dr. Wolmark has proposed Dr. Fisher as Scientific Director of the NSABP. Dr. Fisher has made seminal contributions to breast cancer research and galvanized breast cancer research both in the United States and internationally. His research, together with his colleague Carol Redmond, accumulating the evidence that breast cancer is a systemic disease was a profound achievement. We recognize Dr. Fisher's pioneer-

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ing contributions, his decades of devotion to breast cancer research and his place in the hearts of many American women.

- o We, NSABP and NCI, both have organizational issues before us. You have huge challenges as a group. The administrative restructuring, both accomplished and proposed by NSABP will bring improved and intensified quality control and auditing procedures. Accrual needs to be accelerated and additional clinical trials must be developed.
- o At NCI we also face challenges. Our intramural program is undergoing a rigorous review under the leadership of Drs. Bishop and Calabresi; there are stringent targets for streamlining, and all of us are involved in taking a hard look at what we do and finding better ways to do it. With Dr. Broder and Dr. Adamson's retirements we have had losses in valuable leadership.

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- o Dr. Bruce Chabner's impending departure is a great loss to us. I am totally confident that the clinical trials will be in good hands when Dr. Robert Wittes succeeds Bruce as Acting Director of the Division of Cancer Treatment. Bob knows CTEP inside and out and he has a long-standing relationship with the NSABP. The staff you have worked so closely with--Mike Friedman, Rick Ungerleider, Jeff Abrams, Leslie Ford, and Leo Buscher--and all the others as well, are in place and committed to assisting the NSABP and committed to the importance of this effort.
- o Later this week Dr. Varmus, on behalf of NIH and Dr. Chabner and I will be testifying before Congress on the President's budget request for next fiscal year. As the Administration and the Congress move to reduce the deficit all aspects of funding are under scrutiny.

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- o The Secretary has made it clear that biomedical research is a high priority and that the budget projections for HHS need not necessarily apply across the board, but if they do NIH will experience a budget reduction by the turn of the century of about 10 percent which, accounting for modest inflation, amounts to about a 25 percent cut. When a panel of Nobel laureates testified before the House Subcommittee recently they were asked about the effect of a 30 percent reduction. Please be aware of the economic realities, and that tough choices for all of us lie ahead. We will all be put to the test, and we at NCI will ask for and expect your help in making the difficult choices.
- o All of this change for you and us sends shock waves, but it also offers the opportunity to improve and to strengthen.
- o Again, we all share a deep commitment to the women of America. We have made progress but there is a great deal that needs to be done. Thank you for your attention.

PHS - 47

WOMEN'S HEALTH - PHS**Breast Cancer****QUESTION:**

What does you FY 1995 budget include for Breast Cancer?

ANSWER:

- ▶ For NIH Breast Cancer Research, the budget includes \$387 million, an \$87 million, or 29 percent increase over 1994. The request also amounts to an 69% increase for NIH breast cancer research funding since 1993.
- ▶ The NIH request includes \$10 million for implementation of the Breast Cancer Action Plan, which calls for a wide range of immediate actions to make progress against this disease.
- ▶ The request also includes \$20 million for FDA to continue implementation of the Mammography Quality Standards Act of 1992 (MQSA). FDA will conduct safety and quality inspections of mammography facilities for the first time in FY 1995.
- ▶ For CDC, the budget includes \$46.9 million for CDC's State Breast Cancer Screening and Education program. (This is the same level as FY 1994.)
- ▶ Finally, the HHS budget includes \$320 million for Medicare coverage of mammograms, an increase of +\$30 M (+10%) over 1993.
- ▶ Taken together, these activities underscore the Administration's commitment to prevention and early treatment to improve health outcomes. Breast cancer has a high cure rate if detected early.

HHS Funding for Breast Cancer Research/Prevention
(Program Level in Millions)

	1993	1994	1995	+/- FY 1994	
				\$	%
NIH	\$229	\$300	\$387	+\$87	+29%
CDC.....	43	47	47	--	--
FDA.....	3	13	20	+7	+54%
IHS/AHCPR.....	1	1	1	--	--
Subtotal, PHS	\$276	\$361	\$455	+\$94	+26%
Medicare.....	\$260	\$290	\$320	+\$30	+10%
Total, HHS...	\$515	\$650	\$771	+\$121	+19%