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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Fax list re: SSNs and DOBs (partial) (1 page)	09/16/1998	P6/b(6)
002. list	Fax list re: SSNs and DOBs (partial) (1 page)	09/16/1998	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Eric Morse (Events)
OA/Box Number: 21192

FOLDER TITLE:

Breast Cancer October Event [1]

2011-0619-S

rc290

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

October 21, 1998

ANNOUNCING NEW EFFORTS IN THE FIGHT AGAINST BREAST CANCER

DATE:	October 21, 1998
TIME:	4:00 pm
LOCATION:	East Room White House
FROM:	Jennifer Klein Neera Tanden

I. PURPOSE

To highlight the Administration's strong commitment to the fight against breast cancer through a series of announcements.

II. BACKGROUND

Overview:

During this event marking Breast Cancer Awareness Month, you will make several announcements that will aid in the fight against breast cancer, and you will release a report that details the Administration's commitment and accomplishments over the last five years.

Announcements:

You will announce the largest funding increase in the history of the National Cancer Institute; the largest clinical trial of drugs with the potential to prevent breast cancer; and an expanded mammography outreach campaign. In addition, you will release a five-year report from the Federal Coordinating Committee on Breast Cancer, which charts our progress in breast cancer research, prevention and treatment.

Record Funding Increases for the National Cancer Institute. As part of the recent budget agreement, Congress passed a significant down-payment on the President's 21st Century Research Fund. You will announce that the National Cancer Institute will receive a total budget of over \$2.9 billion in FY 1999, a \$375 million increase that will enable NCI to fund critical new research activities. In addition, you will announce that NCI's breast cancer research activities will receive an increase of \$40 million this year, from \$348 million in FY 98 to \$388 in FY 99. (In FY 93, NCI funded breast cancer research at \$211 million.) Over ten percent of NCI's overall funding increase will go towards initiatives to increase patient participation in clinical trials; efforts to meet the President's challenge to translate progress in genetics into better diagnostic techniques for every major cancer by the year 2000; and other investments to develop new early detection methods. This increase will also fund seven new breast cancer treatment clinical trials, including a trial to expand the use of Herceptin to treat breast cancer earlier.

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

Landmark Report on Progress Against Breast Cancer in the Last Five Years. You will also release a new report from the Federal Coordinating Committee on Breast Cancer highlighting the accomplishments in breast cancer since the Administration took office. This report underscores critical progress the Administration has made, including:

- A significant investment in research--reaching over \$550 million in 1998 that has led to historic advances in breast cancer, such as the identification of new breast cancer genes, and promising new treatments, such as Taxol and Herceptin;
- Improved the quality and availability of prevention tools like mammograms, through efforts such as a new Medicare mammography benefit, an unprecedented outreach campaign to encourage older women to get mammograms, 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, and launching new projects to improve detection and care among low-income and minority women;
- 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 to develop less intrusive surgery methods for patients.

[See attached Executive Summary of Breast Cancer: A Report on the Fight to Prevent, Treat, and Cure the Disease.]

Expanded Awareness Campaign To Help Ensure Women Get Recommended

Mammograms. You will also unveil an expanded outreach and education campaign to encourage women ages 65 years and older to get regularly scheduled mammogram screenings. This year's campaign will emphasize the new mammography Medicare benefit that the President proposed and signed into law that covers annual mammograms and makes them more affordable. HHS is also expanding outreach efforts to special populations -- low-income and minority women -- who tend to have the highest breast cancer mortality rates. For example, the Health Care Financing Administration has initiated a pilot program to provide free mammogram screenings and to air 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. You will also highlight ongoing private-sector activities. [See attached list of corporate activities.]

Administration Funding for Breast Cancer Research and Prevention

The Department of Health and Human Services discretionary funding for breast cancer, which includes the budgets for NIH and CDC, has nearly doubled in the years since 1993 – from approximately \$283 million in FY 1993 to nearly \$550 million today. At the NIH alone funding increased from \$237 million in FY 1993 to an estimated \$433 million in FY 1998. And CDC's resources devoted to breast cancer services have increased from an estimated \$43 million in FY 1993, to \$85 million in FY 1998. In addition, the Department of Defense will invest over \$135 million in FY 99 for innovative, peer-reviewed breast cancer research.

Recent Notable Accomplishments

Mammography Quality Standards Act (MQSA)- On October 9, 1998, the President 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. Senator Mikulski wrote and sponsored this legislation.

Reconstructive Breast Surgery Act - The Congress has also just passed (as part of the budget) new protections to assure that women whose health plans cover mastectomies also cover breast reconstructive surgery. This legislation requires that coverage be provided in a manner determined by the doctor and the patient to be appropriate. Senator Kennedy and Representative Eschoo sponsored this legislation, and Senators D'Amato and Specter worked particularly hard to advance the measure.

III. PARTICIPANTS

Meet and Greet

- Mr. Harold Varmus, National Institutes of Health
- Ms. Sue Bailey, Acting Assistant Secretary for Health Affairs, Department of Defense

Medicare Mammography Initiative Corporate Representatives

- Dagmar T. Farr, Food Marketing Institute
- Jill Froula, American Greetings
- Rebecca Snead, R.Ph., Virginia Pharmacists Association
- Barbara Lardy, American Association of Health Plans
- James P. Schlicht, Zenecca
- Karen Miller, Zenneca
- Richard Dorff, President, Florida Association of Health Maintenance Organizations, Inc.
- Veronica Jacques, Direct Selling Association
- Phil Schneider, Managing Director, Public Affairs National Association of Chain Drug Stores
- Donna Rape, Division Sales Manager, Avon Products, Inc.
- Homer Pearce, Eli Lilly, Inc.

- Freda Lewis-Hall, Eli Lilly, Inc.
- David M. Hendler, Director, Retail Operations
- Nancy C. Yedlin, Pitney Bowes

Speaking Program Participants

- First Lady Hillary Rodham Clinton
- Frances Visco, Esq., President, National Breast Cancer Coalition
- Dr. Nancy Davidson, Director, Breast Cancer Program, Johns Hopkins Oncology Center
- Secretary Donna Shalala

Audience

Breast cancer survivors, advocates, scientists, and government officials

Cancer Survivors in the Audience

- Jean Camak, Washington, DC, White House Volunteer
- Alfreda Elzie, Washington, DC
- Hazel Parago, New Castle, Delaware
- Zora Brown, Washington, DC

Members of the Military in the Audience

- Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs [Blue Room participant]
- Colonel Doris Brown, Director for Medical Research & Development, US Army
- Colonel Leslie A. Raulin, Deputy Director for Congressionally Directed Medical Research Programs
- Master Chief Karen L. M. Kayers, Senior Enlisted Advisor to Assistant Secretary of Defense for Health Affairs

IV. SEQUENCE OF EVENTS

- The First Lady makes remarks and introduces Fran Visco, President of Board of Directors, National Breast Cancer Coalition;
- Fran Visco makes remarks and introduces Dr. Nancy Davidson, a breast cancer scientist and researcher;
- Dr. Nancy Davidson makes remarks and introduces Secretary Donna Shalala;
- Secretary Shalala makes remarks;
- Upon conclusion of Secretary Shalala's remarks, the First Lady will close the program and depart.

V. REMARKS

Provided by Christy Macy.

► **Jason H. Schechter**
10/21/98 03:10:54 PM
.....

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Statement By The President: FDA

THE WHITE HOUSE

Office of the Press Secretary

_For Immediate Release

October 21, 1998

STATEMENT BY THE PRESIDENT

I am extremely pleased that today the Senate, with strong bipartisan support, overwhelmingly voted to confirm Dr. Jane E. Henney to be the next Commissioner of the Food and Drug Administration. I am confident that as the first woman and first oncologist to be confirmed as FDA Commissioner, Dr. Henney will live up to the trust the Senate has placed in her.

The nation now has an FDA Commissioner who is committed to assuring that Americans have safe food, safe and effective drugs and medical devices, and improved public health. Dr. Henney has blazed many trails and no one is more qualified to lead the FDA. She has served four Presidents and helped guide some of America's finest academic health centers. Her expertise in science and technology and lifelong dedication to individual patients will enable her to strike the important balance between the need for timely approval of prescription drugs and medical devices, while maintaining safety and quality.

I commend the Democrats and Republicans who worked to give Dr. Henney a full and fair hearing and help expedite this confirmation. I also want to thank representatives of consumers, physicians, nurses, and the industry for their steadfast and strong support for Dr. Henney. Their combined leadership made a vital contribution toward assuring we have the right person to lead the FDA into the 21st century.

30-30-30

Message Sent To: _____

Patrice L. Stanley 10/21/98 12:53:08 PM

Record Type: Record

To: Neera Tanden/WHO/EOP

cc:

Subject: Breast Cancer

Mayor Beverly O'Neill (Long Beach, CA) is the only mayor attending today's event with HRC. She should be acknowledged. Thanks.

52294

Sunny
Text

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Executive Order 12873 (October 20, 1993) sets a goal that "all government documents printed internally be printed double-sided."

**PHOTOCOPY
PRESERVATION**

WHSO Layout Draft 5

a/o 10/21/98; L. Schwartz, 10:00 a.m.

BREAST CANCER PREVENTION EVENT

Wednesday, October 21, 1998

East Room

EV Gate Opens: 3:00 p.m.

Invite Time: 3:30 p.m.

Principal Time:	3:30 p.m.	Brief	Elevator, State Floor
	3:35 p.m.	Meet	Blue Room
	3:40 p.m.	Event	East Room
	4:30 p.m.	Meet #2	State Dining Room

Approx. 160/Open Press/Business Attire

10 Social Aides

SET UP NOTES GROUND FLOOR: coat check in family theater.

GRAND FOYER/STATE FLOOR: string combo with piano in Grand Foyer, Honors Group in Foyer for announce.

BOOKSELLERS: one table with cloth for distribution of two packets from the National Cancer Institute for guests on departures.

EAST ROOM/EVENT: 10x16 stage at gold curtain; Toast lectern in East Room; WHCA Announce from Blue Room; water at podium; 2 Press risers on both sides of cross hall doors; press pool to provide lighting for the East Room.

BLUE ROOM MEET: furniture removed from Blue Room for meet and greet; WHCA announce for program; screens up between parlor rooms.

2:55 p.m. IN PLACE TIME

3:00 p.m. East Visitors Gate opens and guests proceed to the State Floor and are seated in the East Room.

3:30 p.m. **THE PRESIDENT and THE FIRST LADY** arrive at the elevator on the State Floor and are briefed.
Contact: Jennifer Kleig

3:35 p.m. **THE PRESIDENT and THE FIRST LADY** proceed to the Blue Room to meet event participants.

Blue Room

Secretary Shalala

Dr. Nancy Davidson, Associate Professor, Director, Breast Cancer Research Program at the John Hopkins Oncology Center

Fran Visco, President of the National Breast Cancer Coalition

3:40 p.m. **THE PRESIDENT** and **THE FIRST LADY** are announced into the East Room accompanied by Secretary Donna Shalala, The President of the National Breast Cancer Coalition Fran Visco and The Director of the Breast Cancer Research Program at the John Hopkins Oncology Center, Dr. Nancy Davidson.

PROGRAM BEGINS

THE FIRST LADY makes brief welcoming remarks and introduces **THE PRESIDENT**.

THE PRESIDENT makes remarks and departs.

THE FIRST LADY substantive remarks and introduces Fran Visco, The President of the National Breast Cancer Coalition.

Fran Visco, The President of the National Breast Cancer Coalition makes remarks and introduces the Director of the Breast Cancer Research Program at the John Hopkins Oncology Center, Dr. Nancy Davidson.

Dr. Nancy Davidson makes remarks and introduces Secretary Shalala.

Secretary Shalala makes remarks.

4:25 p.m. **THE FIRST LADY** returns to the podium to thank guests for coming and proceeds to the State Dining Room to meet Medicare Mammography Initiative Corporate Representatives.

4:30 p.m. **THE FIRST LADY** meets the following people in the State Dining Room.

State Dining Room

Mr. Harold Varmus, National Institute of Health
Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs

Medicare Mammography Initiative Corporate Representatives

Dagmar T. Farr, Food Marketing Institute
Jill Froula, American Greetings
Rebecca Snead, R.Ph., Virginia Pharmacists Association
Barbara Lardy, American Association of Health Plans
James P. Schlicht, Zenecca
Karen Miller, Zenneca
Richard Dorff, President, Florida Association of Health Maintenance Organizations, Inc.
Veronica Jacques, Direct Selling Association
Phil Schneider, Managing Director, Public Affairs National Association of Chain Drug Stores
Donna Rape, Division Sales Manager, Avon Products, Inc.
Homer Pearce, Eli Lilly, Inc.
Freda Lewis-Hall, Eli Lilly, Inc.
David M. Hendler, Director, Retail Operations
Nancy C. Yedlin, Pitney Bowes

4:40 p.m. **THE FIRST LADY** departs.

Guests depart East Gate.

BREAST CANCER EVENT (10/21)**Calligraphy****Name Cards - yellow**

The President

Mrs. Clinton

Secretary Shalala

Dr. Nancy Davidson

Fran Visco

Mayor Beverly O'Neill - front row seated

General Reserved Cards

4 pink reserved - survivors in front row

Names to be highlighted at gate - proceed to seat in East Room with pink card

Jean Camak, Washington, DC

Alfreda Elzie, Washington, DC

Hazel Parago (Pa - rah - go), New Castle, Delaware

Zora Brown, Washington, DC

16 blue reserved - State Dining Room guests - to be seated following meet

Guests will arrive NW gate and be escorted by Barbara Woolley

4 green reserved - DoD - Barbara Woolley will give out 4 green cards

guests proceed to seat in East Room

2 MOC cards

Rep. Sherrod Brown (D-OH)

Rep. Diana DeGette (D-CO)

LADIES AND GENTLEMEN

MRS. CLINTON ACCOMPANIED BY

SECRETARY DONNA SHALALA,

DR. NANCY DAVIDSON AND MS. FRAN VISCO

LADIES AND GENTLEMEN

MRS. CLINTON ACCOMPANIED BY

SECRETARY DONNA SHALALA,

DR. NANCY DAVIDSON AND MS. FRAN VISCO

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

General

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

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

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

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

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

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

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

The Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammograms to older women of low income. For more information on how

to get a free or low-cost mammogram and the nearest location, women should contact their local health department or the National Cancer Institute's Cancer Information at 1-800-4-CANCER. Through March 1998, the program has provided more than 1.7 million screenings.

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

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

Scientists understand now more than ever before how a healthy breast cell becomes cancerous, how breast cancer spreads, and why some tumors are more aggressive than others.

We have translated these discoveries into therapies that improve cancer-free survival and initiated the Office of Cancer Survivorship at NCI to help improve the quality of life for those continuing to live with the disease.

With new interagency collaborations and forging private-public partnerships, we have refined technologies for detecting and diagnosing breast cancer and launched awareness and education campaigns targeted at older, low income and minority women usually – who tend to have the highest breast cancer

mortality rates, and improved outcomes and supportive care during and after treatments for patients.

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

In recent years, intensive research into all aspects of breast cancer has led to a flurry of

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

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

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

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

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

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

Specific

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

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

- Q. Should all women take tamoxifen?**

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

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

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

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

Q. Has tamoxifen been overblown?

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

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

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

A. In an effort to foster interagency collaborations among breast cancer programs across the federal government, the Federal Coordinating Committee on Breast Cancer was established as a liaison to the National Action Plan on Breast Cancer. The Federal Coordinating Committee was designed to ensure collaboration between the National Action Plan and other government and

non-government agencies and organizations conducting breast cancer activities while the FCC is solely a government coordinating effort, the National Action Plan on Breast Cancer has focused on forging partnerships with the private sector. The groups are developing more complementary activities so that all parts of the government and private sector can be unified to find a cure for breast cancer.

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

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

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

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

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

Q. How can a woman join the STAR trial?

- A. Women can be put on a mailing list to receive information about STAR by Internet (<http://www.nsabp.pitt.edu>), by mail (National Surgical Adjuvant Breast and Bowel Project, Box 21, Pittsburgh, PA 15261), or by fax

(412-330-4660). Once the trial has begun, women can get information from NCI's Cancer Information Service at 1-800-4-CANCER and the NCI web site for clinical trials information (<http://cancertrials.nci.nih.gov>).

Christy Macey 6-5709

HILLARY RODHAM CLINTON
REMARKS TO BREAST CANCER AWARENESS MONTH EVENT
THE WHITE HOUSE
OCTOBER 21, 1998

It's a great pleasure to join the President in welcoming all of you to the White House, as we come together to ^{mark} recognize Breast Cancer Awareness Month. All of you here have been such powerful voices in the fight against breast cancer, and today, we will celebrate how far we've come in that fight -- and renew our pledge to the task before us. But right now, I want to introduce someone whose decision to take time out of his busy schedule -- this of all days -- to join us is an indication of his commitment to this cause, and to all of you. He wants to highlight some of the important Congressional victories we have just gained -- some of which will have a direct impact on the work that all of you do, day in and day out, to improve the health of America's women. It is a pleasure to introduce to you a person who has been a great champion for the cause of breast cancer, my husband, President Bill Clinton. in the budget

[President speaks]

I want to thank the President for that good news briefing, and again, to express my appreciation to all of you for joining us today. Think how far we've come. When I was a college student, a diagnosis of breast cancer was the equivalent of a death sentence. Today, breast cancer is at the forefront of the nation's health care agenda -- and we have made tremendous strides in preventing, detecting, and treating this disease. That progress could not have happened without the tireless work and commitment of all the people in this room.

Today, we have with us leading breast cancer advocates (including ...); researchers and scientists; corporate sponsors of the Medicare Mammography Initiative; women's health advocates; and top representatives from our federal agencies, including Dr. Harold Varus of NIH, and representatives from the Department of Defense -- who I'd like to ask to stand. I also want to acknowledge the cancer survivors who have joined us -- who are daily reminders of how early detection can save lives. m

A special word of thanks to our speakers this afternoon: Secretary Shalala -- whose unflagging leadership within the Administration has led to major improvements in the health and well-being of America's children and families; Dr. Nancy Davidson -- Director of the Breast Cancer Research at the Johns Hopkins Oncology Center, who represents the many dedicated scientists and researchers across the country who are making extraordinary strides in our fight against breast cancer.

We will also hear from Fran Yisco -- whose private courage and public advocacy on behalf of women with breast cancer is renowned far beyond the walls of this room. In addition to her leadership of the National Breast Cancer Coalition, she's the co-chair of the National Action Plan on Breast Cancer, and serves on the President's Cancer Panel. I'm so pleased she's just been named to the Integration Panel of the Department of Defense Breast Cancer Research Program.

I will never forget the day in 1993 when Fran and so many other passionate breast cancer advocates came here to the White House -- to this room -- armed with the signatures of 2.6 million Americans demanding national action on breast cancer. The ~~public/private~~ partnership that grew out of that meeting, the National Action Plan on Breast Cancer, has worked tirelessly since then to reach its ~~goal~~: the complete eradication of breast cancer.

~~I'm proud that the Clinton Administration has developed strong, working relationships with both the advocacy community and the private sector to reach this goal.~~ And today, I'm proud to release a report highlighting the Administration's accomplishments, and the progress we've all made together in the fight against breast cancer.

First, the Administration has taken the lead in dramatically boosting its investments in cancer research. And these ~~investments~~ have helped lead ^{been} to historic breakthroughs -- including the identification of new breast cancer genes, and promising new treatments. The FDA has recently approved two new drugs -- Herceptin and Taxol -- which will help slow the spread of the disease. Another drug -- Tamoxifen -- has shown to dramatically reduce the incidence of breast cancer in women at high risk for the disease. We celebrate the lives we know will be saved or prolonged by these new scientific discoveries.

Second, the Administration has expanded the availability and quality of prevention tools like mammograms. Too often, women just can't afford the ~~mammograms~~ that could save their lives. This year, thanks to Administration leadership, Medicare began covering annual mammograms for all beneficiaries 40 years and older -- and is making them more affordable. We've also spearheaded a series of unprecedented outreach initiatives -- to make sure older women take advantage of the mammography benefits offered by Medicare.

Third, the Clinton Administration has worked hard to improve access to treatment and quality of care for women with breast cancer. The President has proposed that Medicare cover clinical trial costs -- and we are making it easier ~~easier~~ for physicians to enroll patients in clinical trials. Acknowledging the terrible and persistent racial disparities in treatment, access to care, and general health -- the Administration has ~~proposed~~ an initiative to address racial health inequities in six major areas -- including cancer. And Congress has ensured we can take the first step toward that goal -- by authorizing \$30 million for the President's initiative. And finally, building on the unprecedented efforts begun at the Department of Defense and the FDA -- the National Cancer Institute is ~~fully integrating~~ patients and advocates into the process of setting the nation's research agenda.

Working together, we've brought breast cancer mortality rates down markedly here in the United States -- a decline of 4.5 percent between 1991 and 1995. And we should be proud of that accomplishment. Yet as every person in this room knows all too well -- breast cancer remains the second leading cause of cancer deaths among American women. Today, one in eight women will develop breast cancer; up from one in 20 just two decades ago. This year alone -- approximately 180,000 new cases will be diagnosed, and the disease will claim nearly half a million lives in this decade.

Clearly, we cannot rest on our accomplishments. We must instead rededicate ourselves to the task of preventing, treating, and one day curing breast cancer -- which continues to take such a terrible toll on our own lives, on our communities, and on our nation.

Toward that end, I'm very pleased to announce a number of very important new steps that this Administration is taking to build on and expand our record of progress.

First, as the President just noted, we are making an historic new investment in cancer research. As part of today's budget agreement, Congress has made a significant down-payment on the President's multi-year proposed funding for the National Institutes of Health. And here, I'd like to acknowledge the pivotal role that Vice President Gore has played in pushing for these new resources. As a result of the combined efforts of the President and the Vice President, the National Cancer Institute will receive a total budget of \$2.9 billion in fiscal year 1999 -- a record increase. Those new funds will enable NCI to explore new efforts to pinpoint who is at risk for cancer; develop new interventions to prevent and treat cancer -- and enhance the chances of cancer survival.

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increase

Second, I'm pleased to announce a major new clinical trial of drugs that have the potential to reduce the risk of developing breast cancer. The trial will involve 22,000 women at about 400 sites across the country and Canada -- and will build on the success of previous breast cancer prevention trials by examining two new drugs which have shown promise in reducing the risk of getting breast cancer. I also want to highlight an ongoing trial at NIH that is examining the relationship between diet and disease, which is already showing that what we do -- in our daily lives -- can decrease the chance of getting cancer.

about

that Third, we are launching an expanded outreach and education campaign that will help ensure America's older women get recommended mammograms. It will build on government and private efforts that have been going since I first announced the campaign in 1995. This year, HHS will focus particular attention on low income and minority women -- who continue to suffer disproportionately when it comes to breast cancer. And here, I want to recognize the private sector partners of the Medicare Mammography Initiative -- with special thanks to our national sponsors, Avon, Eli Lilly, and Zenecca, and our corporate supporters: American Greetings, the National Association of Chain Drug Stores; the Food Marketing Institute; 1-800-FLOWERS; the American Association of Health Plans, Direct Selling Association, the Florida Association of HMOs, the National Community Pharmacists Association -- and Pitney Bowes.

I want to take a moment to acknowledge a number of breast cancer survivors who are with us today -- including Hazel Parego (PA-RAH-GO); Zora Brown; and Jean Camak -- a White House volunteer. Alfreda [AL-FREE-DA] Elzie is another survivor here today. She's 47; and an African American. Unfortunately -- that means she's more at risk than many for breast cancer. Luckily, she got the last slot of the day at her church for a free mammogram, which she received from the George Washington Mammovan.

As a result of that first screening, Alfreda was diagnosed with very early breast cancer -- and was treated here in Maryland -- thanks to the Breast Treatment Program paid for by the cigarette Tax. She's finished her therapy -- and is doing fine. Her story is a powerful reminder that early detection can save lives.

I want to thank Jean Lynn, who I believe is also here today. She runs the breast cancer/mammogram van program that in its first two years alone has provided 4,000 screenings to women like Alfreda throughout the DC area. Those working on the frontlines in our communities to help prevent and detect cancer -- dedicated individuals like Jean -- deserve our deepest thanks and appreciation.

Today, we are facing a critical juncture in the fight against breast cancer. Our national commitment is beginning to pay off, as we witness dramatic progress against the disease.

Now is the time to push even harder. To redouble our efforts to pass a strong, enforceable Patients' Bill of Rights; to fight for laws that will end discrimination against individuals based on their genetic information; to end racial disparities that place minority women at far greater risk for dying of breast cancer; to increase access to clinical trials; and to continue to integrate advocates into planning the nation's cancer research agenda. And most importantly -- to support research that builds on the dramatic breakthroughs of the past few months and years. Then -- and only then -- can we truly hope to prevent, detect, treat, and one day cure this cancer that strikes so many of America's women.

And now, I would like to introduce Fran Visco, who has done so much to bring that day closer.



FAX TRANSMISSION

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Office of the Secretary

DATE: 10/20/98

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**Draft Remarks for Secretary Shalala
Breast Cancer Event with First Lady
October 21, 1998**

Let me briefly underscore the remarkable progress we've made against breast cancer -- and the challenges ahead.

As many of you are aware, a controversial exhibit on Sigmund Freud just opened at the Library of Congress.

And as we know, it was Freud who posed the glib question: "What do women want?"

Well, I believe the answer is quite simple.

Women want us to *stand up*...to *step up*...and to never *give up* on their rights and their families.

Women want us to take up their health care concerns.

And when it came to breast cancer, women want us to rise up and fight this disease with everything we've got.

Over the past five years, that's exactly what we've done. And we've stepped up in every creative way possible to defeat breast cancer.

We stepped up to break down the barriers that once divided agencies, actions and efforts against the disease.

And we built a network -- a power grid against breast cancer—that connects and flows through the First Lady's Office to my office...

...to the corridors of the Pentagon and the headquarters of NASA...

...to the labs of our best universities and hospitals...

...to the broadcast airwaves, the boards of private foundations and boardrooms of corporate America -- and right into American homes, hearts and minds.

We stepped up against breast cancer by addressing the demands of prevention, treatment and research.

And we stepped up by boosting the National Cancer Institute with a historic funding increase that will unlock the dark secrets of this disease and shed light on new treatments...

...decode the genetic causes of breast cancer...

...disarm the disease before it starts...

...discover new risk factors and how to treat them...

...And determine not just the causes but the cures.

By stepping up, we've posed ourselves on the brink of a new millennium that offers a brave new world for any woman who faces the fear of breast cancer.

We have much to celebrate.

But until we finally reach that brave new world...

...Until there are no breast cancer survivors—only statistics...

...Until this shadow of this disease is lifted from every woman's life...

...Our challenge is to keep fighting this disease with everything we've got.

What women want is to keep this challenge on our national agenda, and in our minds, our conscious, and our subconscious.

That's what Breast Cancer Awareness Month is all about.

It's why another great First Lady, Betty Ford, helped launch the very first breast cancer awareness campaign 14 years ago.

It's why, every year, we race for the cure with our feet and our science.

It's why, every day, we celebrate the survivors and take strength from our memories of those who succumbed.

And it's why, every day, we want every woman, everywhere, to know how to avoid the risks and save their lives.

One day we will win the race for the cure, the race against this cancer.

...we will consign it to the history books...

...we will remove it from our daughter's lives...

..and we will erase it from every woman's psyche..

10/20/98

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breast cancer.doc

M. Patrick

Because in the words of Eleanor Roosevelt, "What one *has* to do...can be done."

And now I'd like to return the podium to someone who truly understands what women want, our First Lady, Hillary Rodham Clinton.

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DRAFT**Outline and Talking Points****Nancy Davidson, M.D.****White House Breast Cancer Awareness Month Event****October 21, 1998**

- **My name is Nancy Davidson and I am director of the Johns Hopkins Oncology Center's Breast Cancer Program.**
- **I would like to thank Mrs. Clinton, Secretary Shalala and Fran Visco for inviting me to talk about new and promising research for breast cancer.**
- **In my practice as a medical oncologist, I treat women with breast cancer and, as the breast cancer research chair in oncology, I oversee basic research and clinical trials related to breast cancer conducted at Johns Hopkins.**
- **This year, a record number of cancer research results have been reported:**
 - **For example, the Tamoxifen Prevention Trial found that the drug, Tamoxifen, currently used to treat breast cancer, actually prevented breast cancer from occurring in women at high-risk for the disease.**
 - **The drug Raloxifene is reported to have similar preventative effects as Tamoxifen, but without the increased risk of developing endometrial cancer. Studies are now underway to compare both of these drugs.**
 - **Now available to breast cancer patients, the drug, Herceptin, has been shown to help women with advanced breast cancer by targeting a gene that nearly a third of all women with breast cancer have.**

DRAFT



- **At the annual meeting of the American Society of Clinical Oncology, it was reported that Taxol, currently used for treating women with advanced cancer, was shown to reduce the death rate in early stage breast cancer patients, when combined with standard anti-cancer drugs.**
- **As a clinician and researcher, it is gratifying to see years of research yield such great advances in the treatment of breast cancer. Advances in molecular biology have brought us a new understanding about the genetic basis of cancer. This knowledge has led the way for technological developments as well as new and improved therapies that hold promise for the future.**
- **For instance, in our work at Johns Hopkins, we have focused on two types of molecular changes – the detection of an enzyme called telomerase, and the changes in the pattern of DNA methylation in the breast cells.**
- **Telomerase is an enzyme that plays a crucial role in the processes of aging and cancer. Highly sensitive tests now exist to measure the activity of the telomerase enzyme. We at Hopkins, and others, have shown that telomerase is detected in virtually all invasive breast cancers as well as in insitu ductal cancers. It is seldom detected in normal breast cells. Thus, telomerase has the potential of serving as a screening tool in breast cancer.**





- **It is important to stress that progress in laboratory research is valuable only if we can translate it to patient care. Clinical trials are essential to this process.**
- **The state of Maryland recently passed the most comprehensive legislation in the country that requires insurance companies to pay the costs that patients have when enrolled in a clinical trial. This is an important step in helping to overcome the barriers to participating in a clinical trial.**
- **Clearly, we have a long way to go before we can say that breast cancer is no longer a threat to women's health. But, as we approach the new millenium, we have a vast arsenal of knowledge and understanding that will enable us to achieve the great goals we continue to set for ourselves and our patients.**





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MEMO BY FACSIMILE

To: Patrice Stanley, Office of Intergovernmental Affairs
The White House
FAX (202) 456-2889

From: Jubi D. Headley, Jr. *Jubi*
Assistant Executive Director

Subject: Breast Cancer Awareness Month Ceremony (attachments)

Date: October 20, 1998

Per our conversation, I'm faxing you the following:

- A full list of Mayors and cities who have joined the United States Conference of Mayors Campaign Against Breast Cancer (204 as of this moment). Please do let me know exactly how this list will be used and/or distributed during the White House ceremony; and
- A copy of our October 1998 *Breast Cancer Information Exchange* report, "Mayors work with American Cancer Society." It's our hope that this publication might be distributed during tomorrow's ceremony, and again, per our conversation, I understand you'll seek a response to this request from appropriate White House staff.

I also understand that you've invited several Mayors to attend tomorrow's ceremony, including Mayor Oberndorf of Virginia Beach, Mayor Mullins of Palatine, Mayor Flores of Laredo, and Mayor Corradini of Salt Lake City, also our Conference President.

Given that Mayor Oberndorf is unable to attend, and that the other Mayors you've invited may not be able to travel the significant distance required on such short notice, I'd appreciate the chance, should none of these Mayors be available, to reach out to other Mayors who might be able to attend. Please let me know whether this is possible.

Finally, I'd also like any information you have on tomorrow's event (an agenda and/or press release will do).

If you have any questions, please call me directly at (202) 861-6707.

I look forward to hearing from you.

Attachments (2)



THE UNITED STATES CONFERENCE OF MAYORS

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As of October 20, 1998, 204 mayors have joined the campaign.

MEMBERS OF THE MAYORS' CAMPAIGN AGAINST BREAST CANCER

CITY	STATE	MAYOR
Tuscaloosa	AL	Alvin DuPont
Hot Springs	AR	Helen Selig
Little Rock	AR	Jim Dailey
Scottsdale	AZ	Sam Kathryn Campana
Tempe	AZ	Neil G. Giuliano
Yuma	AZ	Marilyn R. Young
Alameda	CA	Ralph Appezato
Alhambra	CA	Barbara A. Messina
Artesia	CA	Timothy J. Keleman
Berkeley	CA	Shirley Dean
Beverly Hills	CA	Meralee Goldman
Camarillo	CA	Charlotte Craven
Compton	CA	Omar Bradley
Culver City	CA	Sandra Levin
Gardena	CA	Donald L. Dear
Gonzales	CA	Elizabeth Williams
Hemet	CA	Robin Reeser Lowe
Huntington Park	CA	Jessica R. Maes
Livermore	CA	Cathie Brown
Long Beach	CA	Beverly O'Neill
Los Angeles	CA	Richard Riordan
Monte Sereno	CA	Suzanne Jackson
Piedmont	CA	Craig Lundin
Richmond	CA	Rosemary M. Corbin
San Bernardino	CA	Judith Valles
San Diego	CA	Susan Golding
San Francisco	CA	Willie L. Brown, Jr.
San Leandro	CA	Shelia Young
San Rafael	CA	Albert J. Boro
Santa Barbara	CA	Harriet Miller

Santa Clara	CA	Judy Nadler
Santa Cruz	CA	Celia Scott
Seaside	CA	Don R. Jordan
Visalia	CA	Wally Gregory
Watsonville	CA	Dennis Osmer
West Hollywood	CA	Steve Martin
Westminster	CA	Frank Fry
Arvada	CO	Robert G. Frie
Colorado Springs	CO	Mary Lou Makepeace
Denver	CO	Wellington E. Webb
Lakewood	CO	Linda Morton
East Hartford	CT	Timothy D. Larson
Meriden	CT	Joseph Marinar
New Haven	CT	John DeStefano, Jr.
Norwalk	CT	Frank J. Esposito
Stamford	CT	Dannel Malloy
West Haven	CT	H. Richard Borer, Jr.
Washington	DC	Marion Barry, Jr.
Hollywood	FL	Mara Giuliani
Key West	FL	Sheila K. Mullins
Miami Beach	FL	Neisen Kasdin
Miami Shores Village	FL	Mary Ross Agosta
Ocala	FL	E. L. Foster
Pembroke Pines	FL	Alex G. Fekete
Tamarac	FL	Joe Schreiber
Atlanta	GA	Bill Campbell
East Point	GA	Patsy Jo Hilliard
Chalan Pago-Ordot	Guam	Rossana San Miguel
Hawaii	HI	Stephen K. Yamashiro
Idaho Falls	ID	Linda Milam
Arlington Heights	IL	Arlene J. Mulder
Carol Stream	IL	Ross Ferraro
Chicago	IL	Richard M. Daley
Chicago Heights	IL	Angelo A. Ciambone
Elgin	IL	Kevin Kelly
Evanston	IL	Lorraine H. Morton
Freeport	IL	Jim Gitz
North Chicago	IL	Jerry L. Johnson
Oak Park	IL	Barbara Furlong
✓ Palatine	IL	Rita Mullins
St. Charles	IL	Sue Klinkhamer
Springfield	IL	Karen Hasara
Village of Niles	IL	Nicholas B. Blase
Bloomington	IN	John Fernandez
Columbia City	IN	Joseph R. Zickgraf

East Chicago	IN	Robert A. Pastrick
Elkhart	IN	James P. Perron
Fort Wayne	IN	Paul Helmke
Gary	IN	Scott King
Hammond	IN	Duane W. Dedelow
Muncie	IN	Dan C. Cannan
New Albany	IN	Douglas England
Cedar Rapids	IA	Lee R. Clancey
Des Moines	IA	Preston A. Daniels
Kansas City	KS	Carol S. Marinovich
Bowling Green	KY	Eldon J. Renaud
Frankfort	KY	William I. May, Jr.
Alexandria	LA	Edward G. Randolph, Jr.
Monroe	LA	Abe E. Pierce, III
Portland	ME	Thomas Kane
Annapolis	MD	Dean L. Johnson
Baltimore	MD	Kurt L. Schmoke
Amesbury	MA	Nicholas J. Costello
X Boston	MA	Thomas M. Menino 496-9610 Virginia Meyer
Chicopee	MA	Richard J. Kos
Lawrence	MA	Patricia A. Dowling
Leominster	MA	Dean Mazzarella
Lynn	MA	Patrick J. McManus
Malden	MA	Richard Howard
Newton	MA	David B. Cohen
Quincy	MA	James Sheets
Revere	MA	Robert J. Haas, Jr.
Taunton	MA	Robert G. Nunes
Waltham	MA	William F. Stanley
Westfield	MA	Richard K. Sullivan, Jr.
Worcester	MA	Raymond V. Mariano
Dearborn	MI	Michael A. Guido
Detroit	MI	Dennis W. Archer
Flint	MI	Woodrow Stanley
Kalamazoo	MI	Robert B. Jones
Lincoln Park	MI	Frank M. Sall
Pontiac	MI	Walter Moore
Southfield	MI	Donald F. Fracassi
Eden Prairie	MN	Dr. Jean L. Harris
Minnetonka	MN	Karen Anderson
St. Louis Park	MN	Gail A. Dorfman
Greenville	MS	Paul C. Artman, Jr.
Jackson	MS	Harvey Johnson, Jr.
Meridian	MS	John Robert Smith
Chillicothe	MO	Jerry Wilford

Columbia	MO
St. Louis	MO
St. Charles	MO
Lincoln	NE
Omaha	NE
Bayonne	NJ
Belleville	NJ
Cherry Hill	NJ
Clifton	NJ
Edison	NJ
Elizabeth	NJ
Gloucester Township	NJ
Hamilton	NJ
Hoboken	NJ
Hope	NJ
Montclair	NJ
Orange	NJ
Sayreville	NJ
Trenton	NJ
Washington Township	NJ
West Orange	NJ
Woodbridge	NJ
Albuquerque	NM
Rio Rancho	NM
Roswell	NM
Las Vegas	NV
Brighton	NY
Hempstead	NY
Mount Vernon	NY
Syracuse	NY
White Plains	NY
Concord	NC
Gastonia	NC
Winston-Salem	NC
Fargo	ND
Grand Forks	ND
Akron	OH
Cincinnati	OH
Cleveland Heights	OH
Columbus	OH
Dayton	OH
Kettering	OH
Mansfield	OH
Newark	OH
Strongsville	OH

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Breast Cancer Information eXchange



October 1998

Mayors Work with American Cancer Society

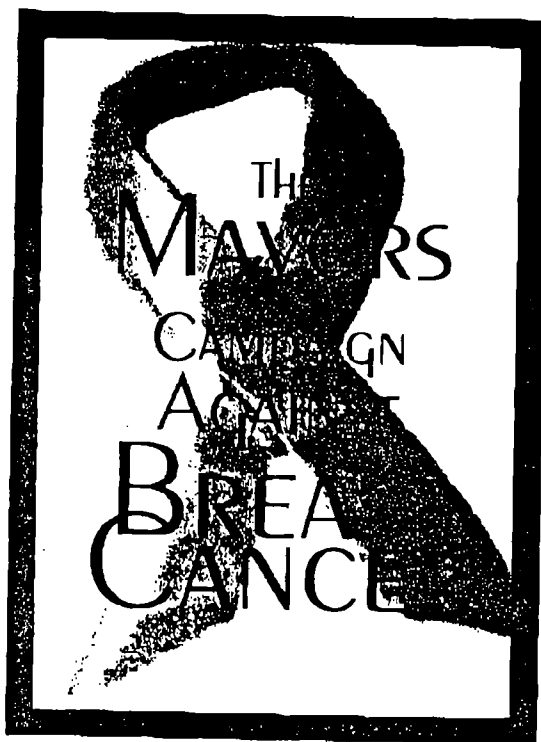
In developing the Mayors' Campaign Against Breast Cancer, The United States Conference of Mayors (USCM) found that cities had forged strong links with local offices (called units) of the American Cancer Society (ACS) to conduct awareness, screening and follow-up initiatives to address this disease. USCM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

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

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

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

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



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District of Columbia - American Cancer Society

A Model for Collaboration

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

Members of the Mayors' Campaign Against Breast Cancer

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However, it is known that early detection and treatment can reduce breast cancer deaths by one-third in women fifty years and older. The mayors' collaborative efforts with their local ACS units have been so significant -- as exemplified by Philadelphia, Boston, Virginia Beach, and Washington, D.C. -- that the national ACS is giving full support to the Mayors' Campaign Against Breast Cancer.

In addition to the *Information Exchange*, other Conference of Mayors publications such as *USMAYOR* and special editions of *Best Practices for Cities* are allowing the mayors to share their experiences in addressing breast cancer. Other means of exchanging perspectives include related activities at USCM's annual and winter meetings; and one-on-one contacts with the Conference staff and cities participating in the campaign.

The Mayors' Campaign grew out of a successful breast cancer awareness forum at the 1997 Winter Meeting, supported by CDC and co-chaired by Mayors Meyera Oberndorf of Virginia Beach and James Garner of Hempstead, New York. Following this forum, the Mayors designated breast cancer as a priority issue in 1997 and recommended that a session be held at the 1997 Annual Meeting to plan for a long-term Mayors' initiative against this disease. At that session, supported by CDC and ACS, the mayors called for a national campaign against breast cancer. If you would like more information about the Mayors' Campaign Against Breast Cancer, please contact Richard C. Johnson, Director of Health Programs for the Conference, at 202/861-6753. The campaign is continuous, so mayors may join at any point during the five-year initiative.

ACS Support for the Mayors' Campaign Against Breast Cancer

"The American Cancer Society (ACS) is pleased to collaborate with the United States Conference of Mayors (USCM) in its campaign against breast cancer with the Centers for Disease Control and Prevention (CDC). In 1996, a survey of mayors found that 85 percent were working with the ACS in their communities. The ACS has been proud to continue that relationship through the USCM/CDC cooperative agreement. From press conferences and rallies to educational programs and screening projects for high-risk, underserved populations, the nation's mayors and the American Cancer Society have made a difference by working together."

A. Marilyn Leitch, M.D., Immediate Past-President
Texas Division, ACS
Associate Professor of Surgery
The University of Texas Southwestern Medical Center

(Dr. Leitch made these remarks at "A Multicultural Approach to Breast Cancer Awareness and Outreach," a forum co-sponsored by the ACS and Zeneca HealthCare Foundation for the Mayors' Campaign Against Breast Cancer -- held on June 19, 1998 in Reno, Nevada at the 1998 Annual Meeting of The United States Conference of Mayors.)

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Mayors and ACS Promote Breast Cancer Awareness

Across the country, mayors are taking the lead with their local ACS units to encourage women to seek screening for early detection of breast cancer. Following are descriptions of successful and representative collaborations in Philadelphia, Boston, and Virginia Beach that can offer inspiration for new efforts in the national initiative against this disease.

Philadelphia Mayor Rendell Helps ACS Launch Breast Cancer Partnership

Philadelphia Mayor Edward Rendell has worked closely with the ACS on a number of cancer control activities, especially in promoting breast cancer awareness for the Delaware Valley area. To this end, he took a lead role with the ACS in the October 1997 press conference that announced the Breast Cancer Partnership -- a united effort of key organizations and groups in the Delaware Valley dedicated to:

- educating women about the importance of breast cancer screening and early detection;
- increasing awareness about the availability of breast cancer resources and services in the area; and
- assisting women in finding no-cost/low-cost screening services.

Each of the member organizations of the Breast Cancer Partnership has agreed to share appropriate resources and refer women to the variety of services in the Delaware Valley. All members participate in quarterly planning meetings and in various Partnership events and activities. Although there may be areas of duplication, the groups are committed to sharing resources for increased awareness and utilization of screening services, especially among underserved groups (such as racial and ethnic minorities, low-income women, and seniors).

Since the kickoff press conference with Mayor Rendell, the groups have coordinated a number of program activities, published a reference brochure for health care agencies, and are currently developing a user-friendly pamphlet for the general public. Judge Midge Rendell,



Philadelphia Mayor Rendell at October 1997 press conference, with ACS representatives and others, announcing Breast Cancer Partnership

the mayor's wife, has also been active locally with Breast Cancer Partnership organizations. This October, the Partnership will report back to the mayor on its one-year progress.

City-Wide Mobile Mammography

Mayor Rendell has also been a longtime supporter of a highly successful mobile mammography program that brings lifesaving services directly to the women who need them most. ACS has sponsored this program since 1990, in cooperation with the Philadelphia Department of Health and the Fox Chase Cancer Center, to provide screening for eligible women enrolled in the city's eight District Health Centers.

Supported by the Pew Charitable Trusts, the program now screens over 1,000 women each year. ACS provides additional funding, training and personnel. The latter are volunteers who work with city employees and physicians at Fox Chase Cancer Center to deliver breast screenings and to insure follow-up procedures and treatment when necessary.

"For many women who take advantage of our mobile mammography program, this is their first mammogram," said Harriet Carter, RT, MHS, former Radiology Services administrator at the Philadelphia Department of Health. "Teaching people that it is within their power to change something, to take control, or change a behavior, that's a gift."

"Access to health care should not be a luxury. Giving women the tool they need to detect early breast cancers

empowers them; it lets them make something happen for themselves. That's so positive."

Relay for Life

In addition to breast cancer initiatives, Mayor Rendell supports other ACS activities, such as Relay for Life, a 24-hour event to raise cancer awareness and funds for a wide range of programs, including patient service, research, and advocacy. This unique event allows participants from all walks of life to join together to fight cancer. The Relay reminds us that progress has been made against cancer and that everyone who participates is making a difference.

Boston Mayor Menino Saves a Life from Breast Cancer

Because of his participation in the campaign against cancer, Boston Mayor Thomas Menino has already helped to save a life. In the fall of 1997, he signed an ordinance allowing four hours of time off per year for all municipal employees to receive appropriate cancer screening. The ACS worked with his office to establish the criteria and develop the supporting collateral materials. As a result of his action, one employee had her first mammogram, and an early stage breast cancer was discovered. Prompt treatment has given the employee a cure.

BankBoston joined Mayor Menino and allotted the same amount of time off for its employees. The Mayor and BankBoston issued a challenge to the business community in the greater Boston area to follow their lead. In an editorial, the *Boston Herald* endorsed the challenge and called for more corporations to follow suit.

Task Force for "Cancer-Free City"

In February of this year, Mayor Menino built upon and expanded his breast cancer efforts by naming a Cancer Control Task Force. Comprised of representatives from the ACS and the public health, medical, business, and cancer survivor communities, the task force is developing a comprehensive plan (due by the end of November) to make Boston "a cancer-free city."

"We know that we can prevent cancer and have taken many steps to eradicate this terrible disease," the mayor said. "But there is more we can do to give people access.



Boston Mayor Menino launching Cancer Control Task Force in partnership with ACS

"This task force will identify who's not getting screened, determine what the obstacles are, and develop a strategy to reach each and every one of these people."

Task Force co-chair David Mulligan, who chairs the Boston Public Health Commission, said that "looking closely at access issues is clearly part of our public health agenda."

During the announcement of the task force, ACS presented Mayor Menino with an award for his leadership on cancer prevention. Donald J. Gudaitis, chief executive officer of the ACS New England Division, saluted the mayor for his vision.

"The appointment of the Cancer Control Task Force will insure that the residents who live in the shadows of Boston's great medical institutions will have equal access to their lifesaving services," said Gudaitis. "As a partner in the cancer control initiative, we pledge our support to increase access to cancer prevention, early detection, and treatment for all Boston residents."

Neighborhood Mammography

The mayor continued his efforts on Boston Public Health Day this spring, when he announced that the City of Boston had purchased two public health vans, one for family health and one for mammography. The mammography van will be operated by the Public Health Commission in cooperation with ACS, Partners HealthCare System, Dana Farber Cancer Institute, and Mobile Diagnostics.

Yvedt Matory, MD, the ACS breast care leader for the Boston area, thanked the mayor and the Boston Public

Health Commission for recognizing the need to make this important contribution to the health of Boston women, thereby helping to break down the barriers to early breast cancer diagnosis. She said the ACS, Dana Farber Institute, and Partners HealthCare are collaborating with Mobile Diagnostics to expand the number of days that mobile mammography is available to Boston health centers, an action that will provide mammograms to an additional 1,600 women. Dr. Matory added that the new van would take the groups another step closer to insuring that all women have access to early cancer detection services.

"Your actions today give us all cause for hope," she told the mayor. "As a surgeon at Brigham and Women's Hospital and a researcher in the field of breast cancer, I see women every day who are surviving because their cancer was diagnosed in its earliest stages. But I also see women who did not have access to health care and mammography, and their struggle against breast cancer is an uphill battle against lost time.

"We can save women's lives," Dr. Matory said. "And every woman in Boston, regardless of her insurance status or her income, should have an equal chance to beat this disease. This initiative helps us give women that chance."

Leadership on Fund-Raising

Boston area ACS staff call Mayor Menino an outstanding supporter of their work. The mayor has made numerous public appearances in support of the Society's cancer control efforts. And thanks to the mayor's leadership, City of Boston employees have sold more daffodils than any other business or organization in the region, as part of ACS's Daffodil Days, a fundraising program that equates this first sign of spring with a sign of hope for cancer patients.

Meyera Oberndorf Survives Breast Cancer And Reaches Out To Others

At this year's American Cancer Society Relay for Life, Virginia Beach Mayor Meyera Oberndorf said of the event, "This proves that one can have a diagnosis of cancer, live well, and survive for many years. People don't have to walk alone in their reach to recovery. There are many people ready to reach out and help."

Mayor Oberndorf speaks from personal experience with the disease. She is a breast cancer survivor who has not let it stop her from serving her community. When she announced her diagnosis, she said that she would continue to serve in office and run for a third term, which she did, and won.

Her personal bout with the disease had a very public and positive effect. The result was that she was able to persuade women not to postpone breast cancer screenings or to become complacent about the disease. She also offered a strong message of hope.

"People should not feel isolated," Mayor Oberndorf said. "They shouldn't feel guilty and shouldn't feel it is something that they caused."

She played a lead role in establishing the Mayors' Campaign Against Breast Cancer and continues to be an inspiring advocate within USCM for her fellow mayors to assume leadership on breast cancer issues.

Long-Term Support for ACS

Mayor Oberndorf has brought that same passion to efforts in Virginia Beach and to her work with organizations like the ACS and the Breast Cancer Coalition, a collaboration between the ACS and the Virginia Beach Department of Public Health. As part of last year's Breast Cancer Awareness Month observance, Mayor Oberndorf read a proclamation at the Lights of Life celebration, a candle-lighting for breast and cervical cancer survivors, sponsored by the Breast Cancer Coalition.

The Coalition also gathered signatures on a mile-long pink ribbon



Virginia Beach Mayor Meyera Oberndorf holding the Breast Cancer Awareness stamp poster at the May 1996 South Hampton Roads Relay for Life

called the Ribbon of Love. This activity was part of the Every Woman's Life Campaign, a public awareness campaign begun by a grant from the CDC and supported by former Virginia Governor George Allen and his wife Susan.

Mayor Oberndorf also backs the Beach Health Clinic, a free clinic that has been a breast cancer screening site under ACS grants. The clinic's screening program is now administered by Virginia Beach General Hospital and Sentara Health System, using a grant from the CDC's Breast and Cervical Cancer Early Detection Project.

Willing to go to any lengths to promote breast cancer awareness, Mayor Oberndorf even climbed a ladder to place a pink ribbon on the city's first Boston Market outlet. But she has long been active with organizations like the ACS, well before her own diagnosis.

For years, Mayor Oberndorf has spoken at ACS events, and local staff say that she deserves a lot of recognition for her efforts. Now that she is a breast cancer survivor, the Mayor makes a significant contribution to her community every day by showing that breast cancer hasn't stopped her from making a difference.

Building Upon Past Collaborations

From press conferences and rallies to educational programs and screening projects for high-risk populations, individual mayors and the ACS have made a difference together. But the ACS would like to do more.

In building upon previous efforts, ACS can provide access to cancer control information and materials. The ACS National Cancer Information Center at 1-800-ACS-2345 and web site at www.cancer.org offer the best information available on a wide variety of cancer-related topics.

ACS also offers contacts to other groups in the cancer control community. For example, the ACS has been providing assistance and resources to organizations whose constituencies include low-income Americans in order to address the cancer-related needs of these populations.

And ACS also has ready-made programs that can play a role in a city's breast cancer awareness activities:

- **Reach to Recovery** is a visitation program for

women with breast cancer. Trained volunteer breast cancer survivors offer support to the newly diagnosed and recent breast cancer patients.

- **I Can Cope** is a patient and family cancer education program. It consists of a series of classes providing information about the disease, as well as assistance in coping with the physical and emotional challenges involved.
- **Look Good...Feel Better** is a program designed to teach female cancer patients beauty techniques to help restore their appearance and self-esteem during cancer treatment. The Cosmetic, Toiletry and Fragrance Association and the National Cosmetology Association are partners in this program.
- **Relay for Life** is a unique event that allows participants from all walks of life to join together to fight cancer. The Relay is a reminder that progress has been made against cancer and that everyone who participates is making a difference.

These are just a few things that can be considered in planning breast cancer activities. Local ACS representatives can offer more information on ways to collaborate.

Good News About Cancer Rates, But Challenges Lie Ahead

This is an exciting time for everyone involved in the field of cancer control. In March of this year, the ACS joined the National Cancer Institute and the Centers for Disease Control and Prevention in delivering a Progress Against Cancer Report Card to the nation.

The overall news was very good. Data show that incidence rates from all cancer sites combined are decreasing. Cancer death rates for all sites are also decreasing.

The report also shows that incidence rates declined for:

- most age groups
- both men and women
- most racial groups

The decline in mortality was greater for men than it was for women, but there were declines in both groups. Just about all racial and ethnic groups are included in the downturn of cancer deaths.

If we look at breast cancer specifically, we see our successes and the challenges we face. After increasing rapidly from 1973 to 1990, breast cancer incidence was level from 1990 to 1995. Breast cancer mortality, also previously on the rise, has dropped

over the past five years, but only for White and Hispanic women. Breast cancer death rates remained level for Black women, and, sadly, may be on the rise for Asian and Pacific Islander women.

The report card did not address socioeconomic groups. Within the groups addressed by the report card are poor and underserved populations who face many barriers to receiving adequate prevention, screening, detection, and treatment measures.

A recent study found that different rates of mammography screening appear to be at the root of differences in breast cancer prognoses between older Black and White women. For women who regularly had mammography, the stage at which cancer was most commonly diagnosed was the same for Whites and Blacks. But Black women were three times less likely in general to undergo mammography screening. Consequently, they were two and a half times more likely than White women to be diagnosed with late-stage breast cancer.

Studies like these point out that while we are enjoying overall success in fighting cancer, there is still much more to do, especially for the poor and underserved. Collaborations like the one between USCM and the ACS are important for reaching more women.

District of Columbia - American Cancer Society, A Model for Collaboration

The ACS National Capital Council, District of Columbia Unit in Washington, D.C., offers an example of a national and local collaboration for breast cancer education and services to the citizens in a high-risk community. Mayor Marion Barry, Jr., and his wife, Cora Masters Barry, have given visible and strong support to these cooperative efforts due to their understanding of the need for breast cancer screening. The mayor is a prostate cancer survivor and promotes all cancer awareness extensively.

American Cancer Society and Local Collaborators

The ACS unit works with a broad network of partners to shape a Breast Health Education Program, including government agencies and officials, local and national health and consumer organizations, women's groups, health care providers and health institutions. By collaborating with these partners and others, ACS is delivering information through established messengers to reach women where they live and work.

Urgent Message to Women: "Do the Right Thing: Get a Mammogram"

The program started by emphasizing the message: "Do the Right Thing: Get a Mammogram." This message was directed at the underserved women in Wards 7 and 8, the location of the ACS unit. Forty percent of the women living in Ward 7 and 60 percent of the women living in Ward 8 had not had a mammogram. ACS estimated that the total annual cost of the preventable mortality was way out of proportion to other wards in the city.

Because women often manage health care for their whole family as well as for themselves, they represent a pivotal target for health-related messages. They need to know more about important issues such as preventing breast cancer mortality, following recommended guidelines, keeping track of scheduled appointments with doc-

tors, and getting appropriate professional advice.

Pilot Activities

The "Do the Right Thing: Get a Mammogram" program was piloted at the Greater Southeast Community Hospital in Washington, D.C. Each month educational programs were conducted in community locations where high-risk women lived, worked or worshipped.

Partner organizations hosted or handled the logistics for the events, and ACS provided a local coordinator and materials. The partner organizations were enthusiastic about the message and were ingenious with their event ideas. The program received the support of the Mayor in the form of proclamations and the participation of public health officers. Community advocates were interviewed about the activities on local radio and television programs.

Church bulletins, newsletters and similar publications advertised free mammography screening and also explained its importance. Women who have participated in the mammography screening program were featured in promotions, encouraging other women to get involved and take charge of their health.

Hospital health educators served as liaison between the community and the ACS unit. They prepared and educated women about mammography, breast self-examination and clinical breast examinations, and provided follow-up. These pilot activities laid the foundation for a continuous campaign.

Campaign Roll-Out

Building on the success of the pilot activities, as described above, the ACS unit has developed a strategy to provide continuous breast health education and screening to women in the service area. Organizations, businesses and individuals in the community are encour-



Washington, DC Mayor Barry, lends support to ACS events throughout the capital city.

aged to plan an activity of their choice. For example, senior outreach programs in the community are identified; education seminars are conducted within the senior facility; mammograms are scheduled at the Greater Southeast Community Hospital; and the hospital health educators conduct follow-up that includes treatment for diagnosed women who are uninsured or underinsured. Posters and displays are regularly distributed through senior centers, churches, public housing developments, beauty salons, community centers, PTA meetings and health care facilities (such as health clinics, hospitals, doctors' offices and dental clinics).

Among the activities proven successful are:

- **Workshops** - Educational sessions that include a discussion of mammography screening, breast self-examinations and clinical breast examinations, and breast cancer treatment.
- **Roundtable and Panel Discussions** - Health professionals describe the services they provide and discuss breast health issues.
- **Booths** - At health fairs or other large gatherings, a health professional staffs a booth and discusses breast health issues.
- **Brown bag lunches** - At work or public meeting places, a health professional discusses breast health with employees during their lunch hour. Women from the community who may not work are also invited to attend and participate in the discussion.

Other ACS local partners include:

- **Organizations** - Professional or trade associations, religious or ethnic organizations, business/social clubs, and community/school-related groups provide venues for communicating about breast cancer awareness.
- **Merchants** - Even today's busiest women shop for essentials at the supermarket, the pharmacy, the dry cleaner or laundry. Posters and brochures are available at these locations.
- **Workplaces** - Many workplace display areas are used to disseminate information.
- **Senior Centers and Outreach** - Many of the women who need breast health information are older. Senior centers and other programs that reach out to older women are key resources for spreading information

about breast health.

- **Greater Southeast Community Hospital and Race for the Cure** - Proceeds from DC's Race for the Cure provide free and low-cost mammograms depending upon patient eligibility.

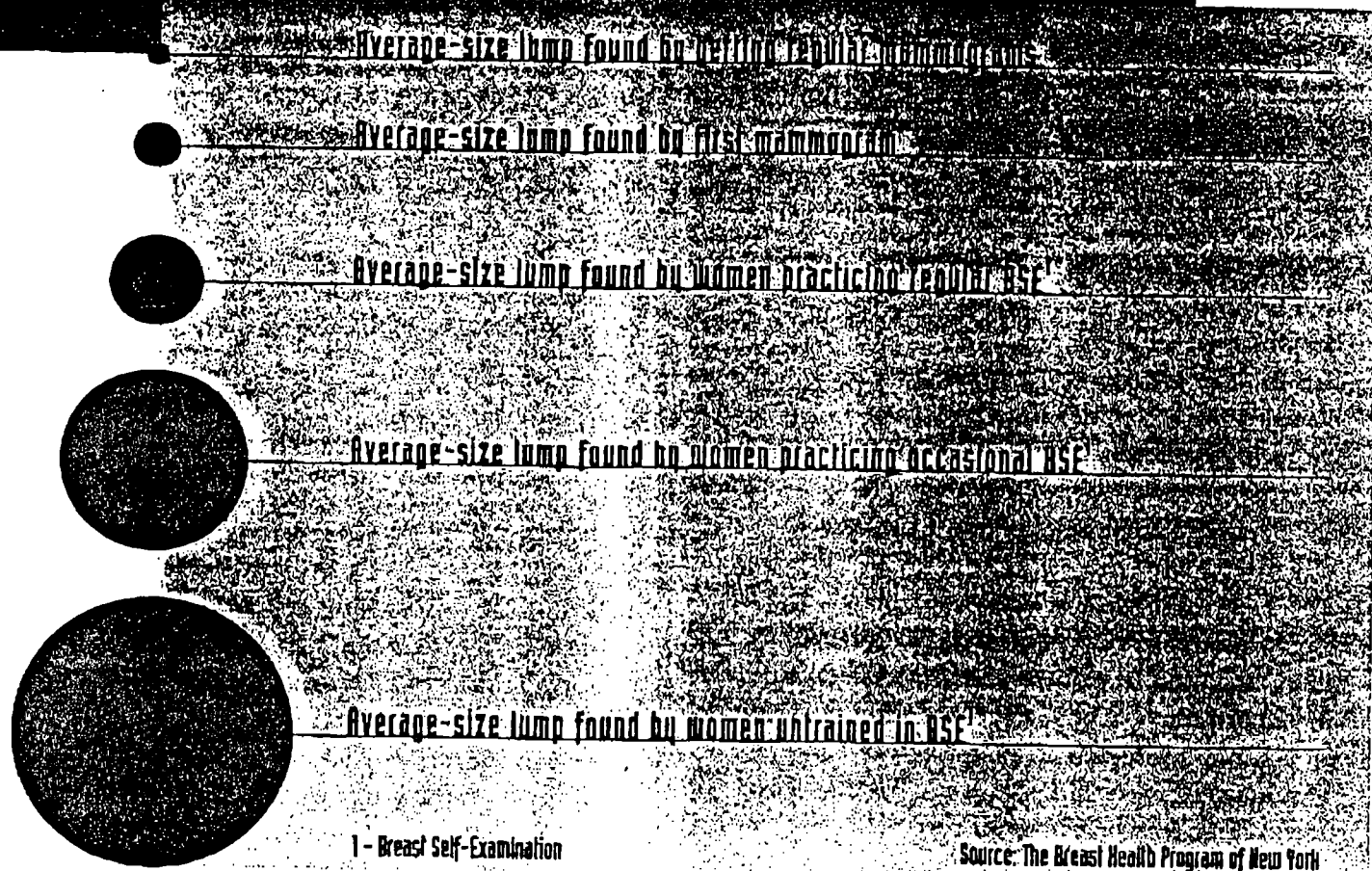
Campaign materials include the following:

- Brochures; flyers; insert cards; refrigerator magnets; bookmarks; and publication lists.

For more information, contact: Deborah Barnes, member of the D.C. Unit Board. Ms. Barnes, who is a health educator, may be reached at Greater Southeast Community Hospital, 1310 Southern Avenue, S.E., Washington, D.C. 20032, telephone: 202/574-5444.

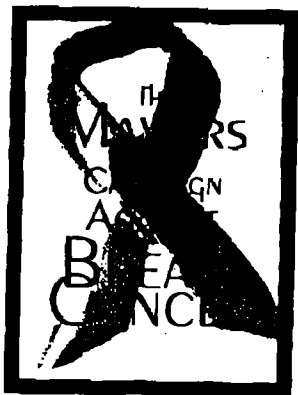
Zora Kramer Brown is Chairperson and Founder of the Breast Cancer Resource Committee (BCRC), which is based in Washington, D.C. A fourth generation breast cancer survivor, Ms. Brown started BCRC in response to the immense need in the African American community for increased education and understanding about breast cancer risk factors, the importance of early screening and detection, and the availability of successful treatment options and support.

Size of tumors detected by mammography



October 1998

BREAST CANCER INFORMATION EXCHANGE



CALL TO JOIN THE MAYORS' CAMPAIGN AGAINST BREAST CANCER

1. I want to join the Mayors' Campaign Against Breast Cancer to establish or expand coalitions, initiatives, and/or other activities for early detection and control.

_____ Yes

_____ No

_____ Not at this time

Mayor _____ city _____ state _____

- 1a) If yes, my staff contact person will be:

name: _____ title _____

agency: _____

mailing _____

address: _____ city _____ state _____

phone: _____ FAX: _____

- 1b) If yes, my city may be contacted by other cities for information about our programs.

_____ Yes

_____ No

Please return by FAX: 202.887.0652
to: Richard Johnson, Director, Health Programs,
U.S. Conference of Mayors
or by mail to:
Richard Johnson, Director, Health Programs,
U.S. Conference of Mayors
1620 Eye Street, N.W., 4th floor,
Washington, D.C. 20006

Thank you!



Cancer Screening Could Save 13,000 African American Lives

52,000¹
Deaths

25%

reduction of
deaths from
breast
cancer²

39,000
Deaths

In this decade, the number of African American women who die from breast cancer could be reduced by 25% if 80 percent followed the National Cancer Institute's Breast Cancer Screening Guidelines during the next ten years.

1 - Estimated deaths for the coming decade

2 - Projected reductions

Source: The National Cancer Institute, 1991

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



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 20 1998

MEMORANDUM FOR THE PRESIDENT

Marking National Breast Cancer Awareness Month, I am pleased to present to you *Breast Cancer: A Report on the Fight to Prevent, Cure, and Treat the Disease*

In these last five years, we have seen great strides toward the eradication of breast cancer. In 1993, at your request, I convened the Conference to Establish the National Action Plan on Breast Cancer (NAPBC). The NAPBC, a public-private partnership, serves as a catalyst for national efforts in six priorities areas identified through the conference, including biological resources, breast cancer etiology, hereditary susceptibility, clinical trials, information dissemination and consumer involvement. I also convened the Federal Coordinating Committee on Breast Cancer in 1994. The FCCBC, a liaison group to the NAPBC, fosters collaboration and cooperation in cross-cutting initiatives and reduces unnecessary duplication of effort in breast cancer programs.

As you read this report, I hope you will be pleased at the breadth of breast cancer activities across the Administration. While we have achieved much, we must recognize the work that lies ahead. Thank you for your continued leadership and commitment to this public health priority.

A handwritten signature in black ink, appearing to read "D. Shalala", is centered below the text.

Donna E. Shalala

Attachment

Breast Cancer:
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Prevent, Treat, and Cure the Disease

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Breast Cancer:

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

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

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

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

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

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

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

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

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

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

OVERVIEW

Background

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

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

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

Declining Mortality Rates

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

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

Increased Funding

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

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

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

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

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

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

SCIENTIFIC PROGRESS IN THE FIGHT AGAINST BREAST CANCER

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

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

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

Advances in Prevention

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

New Drugs Approved that will Save Lives. A true medical breakthrough has been the discovery of a breast cancer prevention agent -- Tamoxifen -- earlier this year. This drug has been shown

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

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

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

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

Advances in Treatment

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

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

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

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

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

Taxol. Early findings of a large, NCI multi-center trial show that the drug Taxol, when used in combination with other standard chemotherapy agents, has a small but significant benefit for breast cancer patients whose disease has spread to nearby lymph nodes. Although the survival advantage is small at this point in the trial, the study is considered important because it is the first to show that Taxol may be beneficial in the initial, post-surgical treatment of some women with localized, node positive breast cancer.

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

Environmental Factors and Breast Cancer. In August 1994, the DHHS Public Health Service's Office on Women's Health established a Federal Interagency Coordinating Committee on the Environment and Women's Health that focuses on how home, work, atmospheric pollutants, exogenous hormones, drugs, and other environmental factors may contribute to the risk of breast cancer and other disorders. Studies supported by the NCI and National Institute for

Environmental Health Sciences (NIEHS) are currently underway on the role of the environment in cancer risk in the northeast and mid-Atlantic portions of the U.S. These studies are testing the risk from organochlorine compounds, PCBs, and estrogen-like chemicals, such as DDT, DDE, and other pesticides. To date, there does not seem to be increased risk of breast cancer from these chemicals overall. However, there are some groups of women who may be more susceptible to the effects of DDT. For example, women who never breast-fed and some women who have certain genetic alterations may be at increased risk if exposed to these chemicals. Likewise, some forms of PCBs (called congeners) may be more estrogenic, making them possible risk factors for breast cancer. Studies are needed on exposures during a woman's childhood or adolescence, when she is more vulnerable to chemical exposures.

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

Advances in Detection

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

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

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

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

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

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

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

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

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

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

research on biological mechanisms, that can improve our understanding of the natural history of breast cancer.

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

Further Research Steps to a Cure

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

Marking Progress

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

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

Other Federal Research Activities

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

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

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

COMMITMENTS TO EARLY DETECTION OF BREAST CANCER

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

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

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

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

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

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

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

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

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

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

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

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

QUALITY OF CARE AND ACCESS TO TREATMENT

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

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

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

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

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

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

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

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

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

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

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

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

NEW APPROACHES IN ADDRESSING THE DISEASE

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

National Action Plan on Breast Cancer

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

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

Accomplishments of the NAPBC include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Federal Coordinating Committee on Breast Cancer

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

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

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

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

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

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

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

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

Other Collaborations

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

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

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

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

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

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

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

organizations, social service and voluntary organizations, and academia.

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

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

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

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

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

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

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

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

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

CHALLENGES AND NEW FRONTIERS

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

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

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

WHSO Layout Draft 5
a/o 10/21/98; L. Schwartz, 10:00 a.m.

BREAST CANCER PREVENTION EVENT
Wednesday, October 21, 1998
East Room

EV Gate Opens:	3:00 p.m.		
Invite Time:	3:30 p.m.		
Principal Time:	3:30 p.m.	Brief	Elevator, State Floor
	3:35 p.m.	Meet	Blue Room
	3:40 p.m.	Event	East Room
	4:30 p.m.	Meet #2	State Dining Room

Approx. 160/Open Press/Business Attire
10 Social Aides

SET UP NOTES GROUND FLOOR: coat check in family theater.
GRAND FOYER/STATE FLOOR: string combo with piano in Grand Foyer, Honors Group in Foyer for announce.
BOOKSELLERS: one table with cloth for distribution of two packets from the National Cancer Institute for guests on departures.
EAST ROOM/EVENT: 10x16 stage at gold curtain; Toast lectern in East Room; WHCA Announce from Blue Room; water at podium; 2 Press risers on both sides of cross hall doors; press pool to provide lighting for the East Room.
BLUE ROOM MEET: furniture removed from Blue Room for meet and greet; WHCA announce for program; screens up between parlor rooms.

2:55 p.m. IN PLACE TIME

3:00 p.m. East Visitors Gate opens and guests proceed to the State Floor and are seated in the East Room.

3:30 p.m. **THE PRESIDENT and THE FIRST LADY** arrive at the elevator on the State Floor and are briefed.
Contact: Jennifer Kleig

3:35 p.m. **THE PRESIDENT and THE FIRST LADY** proceed to the Blue Room to meet event participants.

Blue Room

Secretary Shalala

Dr. Nancy Davidson, Associate Professor, Director, Breast Cancer Research Program at the John Hopkins Oncology Center

Fran Visco, President of the National Breast Cancer Coalition

3:40 p.m. **THE PRESIDENT** and **THE FIRST LADY** are announced into the East Room accompanied by Secretary Donna Shalala, The President of the National Breast Cancer Coalition Fran Visco and The Director of the Breast Cancer Research Program at the John Hopkins Oncology Center, Dr. Nancy Davidson.

PROGRAM BEGINS

THE FIRST LADY makes brief welcoming remarks and introduces **THE PRESIDENT**.

THE PRESIDENT makes remarks and departs.

THE FIRST LADY substantive remarks and introduces Fran Visco, The President of the National Breast Cancer Coalition.

Fran Visco, The President of the National Breast Cancer Coalition makes remarks and introduces the Director of the Breast Cancer Research Program at the John Hopkins Oncology Center, Dr. Nancy Davidson.

Dr. Nancy Davidson makes remarks and introduces Secretary Shalala.

Secretary Shalala makes remarks.

4:25 p.m. **THE FIRST LADY** returns to the podium to thank guests for coming and proceeds to the State Dining Room to meet Medicare Mammography Initiative Corporate Representatives.

4:30 p.m. **THE FIRST LADY** meets the following people in the State Dining Room.

State Dining Room

Mr. Harold Varmus, National Institute of Health
Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs

Medicare Mammography Initiative Corporate Representatives

Dagmar T. Farr, Food Marketing Institute
Jill Froula, American Greetings
Rebecca Snead, R.Ph., Virginia Pharmacists Association
Barbara Lardy, American Association of Health Plans
James P. Schlicht, Zenecca
Karen Miller, Zenneca
Richard Dorff, President, Florida Association of Health Maintenance Organizations, Inc.
Veronica Jacques, Direct Selling Association
Phil Schneider, Managing Director, Public Affairs National Association of Chain Drug Stores
Donna Rape, Division Sales Manager, Avon Products, Inc.
Homer Pearce, Eli Lilly, Inc.
Freda Lewis-Hall, Eli Lilly, Inc.
David M. Hendler, Director, Retail Operations
Nancy C. Yedlin, Pitney Bowes

4:40 p.m. **THE FIRST LADY** departs.

Guests depart East Gate.

BREAST CANCER EVENT (10/21)**Calligraphy****Name Cards - yellow**

The President

Mrs. Clinton

Secretary Shalala

Dr. Nancy Davidson

Fran Visco

Mayor Beverly O'Neill - front row seated

General Reserved Cards

4 pink reserved - survivors in front row

Names to be highlighted at gate - proceed to seat in East Room with pink card

Jean Camak, Washington, DC

Alfreda Elzie, Washington, DC

Hazel Parago (Pa - rah - go), New Castle, Delaware

Zora Brown, Washington, DC

16 blue reserved - State Dining Room guests - to be seated following meet

Guests will arrive NW gate and be escorted by Barbara Woolley

4 green reserved - DoD - Barbara Woolley will give out 4 green cards

guests proceed to seat in East Room

2 MOC cards

Rep. Sherrod Brown (D-OH)

Rep. Diana DeGette (D-CO)

LADIES AND GENTLEMEN

MRS. CLINTON ACCOMPANIED BY

SECRETARY DONNA SHALALA,

DR. NANCY DAVIDSON AND MS. FRAN VISCO

LADIES AND GENTLEMEN

MRS. CLINTON ACCOMPANIED BY

SECRETARY DONNA SHALALA,

DR. NANCY DAVIDSON AND MS. FRAN VISCO

F A C S I M I L E

DATE: 16 Sept 98TO: Neera TandenFAX#: 456-2878

FROM: Elizabeth Summy
Deputy Chief of StaffPhone: 202/690-7431 Fax: 202/401-5783

COMMENTS:*Here is the list.**Thanks*
*z*2 Pages [including this cover]

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Fax list re: SSNs and DOBs (partial) (1 page)	09/16/1998	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Eric Morse (Events)
OA/Box Number: 21192

FOLDER TITLE:

Breast Cancer October Event [1]

2011-0619-S

rc290

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

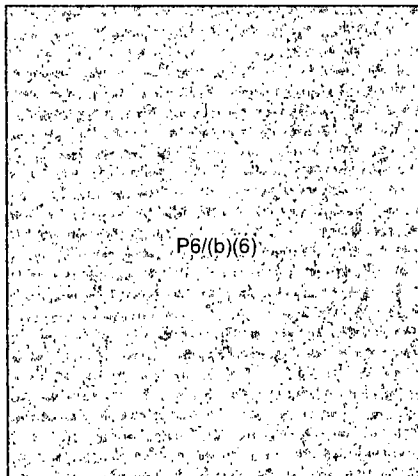
b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

HHS Elizabeth Summy
OWH Anna Kinderman
OWH Susan Wood
FDA Audrey Sheppard
NCI Paul Van Nevel
NCI Nelvis Castro
NCI Dr. Otis Brawley
HCFA James F. Coan



[001]



NATIONAL ACTION PLAN ON BREAST CANCER
A Public/Private Partnership

PHONE: (202) 401-9587
(202) 690-7650

FACSIMILE: (202) 401-9590

DATE: 16 Sept 98

TO: Neera Tandan

FROM: Elizabeth Carey

RECIPIENT'S PHONE: 456-6275

RECIPIENT'S FACSIMILE NUMBER: 456-2878

COMMENTS: Attached please find the NABPC fact sheet. If you have any questions, please do not hesitate to call me at 401-9581 or my colleague Anna Kundermann at 401-1170.

NUMBER OF PAGES: (Including cover) 3

If any problems arise with this FAX transmission, please call Loretta Jones at (202) 401-9587



NATIONAL ACTION PLAN ON BREAST CANCER A Public/Private Partnership

F A C T S H E E T

BACKGROUND

Breast cancer is the second leading cause of cancer deaths among American women. Nearly 179,000 women will be diagnosed with breast cancer in 1998, and more than 43,000 are expected to die from the disease.

In 1993, the National Action Plan on Breast Cancer (NAPBC) was initiated in response to the National Breast Cancer Coalition's 2.6 million signature petition calling for a coordinated national strategy to combat breast cancer through public/private partnerships. President Clinton asked the U.S. Department of Health and Human Services to respond, and in December 1993, Secretary Shalala convened the Secretary's Conference To Establish a National Action Plan on Breast Cancer. The conference brought together more than 300 individuals, including breast cancer advocates, consumers, clinicians, scientists, government officials, educators, and members of Congress and the media, to craft a series of recommendations for action in education, research, public policy, and service delivery. From this conference, a Steering Committee of government and nongovernment representatives was formed to build necessary public/private partnerships and to guide a comprehensive national plan to eradicate breast cancer.

MISSION AND STRATEGY

The mission of the NAPBC is to stimulate rapid progress in eradicating breast cancer by advancing knowledge, research, policy, and services. The Plan serves as a catalyst for national efforts, coordinating activities of government and nongovernment organizations, agencies, and individuals. By encouraging new ideas and mobilizing partnerships, the Plan strives to "jump-start" innovative, long-term efforts that will result in rapid progress in the fight against breast cancer.

ORGANIZATION

Reflecting its unique public/private partnership, the NAPBC has one Co-Chair from the public sector and one from the private sector. Frances M. Visco, Esq., President of the National Breast Cancer Coalition, serves as the private sector Co-Chair. Wanda K. Jones, Dr.P.H., Deputy Assistant Secretary for Health (Women's Health) in the U.S. Department of Health and Human Services, serves as the public sector Co-Chair. The NAPBC Steering Committee includes government and nongovernment representatives from research, policy, health care, breast cancer advocacy, and industry organizations. The Committee establishes NAPBC priorities, guides implementation of initiatives, and ensures coordination across priority areas. Six Working Groups have been established to identify and implement specific initiatives within these priority areas. The U.S. Public Health Service's Office on Women's Health coordinates the implementation of activities and oversees day-to-day operations of the Plan.

PLAN ACTIVITIES AND WORKING GROUP PRIORITY AREAS

NAPBC Grant Program

In 1995, the NAPBC awarded \$9.2 million in small grants and grant supplements for innovative research and outreach projects in each of the Plan's six priority areas. Special emphasis was placed on the development of public/private partnerships in the design and implementation of these projects. Project outcomes are being integrated into ongoing Working Group activities.

Information Action Council Working Group

The Information Action Council (IAC) is identifying strategies to disseminate information about breast cancer, using state-of-the-art information technologies available on the Internet. This group developed and continues to maintain the NAPBC Web site, also available in Spanish, which provides information about Plan activities and is a central gateway to breast cancer information on the Internet. The IAC also

oversees the Bridging the Gap Initiative pilot project, in which community-based organizations link informationally underserved women with breast cancer information available through the Internet. Future activities for the IAC include developing a Web-building toolkit for local breast cancer organizations.

National Biological Resource Banks Working Group

This Working Group has advanced efforts to establish a national inventory of biological specimen banks to facilitate breast cancer research. The group conducted a needs assessment focused on determining the nature and extent of the need for biological resources. In addition, the group developed guidelines for the ethical use of biological tissues in breast cancer research, including a model informed consent form and institutional review board principles of operation. These products have been adopted by the National Cancer Institute and Public Responsibility in Medicine and Research, respectively, for further development and implementation.

Consumer Involvement Working Group

This Working Group has successfully outlined issues related to the involvement of consumer advocates in all aspects of breast cancer service delivery, education, policy, and research. In partnership with the National Alliance of Breast Cancer Organizations and the National Breast Cancer Coalition, the group developed and implemented surveys to explore the nature of the involvement of breast cancer patients and survivors, their representatives, and those at high risk for breast cancer in consumer organizations and in cancer centers. A final report on the results will serve as the basis for future group activities.

Breast Cancer Etiology Working Group

The goal of this Working Group is to expand the scope and breadth of biomedical, epidemiological, and behavioral research activities related to the etiology of breast cancer. This group has convened workshops to review the current state of knowledge and to develop research recommendations in the areas of viruses, hormones and the environment, physical activity, medical ionizing radiation, and electromagnetic fields and light-at-night. The group also has developed and focus group tested the Breast Cancer Comprehensive Questionnaire, a series of high-quality questionnaire modules, along with short and long versions of a core questionnaire, that can be used to clarify emerging risk factors and to enable meta-analyses. Future activities include finalizing and disseminating the comprehensive questionnaire and convening workshops on gene-environment interactions and on multicultural aspects of breast cancer etiology.

Clinical Trials Accessibility Working Group

This Working Group is examining ways to make clinical trials more widely accessible to women with breast cancer and women who are at higher risk for breast cancer. It has reviewed extensively the literature on barriers to participation in clinical trials and is developing strategies to overcome these barriers. To implement one such strategy, this group is conducting patient and physician focus groups to prepare a public awareness campaign about clinical trials. Efforts also are under way to evaluate and improve health care providers' and consumers' access to information about breast cancer clinical trials.

Hereditary Susceptibility Working Group

Members of this Working Group are addressing the fast-moving social, ethical, and legal issues related to genetic testing. They produced and distributed over 30,000 copies of the video, *Genetic Testing for Breast Cancer Risk: It's Your Choice*, and, in partnership with many professional organizations, they developed an educational curriculum, *Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals*. This group also has convened workshops to identify urgent research priorities in breast cancer susceptibility and on privacy and confidentiality in genetics research. In addition, this group is spearheading efforts to establish policies to prevent workplace and health and life insurance discrimination based on results from genetic testing.

FOR MORE INFORMATION CONTACT:

National Action Plan on Breast Cancer ■ U.S. Public Health Service's Office on Women's Health
Room 718F ■ 200 Independence Avenue, SW ■ Washington, DC 20201
Phone (202) 401-9587 ■ Fax (202) 401-9590 ■ <http://www.napbc.org>





National Action Plan on Breast Cancer

1996 Summary of Accomplishments: A Report to the Steering Committee

Background

The National Action Plan on Breast Cancer (NAPBC) is a unique public-private partnership that serves as a catalyst for national efforts to coordinate actions by government and nongovernment organizations, agencies, and individuals to advance breast cancer knowledge, research, policy, and services. The NAPBC was initiated in response to the National Breast Cancer Coalition's 2.6 million-signature petition calling for a coordinated national strategy to combat breast cancer, the second leading cause of cancer deaths among American women. By encouraging new ideas and mobilizing partnerships, the NAPBC strives to "jump-start" innovative, long-term efforts that will result in rapid progress against breast cancer. The work of the NAPBC is guided by a Steering Committee and six Working Groups. Implementation of the NAPBC is coordinated by the U.S. Public Health Service's Office on Women's Health (PHS OWH) within the Department of Health and Human Services.

A Year of Achievement

1996 marked a year of important achievements for the NAPBC, primarily in implementing initiatives to address the priorities of the Plan, but also in building an infrastructure to facilitate Working Group activities. Each of the six Working Groups of the NAPBC were very active in defining specific plans of action and implementing a broad range of initiatives. The second year of the NAPBC grants program was also completed. These Working Group activities put into practice the strategies and goals of the Plan to catalyze and jump-start actions to advance knowledge, research, and policy.

In addition, the Steering Committee addressed necessary infrastructure issues by developing an operating plan, a strategic planning process, and a new budget monitoring system and establishing several ad hoc groups to address ongoing issues related to membership, budget, evaluation, and public-private partnerships. These support mechanisms provided the foundation for involving government and nongovernment representatives at all levels of the implementation of the NAPBC. Although many important operating policies and decisions were made during the year, they are not the focus of this report. This report provides an overview of the NAPBC Working Groups' accomplishments to further national efforts to eradicate breast cancer.

The Working Group on Hereditary Susceptibility

This Working Group is implementing a comprehensive plan to address the needs of individuals carrying breast cancer susceptibility genes and to address the need for education among consumers, health care professionals, and at-risk patient groups. During the past year, the Working Group examined a broad range of critical issues related to genetic susceptibility to breast cancer. The Group:

- *Developed an educational video that explores the clinical and psychosocial issues of cancer predisposition testing.* This video was designed to assist consumers make informed choices about genetic testing. It presents emotional issues and personal choices that face women and families considering genetic testing through personal stories of breast cancer survivors as well as experts' presentations of the pros and cons of testing. Focus groups were convened in December to assess the video's effect and success in delivering its intended messages. Input from these focus groups confirmed that the video

provided a well-balanced overview of the issues. The Susan G. Komen Foundation and the American Cancer Society have expressed interest in helping to market and distribute the video.

Jump-Starting Progress:

The Hereditary Susceptibility Working Group

For many women, the exciting scientific advances to enable the identification of genes that increase the risk of getting breast cancer create a great personal dilemma: Should they be tested and possibly risk insurance and workplace discrimination? The Hereditary Susceptibility Working Group has moved rapidly on several fronts to provide information to assist women in making decisions about genetic testing, educate health professionals about genetic predisposition to cancer, identify research issues requiring immediate attention, and stimulate national policies to protect women and their families.

- *Developed on outline for an educational curriculum on hereditary susceptibility issues for health care providers.* The curriculum was based on nine objectives identified by the Working Group and refined with input from participants in a workshop in April. Cosponsored by the American Society of Clinical Oncology (ASCO), the workshop included representatives of a broad range of health care provider organizations representing physicians, nurses, genetic counselors, social workers, psychologists, and psychiatrists. The cancer genetics core curriculum outline has been disseminated to more than 30 major health care provider organizations for review and endorsement. Several organizations already have begun using the outline to develop curricula for their members.

- *Identified research priorities related to hereditary susceptibility to cancer and strategies for addressing these priorities* during a research workshop in September. The resulting recommendations focused on four areas: basic science, genetic epidemiology, prevention and treatment, and psychosocial issues. Workshop participants included consumer activists representing multiple and diverse perspectives, representatives from the National Cancer Institute (NCI) and the National Center for Human Genome Research (now the National Human Genome Research Institute), and researchers with expertise in each of the four listed disciplines.

- *Conducted a workshop on genetic information in the workplace* in October that was attended by more than 80 people. National policy recommendations to prevent employment discrimination based on genetic information were drafted based on the workshop.

NAPBC Actions To Advance Policy

- *Published an NAPBC position paper on genetic testing in the Journal of Clinical Oncology.*
- *Conducted a workshop and developed national policy recommendations about use and misuse of genetic information in the workplace.*
- *Conducted a workshop and developed policy recommendations about health insurance discrimination and genetic predisposition to cancer.*
- *Worked and continue to work with the National Cancer Institute, National Institutes of Health (NIH) Office on Protection From Research Risks (OPRR), Public Responsibility in Medicine and Research (PRIM&R), and NIH Office of Research on Women's Health to address policies on informed consent.*
- *Provided testimony before a U.S. Senate hearing on genetic testing and privacy issues.*

- *Conducted a conference titled Consumer Leadership Summit: Preparing for the New Era of Genetics and Medicine in December to empower consumers to take action about emerging genetic susceptibility issues. Cosponsored by the National Breast Cancer Coalition, the conference was attended by more than 120 people representing women's health and breast cancer advocacy groups and women's professional and labor organizations. A followup plan will further extend the discussions at the conference into the community and will include sample articles for individuals to submit to their local newspapers and organizational newsletters.*

- *Developed a position paper on hereditary susceptibility testing for breast cancer that was published in the *Journal of Clinical Oncology*. This paper addresses such issues as requiring education for health care providers, informed consent for individuals considering being tested, and prevention of genetic discrimination.*

The Clinical Trials Accessibility Working Group

- *Provided testimony before a U.S. Senate hearing on genetic testing and privacy issues addressed in the Kennedy-Kassebaum health care bill, including protection of privacy of genetic information. Testimony was provided by Working Group members representing government, industry, health care providers, and legal and ethical perspectives.*

- *Developed a Working Group Action Plan to identify and guide the group's activities for the year.*

Mobilizing Partnerships:

Breast cancer clinical trials are critical to the development of new and more effective treatments and prevention strategies. These clinical trials rely on the participation of breast cancer patients and those at risk for breast cancer. Currently, however, only a small percentage of all eligible cancer patients participate in these important research trials. One of the many complex reasons women do not participate is that they may not be knowledgeable about clinical trials. The Clinical Trials Working Group is building necessary partnerships to address this problem by bringing together consumers, scientists, government representatives, health care providers, and health communications experts to increase the availability and user-friendliness of information about clinical trials and to centralize this information in a central registry.

The Clinical Trials Accessibility Working Group

This Working Group is finding ways to make clinical trials more widely accessible to women with breast cancer and women at risk for breast cancer. It is identifying 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 costs of participation. In 1996 the Working Group:

- *Coordinated efforts to enhance the accessibility and user-friendliness of existing information about breast cancer clinical trials.* Members met with NCI staff in May to discuss current clinical trials information systems, such as the Physicians Data Query and CancerFax. A meeting was convened in November to discuss the development of a central registry of breast cancer clinical trials. The meeting focused on encouraging partnerships, reducing the duplication of efforts by groups involved in developing registries, and maximizing the number of trials for which information is widely available to patients, health care providers, and other interested persons.
- *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 compiled into a critical review of the literature that will be submitted for publication in summer 1997.
- *Conducted a meeting in September of NAPBC grantees* studying various aspects of clinical trials recruitment.
- *Using information from the literature review and NAPBC grantee studies, developed 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.
- *Continued consensus-building efforts* with health insurance companies, hospitals, physicians, researchers, Federal agencies sponsoring research, industry, and consumer groups concerning reimbursement for breast cancer clinical trials and monitored the development of policies regarding insurance coverage of randomized controlled trials and informed consent issues.
- *Developed an Action Plan* that set the Working Group's objectives for the year and identified specific activities for implementation.

The National Biological Resource Banks Working Group

This Working Group has focused on establishing a national network of tissue banks to ensure a resource of well-characterized and documented biological materials for multiple areas of breast cancer research. In 1996, the Working Group:

- *Developed and disseminated a survey* to 12,000 researchers around the country to ascertain how much and what types of tissue are needed for breast cancer research. Data have been collected, and analyses are scheduled to be completed in the spring 1997. The results of this effort will be compiled in a database and made available to interested researchers over the Internet.

Catalyzing Action:***The Biological Resource Banks Working Group***

Research studies to understand all aspects of breast cancer biology depend on the availability of normal and breast cancer tissue. However, no national system for obtaining, storing, and registering the tissue available for use in research studies exist, and some researchers have difficulty obtaining tissue to address specific research questions. The Biological Resource Banks Working Group, in collaboration with consumers, scientists, government, and professional organizations, has conducted a series of initiatives to determine the availability and adequacy of existing sources of tissue, addressed ethical and legal issues involved in collecting and using biological materials, and built the foundation for a national breast cancer tissue banks network that can now be maintained by collaborating partners.

- *Convened a workshop in February to address ethical and legal issues related to the collection and use of biological tissue.* Meeting participants drafted a model informed consent form and Institutional Review Board (IRB) guidelines that were presented to a meeting of PRIM&R in May.

- *Completed extensive focus group testing of an informed consent form for tissue procurement, resulting in important modifications that will enhance the clarity of these complex issues.* A report of focus group results has been provided to the President's National Bioethics Advisory Commission and other groups addressing informed consent and patient's rights issues.

- *In collaboration with the National Cancer Institute, developed the Breast Cancer Specimen and Data Information System* and demonstrated the database at national breast cancer meetings. A brochure describing the system and how to access it also has been developed and is being disseminated to researchers across the country.

NAPBC Actions To Advance Research

- *Compiled an extensive database of currently funded breast cancer etiology research.*
- *Developed a publicly accessible database of available breast specimen resources for research.*
- *Developed a marketing plan for increasing recruitment to breast cancer clinical trials.*
- *Developed and initiated focus group testing of a six-module breast cancer core questionnaire to collect comparable data across studies.*
- *Published a special issue of Environmental Health Perspectives titled "Hormones, Hormone Metabolism, Environment, and Breast Cancer."*
- *Developed a model informed consent form for tissue procurement.*

- *Developed consensus recommendations about how tissue available for breast cancer research can be collected, stored, and deposited in a tissue bank for use by researchers.* Issues such as cost, consent, and record keeping were included. Recommendations were developed by participants at a September workshop.

- *Developed a Working Group Action Plan* to identify and guide the group's activities in establishing a national network of tissue banks.

The Etiology Working Group

This Working Group is focusing efforts on expanding the scope and breadth of biomedical, epidemiological, and behavioral research activities related to the etiology of breast cancer, particularly in

the areas of chemicals and hormones, lifestyle factors, ionizing and nonionizing radiation, viruses, and gene/environment interactions. In 1996, the Working Group:

- *Conducted a workshop in September to revise and integrate the modules of the breast cancer core questionnaire* that will enable comparisons across studies and clarify emerging risk factors. Sixty participants including scientists and consumers reviewed questionnaire modules, identified areas of overlap as well as unaddressed issues, and recommended modifications to be incorporated into the final six-module questionnaire. Focus group testing has started on two of the six modules.
- *Completed a supplement issue of Environmental Health Perspectives titled "Hormones, Hormone Metabolism, Environment, and Breast Cancer"*. Reports in this special issue resulted from presentations delivered at a workshop held last year. A separate manuscript summarizing unmet research needs, unresolved issues, and research recommendations has been prepared and will be submitted for publication.

NAPBC Actions To Increase Knowledge

- *Launched the NAPBC Web site.*
- *Developed an educational video on genetic testing.*
- *Designed a program to link the informationally underserved to the Information Superhighway.*
- *Developed a curriculum outline on hereditary susceptibility to breast cancer for use by health professional organizations.*

- In collaboration with the NCI, *compiled a database of currently funded breast cancer etiology grants* funded by the NAPBC, NCI, National Institute of Environmental Health Sciences, Department of Defense, and American Cancer Society. The database will be available through the NAPBC Web site in early 1997.

- *Initiated planning for three research workshops* to be held in 1997, each of which will address important issues in breast cancer etiology. The topics include:

- Viruses, virus-environment interactions, and human breast cancer;
- Electromagnetic fields, light-at-night, and breast cancer; and
- Ionizing radiation and breast cancer.

- Investigated methods to better coordinate and facilitate quick, appropriate response by Federal, State, and local agencies to areas where breast cancer is extraordinarily prevalent, including *the use of video conferencing at various breast cancer cluster sites* as an alternative to convening a single inperson meeting.

- *Developed a Working Group Action Plan* to identify and guide the group's activities during the year.

The Information Action Council

This Working Group is striving to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other information technologies. In 1996 the Working Group:

- *Launched the NAPBC Web site*, which was announced by President Clinton at a White House ceremony

on October 27. In its first month, almost 6,000 individuals accessed the site, 60 percent of whom were users from the United States. The site has been included in more than 30 search engines. Users have sent feedback forms to the NAPBC indicating that the Web site is useful and fills a gap in the current information about breast cancer available on the Internet.

- *Developed a Spanish-language version of the NAPBC Web site* that was launched in January.
- *Conducted 10 regional meetings* in October to assess interest in and the feasibility of teaming community-based organizations and private-sector partners to increase access to breast health information using the Information Superhighway. A report of these meetings and an activity plan were developed and approved by the Steering Committee in November.
- *Initiated development of a Request for Proposals (RFP)* to reach informationally underserved populations with breast cancer information through the Internet. It is anticipated that the RFP will be disseminated in February 1997.
- *Developed a Working Group Action Plan* to guide activities throughout the year.

The Consumer Involvement Working Group

Involving Consumers:

The Consumer Involvement Working Group

The past several years have brought many changes in how health issues are addressed. Among these changes is the increasing involvement of those affected by a disease in the development of national programs and policies. However, consumers are not yet an integral part of many health planning efforts. The Consumer Involvement Working Group is addressing this issue by gathering additional information on the nature and extent of consumer involvement in different organizations and programs to identify gaps in consumer involvement and opportunities for closing those gaps.

This Working Group is defining 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 Working Group seeks to increase and institutionalize consumer participation in ongoing research as well as the review of research for funding and to involve consumers in the design of service delivery and education programs. In 1996, the Working Group:

- *Developed and initiated implementation of a research plan* for a study to assess consumer involvement in activities in areas such as breast cancer research, service delivery, education and outreach, and public policy. Sampling lists and strategies for survey dissemination and data collection have been developed. The ultimate goal is to identify and implement ways to bridge the gaps between the current status and potential status of consumer involvement.
- *Developed a Working Group Action Plan*, which provides the foundation for Working Group activities.

NAPBC Grants Program

In addition to the workshops and initiatives described above for each Working Group, the NAPBC grant program completed its second year. Ninety-nine grants addressing each of the six NAPBC priority areas were funded in fiscal year (FY) 1996. The goals of the grant program were to:

- Provide support for novel, creative pilot program and outreach projects that would yield exceptionally important new information on breast cancer; and
- Support developmental, exploratory, or pilot projects that would serve as the basis for well-defined future research and outreach project applications on breast cancer.

Building Bridges:

The NAPBC Web site

In 1996, the NAPBC made important strides in advancing breast cancer knowledge, research, policy, and services. Information about these accomplishments and the ongoing actions of the NAPBC became more accessible with the launch of the NAPBC Web site by President Clinton. This Web site provides an important bridge between the NAPBC and its constituencies and serves as a gateway to public and private resources on the Internet. This site provides a rare opportunity to communicate directly with a national program and affords the NAPBC an exceptional opportunity to assess the public's interests and concerns and to respond appropriately.

Highlights of Upcoming Activities

Substantial progress was made in implementing NAPBC activities in 1996. Highlights of some of the upcoming NAPBC activities for 1997 include:

- The educational video on genetic testing will be completed, marketed, and distributed.
- The NAPBC Web site will be available in Spanish.
- A Request for Proposals will be issued for subcontracts to increase access among informationally underserved women to breast cancer information using the Information Superhighway.
- Three workshops will be conducted focusing on:
 - The role of viruses in the etiology of human breast cancer;
 - Ionizing radiation and breast cancer; and
 - Possible relationships between electromagnetic
- A video conference to link experts and consumers from various breast cancer cluster sites will be initiated.
- A marketing campaign to encourage enrollment in clinical trials will be developed and implemented.
- Analysis of data from questionnaires sent to 12,000 researchers will be completed to ascertain how much and what types of tissue are needed for breast cancer research.
- A demonstration of the Breast Cancer Specimen and Data Information System will be made at the American Association for Cancer Research meeting in April and an evaluation plan for the database will be developed.
- Focus group testing of the Breast Cancer Core Questionnaire will be completed.
- A draft of the report on the NAPBC study of breast cancer consumer involvement will be issued.

Search the Web Site

The NAPBC, a public/private partnership, is coordinated by the
PHS Office on Women's Health, Department of Health and Human Services.
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FAX TRANSMISSION

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COMMENTS:

These are both From
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url's are on the top.
Lauren

health care professionals, scientists, private industry, Congress, the media and Federal and State government agencies and represent an exciting opportunity to build public-private partnerships among these groups.

Fran Visco, President of the National Breast Cancer Coalition and myself serve as the CoChairs of the Plan. The PHS Office on Women's Health is coordinating the implementation of its activities working with a wide range of public and private organizations. The National Cancer Institute (NCI) with the outstanding leadership of Dr. Samuel Broder, and the CDC, most notably, the Breast and Cervical Cancer Early Detection Program, play a pivotal role in several of the Plan's activities. The Plan actions being given high priority over the next year include:

Establishment of an Information Action Council to address the role of the information superhighway in providing access to information about breast cancer to scientists, consumers and practitioners including opportunities for telemedicine on the information superhighway;

An effort to develop a comprehensive patient data registry and tissue resource bank to increase the availability of data, materials, space, and other information vital to breast cancer research;

With the identification of the BRCA1 gene responsible for some 5 percent of breast cancer, development of a plan for the use and protection of the eventual genetic molecular testing information, and counseling recommendations is underway;

The formulation of an intensified research agenda based on work from the NIH, the DOD, EPA, and private sources on the etiology of breast cancer including environmental influences such as radiation and electromagnetic fields, pesticides and hormones, personal risk factors, and viruses;

Development of actions to assure that clinical trials are more widely available to women with breast cancer and to women at risk, the disease, and actions to lower the barriers to women's participation in research;

Development of outreach strategies to ensure that all women have access to breast cancer prevention, diagnostic, and treatment NCI, ICC,

And finally, actions that will ensure consumer input at all levels in the development of public health programs, research studies and clinical trials.

Early Detection of Breast Cancer

We know that the use of early detection methods for breast cancer coupled with state-of-the-art therapies clearly can save lives. Since we cannot as yet prevent breast cancer, it is crucial that should a woman develop the disease, it be found in the earliest stages when the 5-year survival rates are about 96 percent. Research has proven that mammography saves lives for women aged 50 and over, decreasing death rates from the disease by 30%. But data are uncertain for women in their 40's. Mammography is a 40-year old technology, and it is very clear that we need to develop better methods for detecting breast cancer when it is most treatable.

And this is why I am testifying before you today. I believe that if we can image missiles 15,000 miles away in distant skies and with the Hubble telescope see craters on Mars, we should be able to develop better tools to image small tumors in women's breasts that are right in front of us! Mammography was a bold advance of imaging is advancing at a rapid rate, rivaling that of information processing. Driven by surveillance and target recognition missiles, the defense community has invested tremendous sums in research and development (R&D) of imaging systems. The resulting technology has found other applications in transportation, environmental monitoring, crime prevention, remote sensing, personal security, civil space programs, and biological science.

The medical, defense, and intelligence communities share some challenging information processing, display, and image transmission needs. For example, radiologists and image analysts both must look for subtle changes while rapidly scanning a large number of high- resolution images.

Historically, film has been the medium to meet such imaging needs. Film has high resolution, is convenient to handle, and can be displayed easily; however, it cannot be disseminated easily, processed to allow for detection of change, or fused with other imaging techniques of imaging --fields like defense, space, intelligence, and computer graphics that are estimated to be ten years ahead of medical imaging capacities to help us detect breast cancer at its earliest stages.

From Missiles to Mammograms: Transferring Technologies From the Defense and Intelligence Communities to the Early Detection of Breast Cancer

Let me give you several examples of how defense technology might be applied to the early detection of breast cancer. As you know, the technology of imaging is advancing at a rapid rate, rivaling that of information processing. Driven by surveillance and target recognition missiles, the defense community has invested tremendous sums in research and development (R&D) of imaging systems. The resulting technology has found other applications in transportation, environmental monitoring, crime prevention, remote sensing, personal security, civil space programs, and biological science.

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Historically, film has been the medium to meet such imaging needs. Film has high resolution, is convenient to handle, and can be displayed easily; however, it cannot be disseminated easily, processed to allow for detection of change, or fused with other imaging techniques. As a result, both the intelligence and the medical communities are moving from "hard copy" (film) to "soft copy" (digital images).

For a successful transition from film to digital images, It is necessary to have displays with very high resolution, high brightness, and uniform resolution. At the moment, displays with two of these attributes are available. In response, the National Information Display Laboratory has been developing a monochrome cathode-ray tube display that features all three essential attributes. This display offers excellent potential for radiological as well as intelligence applications.

Firms in the defense and medical research fields have joined together to apply automatic recognition technology used to detect tanks and other military targets to enhance mammographic screening for potential cancers. The concept is based on combining an optical processor and a neural network (computational elements modeled after living brain cells). When searching for military vehicles that are camouflaged by trees or foliage, the system correctly identified 99 percent of the targets with a false-positive rate (identification of nontarget objects) of less than 5 percent. Originally designed for the Department of Defense, this system is now being developed for analysis of Mammograms.

The optical processor extracts characteristic features of the target (in this case the breast) and passes them to the neural network for evaluation. This process is similar to the way radiologists work: they use their optical systems (eyes) to notice features on Mammograms, which are then passed to their neural networks (brain cells) to determine if a lesion is present. Optical processing technology has one significant advantage: speed. Current optical processing allows for 1,000 comparisons between a Mammograms and lesion characteristics per second; in a few years, the rate will increase to 10,000

comparisons per second. The best digital computers can produce fewer than 100 correlations per second. The tremendous speed of this technology gives feedback to radiologists and patients in a reasonable time. The next step is to test this technology in a clinical setting.

The intelligence community has developed several other approaches that may be applicable to early detection of breast cancer: neural nets (or networks), modeled after human brain cells (neurons), to search for cancer cells by examining the context in which they appear; image-processing tools that align Mammograms and magnetic resonance scans, to alert the radiologist to changes that may have occurred over time; and new tools, to allow the physician to visualize--or actually feel immersed in the information.

Historically, adoption of medical applications of new imaging methods has been slow, for several reasons. The obstacles to adopting new technologies include rigorous Food and Drug Administration procedures, limited funds for developing prototypes and models and conducting field tests, and radical deviations from conventional procedures required by the new technology. Recent industry-government technology efforts, however, may herald a change in this historical trend. Research and development programs are ongoing to improve the hardware and software needed to generate, process, analyze, store, and transmit the data used in imaging. As I previously mentioned, in some cases, the military state of the art is more than a decade ahead of medical applications. An aggressive program to further catalyze cooperative efforts between defense R&D investigators and the breast-imaging community is urgently needed if the Nation is to take advantage of this dual-use technology.

Current Activities to Develop Novel Breast Imaging Technologies

Currently, the NCI is supporting the development of some promising new technologies from defense-based research. In September 1991, the NCI held a workshop entitled "Breast Imaging: State-of-the-Art and Technologies of the Future." Because of the promise of digital mammography, a working group was formed to focus on this technology. The enormous potential of this technology and the simultaneous identification of other potential technologies for imaging led to a major NCI program to explore and develop new methods for breast imaging. The program includes:

An international, multi-institutional, multi-disciplinary collaboration of academic centers, industry and NCI to develop and validate digital mammographic systems including computer-aided diagnosis for enhanced image interpretation and telemammography, or image transmission, as the means to bring radiologic expertise to underserved and rural areas.

A joint NCI and NASA technology transfer program in digital imaging, originally developed for space and military applications;

A full range of studies to develop and validate ultrasound, MRI and other technologies free of ionizing radiation toward improved detection and characterization of breast cancer, from basic instrumentation and technology development to their preclinical and clinical evaluation;

Multi-institutional clinical trials to evaluate image-guided stereotactic percutaneous needle biopsy as a minimally invasive, cost-effective alternative to open surgical diagnosis.

Clinical evaluation and validation of breast MRI through centrally coordinated multi institutional clinical trials.

We expect that this program will provide dramatic breakthroughs in imaging capabilities. One of the key issues being considered is how advances in new technologies may effect actual clinical practice. For example it may be that certain new imaging technologies might not be appropriate for screening in

breast cancer at the present time but could prove effective as diagnostic aids. Further clinical evaluation research will ensure that new technologies are firmly supported by scientific evidence before they take their place alongside existing, well-established methods.

Indeed, this is a time of great potential in the science of breast imaging. And there is great urgency to apply the explosion of advances in the computer sciences, telecommunications, physics, and other fields to the early detection of breast cancer. The PHS Office on Women's Health working with the National Cancer Institute is intensifying efforts to stimulate the development of innovative methods of breast imaging--especially for the denser breast tissue of younger women--tissue that can be exceedingly difficult to image with conventional mammography. And we continue to work toward simple screening tests, possibly blood tests, that would pick up molecular evidence of breast cancer or breast cancer susceptibility, and at the same time, might be the basis for new and effective therapies.

Genetic discoveries, including the recent discovery of the BRCA-1 gene, will yield new molecular tests that might have high specificity. But we are not waiting for these events to occur. While pursuing novel approaches we continue to refine our knowledge of the tools we have, including mammography.

There is a true spirit of cooperation underway in all aspects of breast cancer detection. The PHS Office on Women's Health in collaboration with the National Cancer Institute has initiated discussions with the Department of Defense, the Central Intelligence Agency, and the National Aeronautic and Space Administration to translate their uses of this technology to the science of breast cancer detection. The PHS Office on Women's Health and the NCI will continue to build on this initiative to foster the development of novel screening techniques by bringing together researchers from diverse fields and through the work of the NCI's Imaging Development Program to support new studies in this area. The Food and Drug Administration will play a significant role in the transfer of the successful technologies from the laboratory to the public.

Capitol Hill Briefing

To help bring these ideas and this expertise together, next week on Tuesday, October 11, The PHS Office on Women's Health and the NCI in collaboration with the Congressional Caucus for Women's Issues, will sponsor a briefing on "New Frontiers in Breast Imaging and Early Detection," in the U.S. Capitol, Room H-C5. The briefing will examine and summarize current research on breast cancer imaging technologies including Digital Mammography, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), Investigational Ultrasound and Computer Assisted Diagnosis (CAD) and explore the potential contributions that other imaging fields from defense, space and computer graphics, can offer. There will also be exhibits of these technologies on display in the Rayburn House Office Building foyer. It is our hope that this briefing will facilitate collaborations among those in government, academia, and industry who are involved in the imaging field to increase our ability to detect breast cancer and also highlight opportunities for telemedicine on the "information superhighway." We sincerely hope that you will be able to attend.

Summary

In closing, we can realize no greater peace dividend from our national investment in defense than to save the lives of American women. The translation of imaging technologies from defense to breast cancer detection is imminently feasible and the collaborations have begun.

There's an old proverb that says, "He--let's make that she--who has health has hope. And she who has hope has everything." That's what this Initiative on new frontiers in breast cancer imaging is all about--bringing hope for a healthier future. This effort, coupled with research on prevention and treatment will lead to a future free of the threat of breast cancer.

Date: Saturday, October 25, 1997

FACT SHEET

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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 is 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, 33 percent of women ages 50-64, and 45 percent of women age 65 and older reported not receiving a mammogram during the past two years.

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

At the same time, spending on breast cancer research at HHS' National Institutes of Health has increased from \$229 million in FY 1993 to \$401 million in FY 1997, and a proposed budget of \$408 million in FY 1998.

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

And this year, President Clinton proposed, and Congress adopted, the expansion of Medicare coverage which will help pay for annual mammograms for all Medicare beneficiaries age 40 and over. This new benefit will be available starting January 1, 1998.

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 13 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.
- Approximately 180,000 new cases of breast cancer will be diagnosed in 1997, and about 44,000 women are expected to die from breast cancer. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- Death rates from the disease are highest among older, black, and low-income 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. Between 1982 and 1987, **breast cancer** incidence for women increased about 4 percent per year, but recently has leveled off.

The death rate for women with **breast cancer** declined 6.3 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 African Americans (1.6 percent) and women age 65 and older (2.8 percent).

- During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

HHS discretionary funding for **breast cancer** research, prevention and treatment has increased from approximately \$274 million in FY 1993 to an estimated \$513 million in FY 1997. As the Centers for Disease Control and Prevention (CDC) have worked to increase access for all women to mammography screening and follow up services, the resources devoted to **breast cancer** services have increased from an estimated \$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 \$401 million in FY 1997, and a President's budget request of \$408 million in FY 1998. 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:

New Mammography Benefit

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

Mammography Quality Standards

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

These regulations spell out the details for requiring facilities to hire capable technologists, use quality

dedicated equipment that produces clear images, and employ skilled interpreting physicians to interpret the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that any follow-up testing or treatment can begin immediately. The names and locations of FDA certified mammography facilities are available by calling the Cancer Information Service at 1-800-4-CANCER. In addition, the FDA has included a list of all FDA certified mammography facilities in the United States on its internet home page. The address is <http://www.fda.gov/cdrh/faclist.html>.

National Action Plan on Breast Cancer

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

On October 27, 1996, President Clinton launched the National Action Plan on Breast Cancer (NAPBC) Internet web site. The web site, developed by a public/private partnership and coordinated by the Department of Health and Human Services Office on Women's Health, is designed to serve as a gateway to information on breast cancer research, treatment, and prevention. The web site provides answers on frequently asked questions about breast cancer, as well as information on the NAPBC, breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences, publications, and government and private resources. The web site address is: <http://www.napbc.org>.

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

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

Privacy of Genetic Information and Breast Cancer

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

National Breast and Cervical Cancer Early Detection Program

CDC's National **Breast** and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. Resources devoted to **breast cancer** screening services have grown from an estimated \$42 million in FY 1993 to \$81 million in FY 1997. 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.

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



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BH ACCOUNT#: 13

COMMENTS:

Barbara Woolley asked me to send you some information about the National Action Plan on Breast Cancer. I pulled this information from the NAPBC web site -- if you need more information I suggest you look there. I notice, though that there is little if any information from 1998.

Susan Wood at the Office of Women's Health at PHS should be able to help you or provide additional materials. If that is a problem let me know.

***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
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NAPBC History

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In October 1993, the National Breast Cancer Coalition presented President Clinton with a petition signed by 2.6 million Americans, calling for a comprehensive strategy to end the breast cancer epidemic.

In response to this petition, President Clinton asked that the Secretary of the Department of Health and Human Services, Donna E. Shalala, convene a conference to establish a national action plan on breast cancer.

The conference was a unique undertaking, bringing together --for the first time-- 300 individuals including advocates, families and women affected by the disease, clinicians, researchers, members of Congress, other government officials, educators and the media, united in their commitment to develop a comprehensive plan for fighting breast cancer.

The group called for a partnership between government and non-government sectors to identify priorities and develop strategies for progress in these areas. The full recommendations of the conference are contained in the document, "[Secretary's Conference to Establish a National Action Plan on Breast Cancer](#)."

In 1994, President Clinton directed the establishment of the National Action Plan on Breast Cancer. The co-chairs of the Plan are Wanda K. Jones, Dr. P.H., Deputy Assistant Secretary for Health (Women's Health), and Frances M. Visco, Esq., President, National Breast Cancer Coalition. Currently, Susan F. Wood, Ph.D., the Acting Deputy Assistant Secretary for Health (Women's Health), is the DHHS co-chair of the NAPBC. Implementation of the NAPBC is coordinated by the U.S. Public Health Service Office on Women's Health in the Department of Health and Human Services.

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History & Working Groups

Learn about the NAPBC's history.

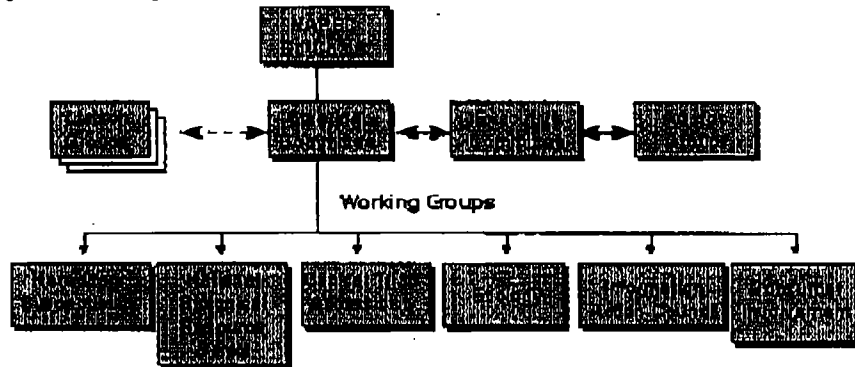
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Here's an overview of the NAPBC organization. Click on the boxes or text to learn more about individual sections of the NAPBC.

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Last Revised: 13-Nov-1997

National Action Plan on Breast Cancer

1996 Summary of Accomplishments: A Report to the Steering Committee

Background

The National Action Plan on Breast Cancer (NAPBC) is a unique public-private partnership that serves as a catalyst for national efforts to coordinate actions by government and nongovernment organizations, agencies, and individuals to advance breast cancer knowledge, research, policy, and services. The NAPBC was initiated in response to the National Breast Cancer Coalition's 2.6 million-signature petition calling for a coordinated national strategy to combat breast cancer, the second leading cause of cancer deaths among American women. By encouraging new ideas and mobilizing partnerships, the NAPBC strives to "jump-start" innovative, long-term efforts that will result in rapid progress against breast cancer. The work of the NAPBC is guided by a Steering Committee and six Working Groups. Implementation of the NAPBC is coordinated by the U.S. Public Health Service's Office on Women's Health (PHS OWH) within the Department of Health and Human Services.

A Year of Achievement

1996 marked a year of important achievements for the NAPBC, primarily in implementing initiatives to address the priorities of the Plan, but also in building an infrastructure to facilitate Working Group activities. Each of the six Working Groups of the NAPBC were very active in defining specific plans of action and implementing a broad range of initiatives. The second year of the NAPBC grants program was also completed. These Working Group activities put into practice the strategies and goals of the Plan to catalyze and jump-start actions to advance knowledge, research, and policy.

In addition, the Steering Committee addressed necessary infrastructure issues by developing an operating plan, a strategic planning process, and a new budget monitoring system and establishing several ad hoc groups to address ongoing issues related to membership, budget, evaluation, and public-private partnerships. These support mechanisms provided the foundation for involving government and nongovernment representatives at all levels of the implementation of the NAPBC. Although many important operating policies and decisions were made during the year, they are not the focus of this report. This report provides an overview of the NAPBC Working Groups' accomplishments to further national efforts to eradicate breast cancer.

The Working Group on Hereditary Susceptibility

This Working Group is implementing a comprehensive plan to address the needs of individuals carrying breast cancer susceptibility genes and to address the need for education among consumers, health care professionals, and at-risk patient groups. During the past year, the Working Group examined a broad range of critical issues related to genetic susceptibility to breast cancer. The Group:

- *Developed an educational video that explores the clinical and psychosocial issues of cancer predisposition testing.* This video was designed to assist consumers make informed choices about genetic testing. It presents emotional issues and personal choices that face women and families considering genetic testing through personal stories of breast cancer survivors as well as experts' presentations of the pros and cons of testing. Focus groups were convened in December to assess the video's effect and success in delivering its intended messages. Input from these focus groups confirmed that the video provided a well-balanced overview of the issues. The Susan G. Komen Foundation and the American Cancer Society have expressed interest in helping to market and distribute the video.

Jump-Starting Progress:

The Hereditary Susceptibility Working Group

For many women, the exciting scientific advances to enable the identification of genes that increase the risk of getting breast cancer create a great personal dilemma: Should they be tested and possibly risk insurance and workplace discrimination? The Hereditary Susceptibility Working Group has moved rapidly on several fronts to provide information to assist women in making decisions about genetic testing, educate health professionals about genetic predisposition to cancer, identify research issues requiring immediate attention, and stimulate national policies to protect women and their families.

- *Developed an outline for an educational curriculum on hereditary susceptibility issues for health care providers. The curriculum was based on nine objectives identified by the Working Group and refined with input from participants in a workshop in April. Cosponsored by the American Society of Clinical Oncology (ASCO), the workshop included representatives of a broad range of health care provider organizations representing physicians, nurses, genetic counselors, social workers, psychologists, and psychiatrists. The cancer genetics core curriculum outline has been disseminated to more than 30 major health care provider organizations for review and endorsement. Several organizations already have begun using the outline to develop curricula for their members.*

- *Identified research priorities related to hereditary susceptibility to cancer and strategies for addressing these priorities during a research workshop in September. The resulting recommendations focused on four areas: basic science, genetic epidemiology, prevention and treatment, and psychosocial issues. Workshop participants included consumer activists representing multiple and diverse perspectives, representatives from the National Cancer Institute (NCI) and the National Center for Human Genome Research (now the National Human Genome Research Institute), and researchers with expertise in each of the four listed disciplines.*

- *Conducted a workshop on genetic information in the workplace in October that was attended by more than 80 people. National policy recommendations to prevent employment discrimination based on genetic information were drafted based on the workshop.*

NAPBC Actions To Advance Policy

- *Published an NAPBC position paper on genetic testing in the Journal of Clinical Oncology.*
- *Conducted a workshop and developed national policy recommendations about use and misuse of genetic information in the workplace.*
- *Conducted a workshop and developed policy recommendations about health insurance discrimination and genetic predisposition to cancer.*
- *Worked and continue to work with the National Cancer Institute, National Institutes of Health (NIH) Office on Protection From Research Risks (OPRR), Public Responsibility in Medicine and Research (PRIM&R), and NIH Office of Research on Women's Health to address policies on informed consent.*
- *Provided testimony before a U.S. Senate hearing on genetic testing and privacy issues.*

- *Conducted a conference titled Consumer Leadership Summit: Preparing for the New Era of Genetics and Medicine in December to empower consumers to take action about emerging genetic susceptibility issues. Cosponsored by the National Breast Cancer Coalition, the conference was attended by more than 120 people representing women's health and breast cancer advocacy groups and women's professional and labor organizations. A followup plan will further extend the discussions at the conference into the community and will include sample articles for individuals to submit to their local newspapers and*

organizational newsletters.

- *Developed a position paper on hereditary susceptibility testing for breast cancer* that was published in the *Journal of Clinical Oncology*. This paper addresses such issues as requiring education for health care providers, informed consent for individuals considering being tested, and prevention of genetic discrimination.

The Clinical Trials Accessibility Working Group

- *Provided testimony before a U.S. Senate hearing on genetic testing and privacy issues* addressed in the Kennedy-Kassebaum health care bill, including protection of privacy of genetic information. Testimony was provided by Working Group members representing government, industry, health care providers, and legal and ethical perspectives.

- *Developed a Working Group Action Plan* to identify and guide the group's activities for the year.

Mobilizing Partnerships:

Breast cancer clinical trials are critical to the development of new and more effective treatments and prevention strategies. These clinical trials rely on the participation of breast cancer patients and those at risk for breast cancer. Currently, however, only a small percentage of all eligible cancer patients participate in these important research trials. One of the many complex reasons women do not participate is that they may not be knowledgeable about clinical trials. The Clinical Trials Working Group is building necessary partnerships to address this problem by bringing together consumers, scientists, government representatives, health care providers, and health communications experts to increase the availability and user-friendliness of information about clinical trials and to centralize this information in a central registry.

The Clinical Trials Accessibility Working Group

This Working Group is finding ways to make clinical trials more widely accessible to women with breast cancer and women at risk for breast cancer. It is identifying 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 costs of participation. In 1996 the Working Group:

- *Coordinated efforts to enhance the accessibility and user-friendliness of existing information about breast cancer clinical trials.* Members met with NCI staff in May to discuss current clinical trials information systems, such as the Physicians Data Query and CancerFax. A meeting was convened in November to discuss the development of a central registry of breast cancer clinical trials. The meeting focused on encouraging partnerships, reducing the duplication of efforts by groups involved in developing registries, and maximizing the number of trials for which information is widely available to patients, health care providers, and other interested persons.

- *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 compiled into a critical review of the literature that will be submitted for publication in summer 1997.

- *Conducted a meeting in September of NAPBC grantees* studying various aspects of clinical trials recruitment.

- *Using information from the literature review and NAPBC grantee studies, developed 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.

- *Continued consensus-building efforts* with health insurance companies, hospitals, physicians, researchers, Federal agencies sponsoring research, industry, and consumer groups concerning reimbursement for breast cancer clinical trials and monitored the development of policies regarding

insurance coverage of randomized controlled trials and informed consent issues.

- *Developed an Action Plan* that set the Working Group's objectives for the year and identified specific activities for implementation.

The National Biological Resource Banks Working Group

This Working Group has focused on establishing a national network of tissue banks to ensure a resource of well-characterized and documented biological materials for multiple areas of breast cancer research. In 1996, the Working Group:

- *Developed and disseminated a survey* to 12,000 researchers around the country to ascertain how much and what types of tissue are needed for breast cancer research. Data have been collected, and analyses are scheduled to be completed in the spring 1997. The results of this effort will be compiled in a database and made available to interested researchers over the Internet.

Catalyzing Action:

The Biological Resource Banks Working Group

Research studies to understand all aspects of breast cancer biology depend on the availability of normal and breast cancer tissue. However, no national system for obtaining, storing, and registering the tissue available for use in research studies exist, and some researchers have difficulty obtaining tissue to address specific research questions. The Biological Resource Banks Working Group, in collaboration with consumers, scientists, government, and professional organizations, has conducted a series of initiatives to determine the availability and adequacy of existing sources of tissue, addressed ethical and legal issues involved in collecting and using biological materials, and built the foundation for a national breast cancer tissue banks network that can now be maintained by collaborating partners.

- *Convened a workshop in February* to address ethical and legal issues related to the collection and use of biological tissue. Meeting participants drafted a model informed consent form and Institutional Review Board (IRB) guidelines that were presented to a meeting of PRIM&R in May.

- *Completed extensive focus group testing of an informed consent form* for tissue procurement, resulting in important modifications that will enhance the clarity of these complex issues. A report of focus group results has been provided to the President's National Bioethics Advisory Commission and other groups addressing informed consent and patient's rights issues.

- *In collaboration with the National Cancer Institute, developed the Breast Cancer Specimen and Data Information System* and demonstrated the database at national breast cancer meetings. A brochure describing the system and how to access it also has been developed and is being disseminated to researchers across the country.

NAPBC Actions To Advance Research

- *Compiled an extensive database of currently funded breast cancer etiology research.*
- *Developed a publicly accessible database of available breast specimen resources for research.*
- *Developed a marketing plan for increasing recruitment to breast cancer clinical trials.*
- *Developed and initiated focus group testing of a six-module breast cancer core questionnaire to collect comparable data across studies.*
- *Published a special issue of Environmental Health Perspectives titled "Hormones, Hormone Metabolism, Environment, and Breast Cancer."*
- *Developed a model informed consent form for tissue procurement.*

- *Developed consensus recommendations about how tissue available for breast cancer research can be collected, stored, and deposited in a tissue bank* for use by researchers. Issues such as cost, consent, and record keeping were included. Recommendations were developed by participants at a September workshop.

- *Developed a Working Group Action Plan* to identify and guide the group's activities in establishing a national network of tissue banks.

The Etiology Working Group

This Working Group is focusing efforts on expanding the scope and breadth of biomedical, epidemiological, and behavioral research activities related to the etiology of breast cancer, particularly in the areas of chemicals and hormones, lifestyle factors, ionizing and nonionizing radiation, viruses, and gene/environment interactions. In 1996, the Working Group:

- *Conducted a workshop in September to revise and integrate the modules of the breast cancer core questionnaire* that will enable comparisons across studies and clarify emerging risk factors. Sixty participants including scientists and consumers reviewed questionnaire modules, identified areas of overlap as well as unaddressed issues, and recommended modifications to be incorporated into the final six-module questionnaire. Focus group testing has started on two of the six modules.

- *Completed a supplement issue of Environmental Health Perspectives titled "Hormones, Hormone Metabolism, Environment, and Breast Cancer"*. Reports in this special issue resulted from presentations delivered at a workshop held last year. A separate manuscript summarizing unmet research needs, unresolved issues, and research recommendations has been prepared and will be submitted for publication.

NAPBC Actions To Increase Knowledge

- *Launched the NAPBC Web site.*
- *Developed an educational video on genetic testing.*
- *Designed a program to link the informationally underserved to the Information Superhighway.*
- *Developed a curriculum outline on hereditary susceptibility to breast cancer for use by health professional organizations.*

- In collaboration with the NCI, *compiled a database of currently funded breast cancer etiology grants* funded by the NAPBC, NCI, National Institute of Environmental Health Sciences, Department of Defense, and American Cancer Society. The database will be available through the NAPBC Web site in early 1997.

- *Initiated planning for three research workshops* to be held in 1997, each of which will address important issues in breast cancer etiology. The topics include:

- *Viruses, virus-environment interactions, and human breast cancer;*
- *Electromagnetic fields, light-at-night, and breast cancer; and*
- *Ionizing radiation and breast cancer.*

- Investigated methods to better coordinate and facilitate quick, appropriate response by Federal, State, and local agencies to areas where breast cancer is extraordinarily prevalent, including *the use of video conferencing at various breast cancer cluster sites* as an alternative to convening a single inperson meeting.

- *Developed a Working Group Action Plan* to identify and guide the group's activities during the year.

The Information Action Council

This Working Group is striving to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other information technologies. In 1996 the Working Group:

- *Launched the NAPBC Web site*, which was announced by President Clinton at a White House ceremony on October 27. In its first month, almost 6,000 individuals accessed the site, 60 percent of whom were users from the United States. The site has been included in more than 30 search engines. Users have sent feedback forms to the NAPBC indicating that the Web site is useful and fills a gap in the current information about breast cancer available on the Internet.
- *Developed a Spanish-language version of the NAPBC Web site* that was launched in January.
- *Conducted 10 regional meetings* in October to assess interest in and the feasibility of teaming community-based organizations and private-sector partners to increase access to breast health information using the Information Superhighway. A report of these meetings and an activity plan were developed and approved by the Steering Committee in November.
- *Initiated development of a Request for Proposals (RFP)* to reach informationally underserved populations with breast cancer information through the Internet. It is anticipated that the RFP will be disseminated in February 1997.
- *Developed a Working Group Action Plan* to guide activities throughout the year.

The Consumer Involvement Working Group

Involving Consumers:

The Consumer Involvement Working Group

The past several years have brought many changes in how health issues are addressed. Among these changes is the increasing involvement of those affected by a disease in the development of national programs and policies. However, consumers are not yet an integral part of many health planning efforts. The Consumer Involvement Working Group is addressing this issue by gathering additional information on the nature and extent of consumer involvement in different organizations and programs to identify gaps in consumer involvement and opportunities for closing those gaps.

This Working Group is defining 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 Working Group seeks to increase and institutionalize consumer participation in ongoing research as well as the review of research for funding and to involve consumers in the design of service delivery and education programs. In 1996, the Working Group:

- *Developed and initiated implementation of a research plan* for a study to assess consumer involvement in activities in areas such as breast cancer research, service delivery, education and outreach, and public policy. Sampling lists and strategies for survey dissemination and data collection have been developed. The ultimate goal is to identify and implement ways to bridge the gaps between the current status and potential status of consumer involvement.
- *Developed a Working Group Action Plan*, which provides the foundation for Working Group activities.

NAPBC Grants Program

In addition to the workshops and initiatives described above for each Working Group, the NAPBC grant program completed its second year. Ninety-nine grants addressing each of the six NAPBC priority areas were funded in fiscal year (FY) 1996. The goals of the grant program were to:

- Provide support for novel, creative pilot program and outreach projects that would yield exceptionally important new information on breast cancer; and
- Support developmental, exploratory, or pilot projects that would serve as the basis for well-defined future research and outreach project applications on breast cancer.

Building Bridges:***The NAPBC Web site***

In 1996, the NAPBC made important strides in advancing breast cancer knowledge, research, policy, and services. Information about these accomplishments and the ongoing actions of the NAPBC became more accessible with the launch of the NAPBC Web site by President Clinton. This Web site provides an important bridge between the NAPBC and its constituencies and serves as a gateway to public and private resources on the Internet. This site provides a rare opportunity to communicate directly with a national program and affords the NAPBC an exceptional opportunity to assess the public's interests and concerns and to respond appropriately.

Highlights of Upcoming Activities

Substantial progress was made in implementing NAPBC activities in 1996. Highlights of some of the upcoming NAPBC activities for 1997 include:

- The educational video on genetic testing will be completed, marketed, and distributed.
- The NAPBC Web site will be available in Spanish.
- A Request for Proposals will be issued for subcontracts to increase access among informationally underserved women to breast cancer information using the Information Superhighway.
- Three workshops will be conducted focusing on:
 - The role of viruses in the etiology of human breast cancer;
 - Ionizing radiation and breast cancer; and
 - Possible relationships between electromagnetic
- A video conference to link experts and consumers from various breast cancer cluster sites will be initiated.
- A marketing campaign to encourage enrollment in clinical trials will be developed and implemented.
- Analysis of data from questionnaires sent to 12,000 researchers will be completed to ascertain how much and what types of tissue are needed for breast cancer research.
- A demonstration of the Breast Cancer Specimen and Data Information System will be made at the American Association for Cancer Research meeting in April and an evaluation plan for the database will be developed.
- Focus group testing of the Breast Cancer Core Questionnaire will be completed.
- A draft of the report on the NAPBC study of breast cancer consumer involvement will be issued.

The NAPBC, a public/private partnership, is coordinated by the
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Steering Committee Activities & Meetings

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NATIONAL ACTION PLAN ON BREAST CANCER Steering Committee meeting November 10, 1997

Steering Committee members present: Frances M. Visco (Co-Chair), Susan F. Wood

(Co-Chair), Doris Browne, Kay Dickersin, Arlyne Draper, Leslie Ford, Janyce N. Hedetniemi, Mary Jo Ellis Kahn, Sarah Kovner [Department of Health and Human Services (HHS) Liaison],

Amy S. Langer, Susan M. Love, Alan Rabson, Irene Rich, Susan Sieber

Staff members present: Elizabeth Carey, Anna L. Kindermann, Debbie Saslow [U.S. Public Health Service's Office on Women's Health (PHS OWH)]; Alex Valadez (Academy Associates); Helene Quick, Jacqueline Tressler (R.O.W. Sciences, Inc.); ***Staff members present for Working Group updates only:*** Joyce Cusack, Anna Hodgson, Terri Kaufman, Marsha Reichman (R.O.W. Sciences, Inc.)

Observer: Suzanne Haynes (PHS OWH)

WELCOME AND OVERVIEW OF THE MEETING

Mr. Valadez called the meeting to order. Ms. Visco asked for a moment of silence for Collette Haines, whose mother and grandmother have been diagnosed with breast cancer, and in memory of Elaine Ominsky, a breast cancer activist who recently died of breast cancer.

Ms. Visco welcomed the participants and thanked the members of the Steering Committee and the PHS OWH staff for their work. She urged members to refocus on the mission of the NAPBC: to bring together a diverse group to focus on gaps in breast cancer knowledge, research, policy, and services and to act as a catalyst in directing attention to overlooked areas of research.

STATUS OF THE NEW NAPBC CO-CHAIR

Ms. Kovner introduced Dr. Wood, the Acting Deputy Assistant Secretary for Health and NAPBC Co-Chair, who updated the group on the status of the openings for the permanent position of Deputy Assistant Secretary for Health and the NAPBC Coordinator, which she expects to be filled in the near future. Ms. Wood also urged the Steering Committee members to move forward and to stay true to the goals and mission of the NAPBC.

Dr. Wood described the process for filling government positions. Although many people will be involved in reviewing candidates for the position of NAPBC Coordinator, Dr. Wood will make the final decision. The Deputy Assistant Secretary for Health and NAPBC Co-Chair will be selected by the Assistant Secretary for Health (either the Acting Assistant Secretary, John Eisenberg or, pending his confirmation for that position, David Satcher).

Dr. Wood called the participants attention to a packet of information about the final disposition of \$14 million of the FY97 appropriation for the NAPBC and other Federal and private sector cross-cutting initiatives.

CHARGE FOR THE MEETING

- o WORKING GROUP UPDATES AND BUDGET APPROVAL REQUESTS
- o MEMBERSHIP AD HOC GROUP PRESENTATION
- o FINANCE AD HOC GROUP PRESENTATION
- o COMPENDIUM OF GRANTS
- o CLOSING REMARKS

Mr. Valadez delivered general instructions for procedures during the meeting.

In order to accommodate Dr. Sieber's early departure from the Steering Committee meeting, the Etiology update and budget approval requests were moved up on the agenda.

Etiology

Dr. Sieber gave an update on three upcoming workshops that will be convened by the Etiology Working Group. The Workshop on Physical Activity and Breast Cancer will take place on November 13 and 14 in Albuquerque, New Mexico. Approximately 75 participants will attend the workshop and develop recommendations for future actions in this area of research. The Workshop on Medical Ionizing Radiation and Human Breast Cancer will take place in Washington, DC, on November 17 and 18, immediately followed by the Workshop on Electromagnetic Fields, Light-At-Night, and Human Breast Cancer on November 18 and 19. The Working Group anticipates that both these workshops will be well attended by scientists and consumer advocates and also will result in recommendations for future actions.

Dr. Sieber announced that several new members have joined the Etiology Working Group. There will be an in-person full Working Group meeting in Washington, DC, on December 12.

Multicultural aspects of breast cancer etiology. Dr. Sieber presented proposals for three activities. The first was for a workshop on multicultural aspects of breast cancer etiology. This activity would have two steps: (1) a summary of the state of knowledge in this area, including a comprehensive literature search and a detailed review of relevant organizations and their activities, and (2) a 3-day workshop, preceded by a 1-day planning meeting. The workshop would offer a forum to review and discuss the current state of knowledge on this topic and to make recommendations for future initiatives. Although the workshop is currently planned as a 3-day event, it may be reduced to 2 and ½ days. Col. Browne added that various groups contacted by the Working Group had indicated considerable interest in participating in the workshop.

In a discussion of this proposal, participants expressed several concerns. Ms. Visco was concerned that multicultural aspects of breast cancer might be a divisive issue and hoped that all sides of issues would be explored. Dr. Dickersin questioned whether the budget had adequate funds for the literature search and commented that the search results should be made public.

Other concerns involved a possible duplication of effort and ensuring that the literature review and the workshop would result in publishable documents.

DECISION. The Steering Committee agreed that, as a matter of policy, proposed literature reviews and NAPBC workshops should generate publishable proceedings or reports.

DECISION. The Steering Committee approved the literature search and the concept of the workshop on multicultural aspects of breast cancer. Additional information on the workshop budget will be provided to the Steering Committee for approval before the February meeting.

Several related questions were discussed concerning the level of review required for Working Group products once an activity has been approved. It was suggested that the role of the Steering Committee is to provide concept approval of documents, rather than editing. The issue of whether the Steering

to provide concept approval of documents, rather than editing. The issue of whether the Steering Committee reviews activities/publications that do not require additional funding also was discussed. Ms. Visco suggested that the Finance Ad Hoc Group revisit these issues in order to formulate a policy that could be incorporated into the Operating Plan.

Interagency rapid response resource. Dr. Sieber then presented a proposal for developing an interagency rapid response resource related to areas with higher than normal reported incidence of breast cancer. The activity would include a 1 ½-day meeting of Federal and state representatives of seven sites that are investigating breast cancer clusters to discuss coordinating responses to apparent high-risk areas in the United States. The coordinated response would involve identifying available databases to search for information and recommended actions to undertake.

A question was raised as to how this workshop would differ from or be related to the National Cancer Institute (NCI) Workshop on Environmental Clusters of Breast Cancer, which is being funded with part of the \$14 million FY97 appropriation for the NAPBC. Participants responded that the proposed NAPBC workshop would be specific to regions that are currently undergoing evaluation, and it would be more of a "how-to" workshop. Dr. Haynes added that the NCI workshop was designed as a methods conference that would answer such questions as "A What do we know about the pros and cons of doing cluster analysis?" and "A What are the new mortality data sets?" After considerable discussion, several participants advocated merging the two workshops.

DECISION. The Steering Committee agreed that no additional funding should be provided for the rapid response workshop, but recommended that the organizers of the NCI Workshop on Environmental Clusters of Breast Cancer coordinate with the organizers of the Rapid Response workshop and consider integrating into their event the ideas and proposed participants (in particular the advocates) of the NAPBC workshop.

Breast Cancer Core Questionnaire. The final budget request from the Etiology Working Group was for supplemental funding for developing and implementing dissemination activities for the Breast Cancer Core Questionnaire. There are three parts to this activity: development of an interviewers manual, translation of the questionnaire and manual into Spanish, and dissemination of the questionnaire and the manual through the NAPBC Web site and other methods.

In response to a question about the testing, evaluation, and peer review process for the questionnaire, Dr. Sieber responded that each module had been reviewed by members of the Working Group who are experts in the particular subject areas. Each module has undergone focus group testing and has been revised accordingly. In regard to the quality and usefulness of the instrument, Dr. Sieber explained that the development of each module was overseen by a prominent academic epidemiologist in the field, with assistance from an NCI epidemiologist and other academic and government epidemiologists.

Dr. Haynes suggested sending the instrument to the cognitive testing unit of the Centers for Disease Control (CDC) to evaluate the appropriateness of the wording of the questions. The CDC evaluation could augment the testing planned by the Working Group.

DECISION. The Steering Committee agreed to submit the core questionnaire to CDC and other appropriate agencies for review, incorporate their feedback into the questionnaire, and develop the interviewer's manual. It also was agreed that funding for the interviewers manual should be less than \$30,000, and substantive efforts should be made to further reduce this amount.

In response to a question about research grant requests for applications (RFAs) that might result from the upcoming Etiology workshops, Dr. Sieber replied that she did not believe any restrictions would be attached to RFAs, but the workshop participants would determine the grant criteria. Also, Ms. Visco requested that the Steering Committee members be provided with copies of the letter to NCI concerning research on viruses and human breast cancer.

MEMBERSHIP AD HOC GROUP PRESENTATION

Dr. Love gave an update on recent membership changes. Jane Reese-Coulbourne has resigned from the Steering Committee and as Co-Chair of the Consumer Involvement Working Group, and a new Co-Chair will need to be appointed. The Membership Ad Hoc Group finally resolved that Ed Sondik should be asked to resign from the Steering Committee because he no longer is affiliated with a member organization.

Acting on recommendations from the previous Steering Committee meeting, the Membership Ad Hoc Group revised language in the Operating Plan concerning membership requirements. Four main areas were addressed: nonparticipating Steering Committee members, active Working Group Co-Chairs who were nonparticipating Steering Committee members, individual qualifications versus organizational affiliation as membership criteria, and procedures for filling Steering Committee vacancies.

Dr. Love clarified several points for the Steering Committee. Anyone on the Steering Committee can add names to the list of organizations (government agencies, as well as private organizations) from which to solicit new members. Also, nominations for Working Group Co-Chairs can be made by individuals who are not members of the Working Group.

In response to a question about the status of the Executive Committee, Ms. Visco replied that, as specified in the operating plan, the Executive Committee consists of the NAPBC Co-Chairs, plus the NAPBC Coordinator as a nonvoting member.

After Dr. Love reviewed new revisions to the Operating Plan language, the group agreed on the following changes:

- Define the term Aorganization@ as a government agency, a nongovernment agency, or both.
- Clarify that the statement, AEach organization or agency may have only one representative and one vote,@ refers to Steering Committee members who are not Working Group Co-Chairs.
- Clarify that individual Steering Committee members may be nominated by a variety of people or organizations (for example, Steering Committee, Working Group members, or other organizations) and are approved by the NAPBC Co-Chairs.
- Clarify that NAPBC Co-Chairs vote on nominations proposed by Working Group members or the Steering Committee when the vacancy is a Working Group Co-Chair.

After discussing proposed revisions addressing nonparticipation, Steering Committee members agreed to maintain the status quo.

DECISION. The Steering Committee **approved** the revised Operating Plan language on membership pending modification and clarification of Steering Committee members roles and responsibilities.

Ms. Visco requested a change in the letter soliciting Steering Committee nominations from organizations and clarification of the mission of the NAPBC. Ms. Langer requested that the letter soliciting nominations from Working Group members be clarified in its direction to NAPBC Working Group members.

WORKING GROUP UPDATES AND BUDGET APPROVAL REQUESTS

Clinical Trials

Dr. Dickersin reported that the Working Group participated in a meeting at the Food and Drug Administration (FDA) with major pharmaceutical companies and individuals involved with the Physicians Data Query Database (PDQ). The meeting resulted in an informal agreement that the pharmaceutical companies will register their trials with PDQ.

Drs. Ford and Dickersin presented a supplementary budget request for \$37,267 for 11 additional focus groups to facilitate developing a marketing campaign on clinical trials targeted to the public. The original budget for this activity included funding for a literature review (that should result in a publishable paper) and for six focus groups, but, as the project progressed, it became clear that additional focus groups were needed.

In response to questions, Drs. Ford and Dickersin explained that the project could not be transitioned to NCI until after the focus groups were completed, which the Working Group anticipated would occur before Christmas. Dr. Ford also asserted that the amount of the budget request appeared to be firm. A request for \$8,000 for Planning and Communication, in addition to the \$26,000 allocated to this Working Group at the onset of the Plan for these expenses, generated some discussion. It was suggested that a provision for small amounts such as this should be built into the Working Group budgets. The Finance Ad Hoc Group will examine this issue.

DECISION. The Steering Committee **approved** the Clinical Trials Working Groups request for \$37,267 in supplemental funding for focus groups. A request for \$8,000 for planning and communication also was **approved**.

Biological Resource Banks

Dr. Love reported that the Biological Resources Working Group members believe they have accomplished their goals and are planning to Asunset,@ or dissolve. They will hold a meeting in February to write the final report, as well as a series of publishable documents on the Working Groups accomplishments. These documents will include the final report on the needs assessment and a report on the process of developing the model informed consent form.

Model informed consent form. The Ethical Task Force under Pat Barr has developed a model informed consent form and a document highlighting the Institutional Review Board issues. Task Force members also met with the American College of Surgeons about the form. Sheila Taube and Daniel Miller will oversee the pilot testing of the form, and NCI will develop a related brochure.

Master Agreement Order (MAO) for the Breast Cancer Specimen and Data Referral System Project. The MAO for the Web site has been completed. All the identified tissue resources in the United States are posted on the Web site. Of the more than 1,000 hits received between January to September, 25 percent were from researchers looking for breast cancer tissue. An ombudsman, or tissue expediter, has been assigned to the Web site to help individuals locate tissue.

Needs assessment. The needs assessment has been completed, and the final report is being written. Dr. Rabson will try to facilitate having the document published in the *Journal of the National Cancer Institute*, and the document will be placed on the NAPBC Web site.

NAPBC-CAP meeting. Working Group members met with members of the College of American Pathologists (CAP) to discuss the availability of tissue for research. At the meeting, it became clear that storage space is the major issue in availability of tissue. The group made several suggestions for the solution of this problem, including the submission of specimens to centralized repositories when pathologists are ready to discard them.

In response to questions, Dr. Love commented that tissue resources are available, but the main difficulty is connecting people who need tissue with these resources. However, there is a lack of resources for particular types of tissue. Individuals who are looking for tissue can be referred to Dr. Roger Aamodt, Chief of NCI's Resources Development Branch, or to Marianna Bledsoe, a tissue expediter at the branch.

Information Action Council

Ms. Draper presented an update on the Bridging the Gap pilot project. The Information Action Council (IAC) has funded five pilot project sites to train women to access and understand breast cancer-related information on the Internet. The pilot project sites are Bowling Green, Kentucky;

Anchorage, Alaska; San Francisco, California; Little Rock, Arkansas; and Boston, Massachusetts. The IAC also has implemented a mentoring program to assist the pilot project sites.

Ms. Draper presented the IAC's request for \$141,364, which contained items in three categories: (1) Web maintenance, in the amount of \$134,457, which includes labor for preparation and placement of all Working Group materials on the Web site and other direct costs, such as the purchase of hardware and software and continuation of the services of an outside vendor on an interim basis; (2) Marketing to increase public knowledge and use of the Web site, in the amount of \$6,907, which includes labor, as well as mailing, printing, photocopying, and telephone expenses; and (3) Translation costs in the amount of \$49,000, which includes editing, as well as the translation itself. The goal of these activities is to post information quickly; identify direct, accurate links; provide online registration for workshops and meetings; and incorporate the most efficient technology into the operation of the Web site. Ms. Draper then raised the issue of whether marketing should be budgeted as a separate allocation, as proposed, or would be more appropriately included in the Working Group's planning and communication allocation.

In answer to a question about the original budget for Web maintenance, PHS OWH reported that \$126,000, plus an additional amount for services from Scientific Applications International Corporation, was budgeted for initiation and maintenance of the Web site. The amount originally budgeted has been expended, and the new budget request includes transition costs. The participants discussed whether the figure for Web maintenance was appropriate. Ms. Visco commented that funding for maintaining and updating the Web site clearly would be approved, but the amount must be reviewed. She requested that more detailed background information, including the amount and allocation of past expenditures, be sent to the Steering Committee members as soon as possible. Ms. Draper asked the Steering Committee members to respond to the information as quickly as possible.

DECISION. The Steering Committee approved funding for Web site maintenance pending additional budget information, including comparisons with past expenditures. Ms. Langer requested additional information on the number of people accessing the Spanish version of the NAPBC Web site and suggested using volunteer translators. Ms. Draper replied that volunteer translators would not be appropriate for the material on the Web site.

Participants discussed improving the procedures for submitting budget information to the Steering Committee. Participants suggested that, in order to avoid lengthy discussions at Steering Committee meetings, detailed budgets should be developed and submitted in advance for review by the full Steering Committee. Ms. Kahn also suggested that the Steering Committee delineate exactly what budget information is needed in order to make informed decisions, including the items to review and the extent of detail.

DECISION. The Steering Committee agreed that detailed budget information should be sent to the full Steering Committee members two weeks in advance of the meetings.

Participants discussed appropriate responses to inquiries to the NAPBC. Ms. Visco commented that she did not approve of the breast cancer resource list that had been developed to accompany a form letter. Ms. Draper responded that Web site inquiries were answered with a form letter. It was explained that there are both Web site inquiries and written inquiries; the draft letter and accompanying resource list had been developed, as requested at the previous Steering Committee meeting, to be used in response to written inquiries. The group agreed that written inquiries should be answered with a form letter, a brochure, and referral to NCI's 1-800 information telephone line.

DECISION. The Steering Committee members agreed that both Web site and written inquiries should be responded to with a form letter and referral to NCI.

1-800 information telephone line. A brochure would be included with responses to written inquiries.

In response to a question about approval for Web site material, Ms. Draper stated that only material approved by the Steering Committee was posted on the Web site. Dr. Saslow clarified that any documents of substance are provided to the Steering Committee for review and approval.

Ms. Draper also introduced in concept the Working Groups proposal to develop a toolkit that would facilitate the development of local breast cancer-related Web sites. Ms. Draper emphasized that the Working Group envisions the project as a public/private partnership and does not require additional funding at this time. Ms. Draper would like feedback from Steering Committee members on this activity before moving forward with planning.

Consumer Involvement

The Consumer Involvement Survey and the Consumer Involvement Cancer Center Survey were mailed, and 200 surveys from each mailing were returned. The National Alliance of Breast Cancer Organizations will mail the Industry Consumer Survey within the next week and a half. Analysis has been completed on the consumer survey and the cancer center survey; after Ms. Hedetniemi receives the analysis from the contractor, she will forward it to Steering Committee members for their review (probably within a month). Ms. Hedetniemi anticipates completing a full report for presentation at the next Steering Committee meeting.

The Consumer Involvement Working Group is requesting additional funding in the amount of \$29,883, primarily to continue administrative activities through December 1998. This amount, plus funds remaining in the previous budget, would enable the Working Group to plan and convene a 1-day full Working Group meeting, to hold bimonthly conference calls, and to conduct background research and develop new activities.

In response to a question about the government consumer involvement survey, Ms. Hedetniemi replied that it might be possible to produce and disseminate it through the Federal Coordinating Committee. She will ask the contractor to modify the questionnaire.

DECISION. The Steering Committee **approved** funding the Consumer Involvement Working Groups request for supplemental funding in the amount of \$29,883.

Hereditary Susceptibility

Ms. Kahn provided an update on ongoing Working Group activities. The 13-minute video on genetic testing has been completed and is available at no charge through the NCI 1-800 telephone line. The video also will be mailed to special organizations and consumer groups; larger quantities can be obtained from R.O.W. Sciences. Ordering information for the video and accompanying fact sheet will be posted on the NAPBC Web site. The Working Group has received Amail-back cards@ from the first shipment of 20,000 videos, and many respondents are asking for more brochures.

The American Society of Clinical Oncology (ASCO) has endorsed *Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of the Basic Fundamental Knowledge Needed by All Health Care Professionals*, although formalities have not yet been completed. ASCO also has incorporated large portions of this document into its curriculum outline. The document will be available through the Web site or through PHS OWH.

The Working Group convened the Workshop on Privacy and Confidentiality in Genetic Research on September 16 and 17. The Working Group prepared a background paper for the workshop and is in the process of producing a publishable document with information from the workshop. Participants learned that the insurance industrys strategy on this issue is to have access to the entire medical record and to require that genetic information be included in the medical record.

AThe Position Paper on the Ethical Use and Marketing of Genetic Testing@ states that marketing firms should use truth in advertising and factual, balanced presentations.

FINANCE AD HOC GROUP PRESENTATION

Ms. Kindermann presented an update of the NAPBC FY97 Working Group budgets. She explained that this update covered expenditures through the third quarter of FY97; the figures for

the fourth quarter should be available within a month. Ms. Kindermann also noted an asterisk beside the total budget figure denoted that the budget request for that Working Group had been previously approved during May or June conference calls.

In response to an inquiry about the total budget for FY98, Ms. Kindermann replied that, as requested by the Steering Committee, there was no new funding for the support contract, and the current level for administration C\$750,000C would be maintained. A participant requested an update on Working Group expenditures and the balance remaining on the support contract.

COMPENDIUM OF GRANTS

Dr. Wood indicated that the *Compendium of Grants* was developed in response to a request to have an analysis or report on grants that were funded. All grantees were contacted for information. Because many of the grants are still in progress or part of a larger, ongoing project, final data were difficult to obtain. Therefore, the compendium is a summary of progress to date rather than a final analysis.

Participants discussed the possibilities of obtaining more information. Ms. Draper requested information on any grant products (e.g., publications, CD ROMs, Web sites) that might be appropriate for posting on the NAPBC Web site. Because the grants are not officially from the NAPBC or PHS OWH, grantees are not required to deliver reports to the NAPBC. However, the grants are funded by NCI, and therefore grantees are subject to its monitoring and required to file a final report. PHS OWH will try to collect, through NCI, the final reports on the grants, which will be sent to the co-chairs of the appropriate Working Groups for further dissemination.

FUTURE DIRECTIONS

Participants decided to delay a discussion of future directions. A suggestion was made to address this topic during a retreat. After some discussion, participants decided to replace the February 23 Steering Committee Meeting with a 2-day meeting (1-day retreat, 1-day business meeting) in February. The Steering Committee will be polled for their availability during the month of February for this event. Minimal staff support would be required for the retreat.

The topic of Steering Committee membership was revisited briefly, with Col. Browne informing the group that a list of potential member organizations for representation on the Steering Committee had been compiled, and that all the organizations were currently represented except for ASCO and the American College of Radiology. Several members commented that several NAPBC members are also members of these organizations. Ms. Visco requested a list of Steering Committee members that outlines the duration of their terms. She also clarified that organizations hold a 2-year term, but the term can be renewed.

The issue of nonparticipating members also was revisited. Ms. Visco stated that, under the terms of the present membership and operating plans, if a member is not participating, the Steering Committee or Co-Chairs recommend that the person be asked to resign.

CLOSING REMARKS

In closing, Dr. Wood expressed her appreciation to Steering Committee members for the opportunity to work with them and commented that she hopes the NAPBC will continue its exciting and productive work. Ms. Visco thanked Dr. Wood and the PHS OWH staff and commented that she values the Steering Committee members diversity of opinion and outlooks.

SUMMARY OF DECISIONS

- The Steering Committee agreed that, as a matter of policy, proposed literature reviews and NAPBC workshops should generate publishable proceedings or reports.
- The Steering Committee **approved** the literature search and the concept of the workshop on multicultural aspects of breast cancer. Revised budget estimates for the workshop will be provided to the Steering Committee for approval before the February meeting.
- The Steering Committee agreed that no additional funding should be provided for the rapid response workshop but recommended that the organizers of the NCI Workshop on Environmental Clusters of Breast Cancer consider integrating into their event the ideas and proposed participants (in particular the advocates) of the NAPBC workshop.
- The Steering Committee agreed to submit the core questionnaire to CDC, NCI, and other appropriate agencies for review, incorporate their feedback into the questionnaire, and develop the interviewers manual. It also was agreed that funding for the interviewers manual should be less than \$30,000, and substantive efforts should be made to further reduce this amount.
- The Steering Committee **approved** the revised Operating Plan language on membership pending modification and clarification of Steering Committee members roles and responsibilities.
- The Steering Committee **approved** the Clinical Trials Working Groups request for \$37,267 in supplemental funding for focus groups. The Steering Committee also **approved** the Working Groups \$8,000 request for planning and communication.
- The Steering Committee **approved** funding for Web site maintenance pending additional budget information, including comparisons with past expenditures.
- The Steering Committee agreed that detailed budget information should be sent to the full Steering Committee members two weeks in advance of the meetings.
- The Steering Committee members agreed that both Web site and written inquiries should be responded to with a form letter and referral to NCI's 1-800 information telephone line. A brochure would be included with responses to written inquiries.
- The Steering Committee **approved** funding the Consumer Involvement Working Groups request for supplemental funding in the amount of \$29,883.

SUMMARY OF ACTION ITEMS

Steering Committee members will do the following:

- Review the IAC's proposal for a toolkit for local breast cancer-related Web sites and return comments on this activity to Arlyne Draper.
- The Membership Ad Hoc Group will submit revised Operating Plan language to the Steering Committee for final approval.
- The Membership Ad Hoc Group will implement recommended changes to the letters soliciting Steering Committee nominations.
- Send to Steering Committee members a copy of the letter to NCI concerning research on viruses and human breast cancer.
- Send to Steering Committee members for approval revised budget estimates for the workshop on multicultural aspects of breast cancer.
- Send to Steering Committee members additional budget information on Web site maintenance, including the original amount budgeted, past expenditures, and how the money was allocated.
- Request from NCI the final reports on the NAPBC grants, which will be sent to the co-chairs of the appropriate working groups for further dissemination.
- Poll the Steering Committee for their availability during the month of February for a 2-day meeting (1-day retreat, 1-day business meeting).
- Distribute the final core questionnaire to Steering Committee members.
- Prepare for Steering Committee members a fourth quarter report on working group expenditures and the balance remaining on the support contract.

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. list	Fax list re: SSNs and DOBs (partial) (1 page)	09/16/1998	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Eric Morse (Events)
OA/Box Number: 21192

FOLDER TITLE:

Breast Cancer October Event [1]

2011-0619-S

rc290

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

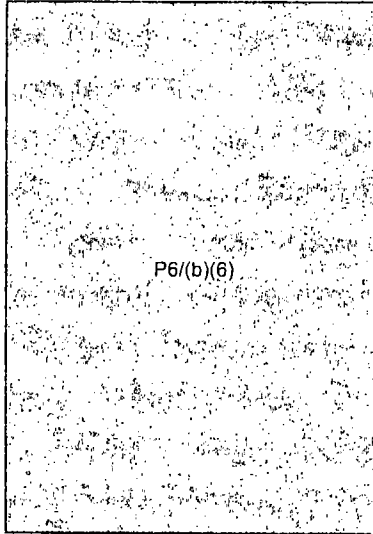
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Revised

HHS Elizabeth Summy
OWH Anna Kinderman
OWH Susan Wood
FDA Audrey Sheppard
NCI Paul Van Nevel
NCI Nelvis Castro
NCI Dr. Otis Brawley
HCFA James F. Coan
HCFA Sandra K. Kappert



[002]

CDC
Katie Chan

National Action Plan on Breast Cancer

1997 Summary of Accomplishments: A Report to the Steering Committee

Background

The National Action Plan on Breast Cancer (NAPBC) is a unique public/private partnership that serves as a catalyst for national efforts to coordinate actions by government and nongovernment organizations, agencies, and individuals to advance breast cancer knowledge, research, policy, and services. The NAPBC was initiated in response to the National Breast Cancer Coalition's 2.6 million-signature petition calling for a coordinated national strategy to combat breast cancer, the second leading cause of cancer deaths among American women. By encouraging new ideas and mobilizing partnerships, the NAPBC strives to "jump-start" innovative, long-term efforts that will result in rapid progress in the fight against breast cancer. The work of the NAPBC is guided by a Steering Committee and six Working Groups. Implementation of the NAPBC is coordinated by the U.S. Public Health Service's Office on Women's Health (PHS OWH) within the Department of Health and Human Services.

A Second Year of Achievement

In 1997, the NAPBC reached a new level of achievement. Building on the infrastructure and plans developed in 1996, the partnership moved decisively into the implementation stage, completing an impressive number of activities and initiatives that addressed the priorities of the Plan. Workshops in groundbreaking areas of research successfully demonstrated the effectiveness of a public/private partnership, as researchers and advocates examined the current state of the science, identified research gaps, and developed comprehensive recommendations for future research and actions. During the year, the Working Groups developed questionnaires and survey instruments, prepared publishable papers on a variety of urgent topics, and assisted with pertinent state and Federal legislation. These initiatives not only have significantly advanced knowledge in specific research areas but also have brought public awareness and the attention of high-level legislators and policymakers to important issues related to breast cancer.

The Steering Committee continued to guide the efforts of the Working Groups, refine the infrastructure of the Plan, and gain the support and collaboration of new public and private partners. In addition to reviewing Working Group budgets and activities, the Committee addressed membership issues in a continuing effort to enhance the diversity and expertise of the group. Although many important operating policies and decisions were made during the year, they are not the focus of this report. This report provides an overview of the NAPBC Working Groups' accomplishments in their second year to further national efforts to eradicate breast cancer.

The Hereditary Susceptibility Working Group

This Working Group is implementing a comprehensive plan to address the needs of individuals carrying breast cancer susceptibility genes and to advance education among consumers, health care professionals, and at-risk patient groups. During the past year, the Working Group examined a broad range of critical issues related to genetic susceptibility to breast cancer. In 1997, the Working Group:

- ✓ *Disseminated over 30,000 copies of the video, Genetic Testing for Breast Cancer Risk: It's Your Choice, to medical practitioners, cancer centers, and breast cancer organizations. This video was designed to assist consumers in making informed choices about genetic testing. Through personal stories of breast cancer survivors, as well as experts' presentations of the pros and cons of testing, it will help women answer the complex issues of genetic testing, including how it is done, what the results mean, and what effects the results may have on them and their families. The video also can be viewed on OncoLink, the University of Pennsylvania Cancer Center Web site (the NAPBC is among the site's sponsors). In addition, the NAPBC has received several requests to broadcast the video nationally and internationally.*

NAPBC Actions To Advance Policy

- ◆ *Held a press conference to discuss an article, published in Science, that addressed workplace discrimination based on genetic testing information. The conference produced articles in newspapers across the country and stimulated public awareness of this issue.*
- ◆ *Participated in a White House event at which President Clinton announced that legislation would be submitted to Congress to prevent discrimination in the health insurance industry on the basis of information from genetic tests.*

Jump-Starting Progress: The Hereditary Susceptibility Working Group

For many women, the exciting scientific advances to enable the identification of genes that increase the risk of developing breast cancer create a great personal dilemma: Should they be tested and possibly risk insurance and workplace discrimination? The Hereditary Susceptibility Working Group has moved rapidly on several fronts to provide information to assist women in making decisions about genetic testing, educate health professionals about genetic predisposition to cancer, identify research issues requiring immediate attention, and stimulate national policies to protect women and their families.

- ✓ *Developed the "Position Paper on the Ethical Marketing and Use of Genetic Testing" to improve understanding and consensus on principles formulated to facilitate the ethical marketing and use of genetic testing.*
- ✓ *Held a press conference to discuss an article, published in Science on March 21, that addressed discrimination in the workplace based on genetic testing information. The conference produced articles in newspapers across the country and stimulated public awareness of this issue.*

- ✓ *Convened the Workshop on Privacy and Confidentiality in Genetics Research* on September 16 and 17. The workshop was cosponsored by the National Human Genome Research Institute. At the workshop, over 100 researchers, legal and insurance experts, and patient advocates assessed protection mechanisms for confidentiality in genetics research, addressed key privacy and confidentiality issues, and developed a set of policy recommendations. Prior to the workshop, the Working Group prepared and disseminated to participants a background paper. Working Group members also worked with representatives at the U.S. Department of Health and Human Services to develop sections of the Secretary's Report on Privacy and Health Research.
- ✓ *Completed Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals and developed a dissemination plan.* The outline will serve as a framework for genetics education efforts for health care providers and establish competencies expected of them. It also will serve as a resource guide and a foundation for establishing curricula on hereditary susceptibility to cancer. One such curriculum, based on the NAPBC document, already has been developed by the American Society of Clinical Oncology.
- ✓ *Participated in a White House event at which President Clinton announced that legislation would be submitted to Congress "that will ban all health plans, group and individual, from denying coverage or from raising premiums on the basis of genetic tests."* The U.S. Department of Health and Human Services Secretary Donna Shalala spoke about the efforts of the NAPBC in addressing genetic discrimination and health insurance.
- ✓ *Served as a major information resource on the status of state legislation on health insurance and workplace policies related to genetic information.* In response to requests from the public, the media, and state and Federal policymakers, the Working Group provided current information on legislation around the country.

Educating Consumers and Providers

- ◆ *To assist consumers in making informed choices about genetic testing, disseminated over 30,000 copies of the video, Genetic Testing for Breast Cancer Risk: It's Your Choice, to medical practitioners, cancer centers, and breast cancer organizations.*
- ◆ *Developed a dissemination plan for the finalized Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals, a framework for health care providers' genetics education efforts.*

The Clinical Trials Accessibility Working Group

This Working Group is investigating methods to make clinical trials more widely accessible to women with breast cancer and women at risk for breast cancer. It is identifying barriers to participation in clinical trials, including barriers associated with the informed consent process,

patients' and physicians' misperceptions about clinical trials, and costs of participation. In 1997, the Working Group:

- ✓ *Developed a plan for conducting further research—including focus groups with consumers, health professionals, and cancer patients—to obtain information for formulating a marketing communications strategy to demystify breast cancer clinical trials, promote awareness, and encourage women to learn about and enroll in such trials.*
- ✓ *Conducted focus groups on participation in clinical trials. Nine consumer and five physician telephone focus groups were completed.*
- ✓ *In preparation for writing two publishable papers, analyzed and compiled information from a critical review of the literature on barriers to and facilitators of consumer participation in clinical trials.*
- ✓ *Continued consensus-building efforts with health insurance companies, hospitals, physicians, researchers, Federal agencies sponsoring research, industry representatives, and consumer groups concerning reimbursement for breast cancer clinical trials and monitored the development of policies on informed consent issues and insurance coverage of randomized controlled trials.*

***Mobilizing Partnerships:
The Clinical Trials Accessibility Working Group***

Breast cancer clinical trials are critical to the development of new and more effective treatments and prevention strategies. These clinical trials rely on the participation of breast cancer patients and those at risk for breast cancer. Currently, however, only a small percentage of all eligible cancer patients participate in these important research trials. One of the many complex reasons women do not participate is that they may not be knowledgeable about clinical trials. The Clinical Trials Working Group is building necessary partnerships to address this problem by bringing together consumers, scientists, government representatives, health care providers, and health communications experts to make information about clinical trials more available and user-friendly and to centralize this information in a registry.

The National Biological Resource Banks Working Group

This Working Group has focused on establishing a national network of tissue banks to ensure a resource of well-characterized and well-documented biological materials for multiple areas of breast cancer research. In 1997, the Working Group:

- ✓ *Completed the analysis of results from the Needs Assessment Survey that was sent to 20,000 researchers across the country to ascertain the quantities and types of tissue needed for breast cancer research. The results of this survey suggest that researchers want to access epidemiologically well-described materials suitable for conducting population-based studies on breast cancer; many of these materials currently are available but not to all interested researchers. Survey results were compiled in a final report that can be viewed on the NAPBC Web site.*

- ✓ *Met with members of the College of American Pathologists to discuss the availability of tissue for formal and informal research, and in particular how long tissues are retained. During the meeting, participants explored current practice regarding retention of tissue blocks beyond the required time limitations and incentives needed to encourage longer retention.*
- ✓ *Developed guidelines for Institutional Review Boards (IRBs) and others, a model patient consent form, and a patient fact sheet. After these documents were revised at a June 1997*

Catalyzing Action:
The Biological Resource Banks Working Group

Research studies to understand all aspects of breast cancer biology depend on the availability of normal and breast cancer tissue. However, no national system for obtaining, storing, and registering the tissue available for use in research studies exists, and some researchers have difficulty obtaining tissue to address specific research questions. The Biological Resource Banks Working Group, in collaboration with consumers, scientists, government agencies, and professional organizations, conducted a series of initiatives to determine the availability and adequacy of existing sources of tissue, addressed ethical and legal issues involved in collecting and using biological materials, and built the foundation for a national breast cancer tissue banks network that could be maintained by collaborating partners. The Working Group has successfully accomplished its objectives and is preparing a final report on its achievements.

workshop convened by the Working Group, Public Responsibility in Medicine and Research (PRIM&R), a trade group for Institutional Review Boards, presented them at its annual meeting in December. PRIM&R will disseminate the IRB guidelines to researchers, ethicists, professional societies, IRBs, and advocates. The National Cancer Institute (NCI) will coordinate and support field testing studies to validate the model informed consent form. The workshop summary and the other documents can be viewed on the NAPBC Web site.

- ✓ *Assisted with the transition to NCI of the responsibility for implementing a network of tissue banks. NCI has hired an ombudsman to serve as a central point of contact for researchers needing biological materials for breast and other cancer research studies. Information on tissue repositories can be obtained on the NCI Web site (<http://cancernet.nci.gov/research.htm>) or by contacting Marianna Bledsoe of the Cancer Diagnosis Program, National Cancer Institute, National Institutes of Health (301-496-7147).*

The Etiology Working Group

This Working Group is focusing efforts on expanding the scope of biomedical, epidemiological, and behavioral research activities related to the etiology of breast cancer, particularly in the areas of chemicals and hormones, lifestyle factors, ionizing and non-ionizing radiation, viruses, and gene/environment interactions. In 1997, the Working Group:

- ✓ *Completed focus group testing on all modules of the Breast Cancer Core Questionnaire and continued to integrate the comments into the modules. In collaboration with scientists*

and consumers, the Working Group designed the core questionnaire to provide a standardized set of questions, for use by all researchers, on environmental factors linked to breast cancer.

✓ *Convened workshops to explore several aspects of breast cancer etiology:*

- ▶ Workshop on Viruses and Human Breast Cancer: Exploring the Links. The workshop recommendations will be published in the *Journal of Infectious Diseases*
- ▶ Workshop on Physical Activity and Breast Cancer, cosponsored by the American Cancer Society and the Susan G. Komen Breast Cancer Foundation.
- ▶ Workshop on Medical Ionizing Radiation and Human Breast Cancer.
- ▶ Workshop on Electromagnetic Fields, Light-At-Night, and Human Breast Cancer.

NAPBC Actions To Advance Research

- ◆ *Developed guidelines for Institutional Review Boards and others, a model patient consent form, and a patient fact sheet.*
- ◆ *Convened workshops on a variety of research areas related to breast cancer etiology: viruses, physical activity, medical ionizing radiation, and electromagnetic fields and light-at-night.*
- ◆ *Conducted focus groups on participation in breast cancer clinical trials.*
- ◆ *Completed focus group testing of a six-module breast cancer core questionnaire designed to collect comparable data across studies.*
- ◆ *Produced a supplement to Environmental Health Perspectives based on presentations at the Workshop on Hormones, Hormone Metabolism, Environment, and Breast Cancer.*

Findings from each workshop are being prepared for submission to scientific journals for publication.

Understanding the Causes of Breast Cancer

Understanding the etiology, or causes, of breast cancer is critical to understanding how to prevent the disease from ever occurring and to improving treatment. Scientists know that independently and in combination, genetic, biologic, lifestyle, and environmental factors all may contribute to the initiation of breast cancer. With the assistance of consumer advocates and prominent researchers, the Etiology Working Group determines what is known about these factors and explores areas for further research.

✓ *Summarized and forwarded recommendations from the Workshop on Viruses and Human Breast Cancer to the Director of the National Cancer Institute and officials at the Department of Defense for incorporation into their research priorities.*

✓ *Published papers based on presentations from the 1995 Workshop on Hormones, Hormone Metabolism, Environment, and Breast Cancer in a supplement to the journal, *Environmental Health Perspectives*.*

- ✓ *Developed a list of resources* with information on individuals and public and private agencies that are involved in examining geographical areas in which there are elevated breast cancer rates.

The Information Action Council

The goal of this Working Group is to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other information technology. In 1997, the Working Group:

- ✓ *Introduced a new NAPBC Web site design* that provides easier access to the most current information and to frequently used sections of the site.
- ✓ *Expanded the NAPBC Web site*, linking with breast cancer information and resources from around the country and increasing the availability of information about NAPBC activities and efforts.
- ✓ *Augmented the information available through the NAPBC Web site by providing additional information* on breast cancer-related resources in response to online requests.
- ✓ *Developed and placed on the NAPBC Web site the "Guide to Volunteering in the Fight Against Breast Cancer,"* which directs readers to volunteer opportunities with breast cancer advocacy organizations.
- ✓ *Implemented the Bridging the Gap Initiative pilot project*, through which five community-based organizations across the nation are finding innovative ways to link informationally underserved women with breast cancer information through new technologies such as the Internet and Web TV. The Working Group is providing oversight to the Bridging the Gap Initiative pilot project organizations in program activities, such as community outreach, peer advisor training, Internet access training, partnership building, and other tasks that advance the project goals.

Bridging the Gap: Linking Women to Breast Cancer Information

Operating on the knowledge that there is a wealth of breast cancer information available over the Internet and on the principle that underserved women could benefit from this information, the Information Action Council developed the Bridging the Gap Initiative. Through a competitive procurement process in the third quarter of FY97, the Information Action Council awarded contracts to five community groups across the nation to link women to breast cancer information. The goals of the pilot project are to make the Internet available as a primary source of breast cancer information; to have women act on the health knowledge they gain through the Internet; and to expand breast cancer information networks within communities of underserved populations. Over the next two years, the IAC will observe programs in Anchorage, Alaska; Boston, Massachusetts; Bowling Green, Kentucky; Little Rock, Arkansas; and San Francisco, California, to evaluate the impact of the pilot project on the breast health practices of the diverse populations reached by this initiative.

The Consumer Involvement Working Group

This Working Group 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 Working Group seeks to increase and institutionalize consumer participation in ongoing research, as well as in the review of research for funding, and to involve consumers in the design of service delivery and education programs. In 1997, the Working Group:

- ✓ *Developed survey instruments* for (1) consumer organizations, (2) cancer centers, and (3) pharmaceutical companies. The purpose of the surveys was to explore the nature and extent of involvement of breast cancer consumers (patients and survivors, their representatives, or those at risk) as consumer advocates in research, service delivery, public policy, and education and outreach. In collaboration with the National Alliance of Breast Cancer Organizations (NABCO) and the National Breast Cancer Coalition (NBCC), the Working Group pilot tested the consumer organization and cancer center surveys and developed strategies for survey dissemination and data collection.

Involving Consumers

The past several years have brought many changes in how health issues are addressed. Among these changes is the increasing involvement of those affected by a disease in the development of national programs and policies. However, consumers are not yet an integral part of many health planning efforts. The Consumer Involvement Working Group is addressing this issue by gathering additional information on the nature and extent of consumer involvement in different organizations and programs to identify gaps in consumer involvement and opportunities for closing those gaps.

- ✓ *Established a database* of cancer centers and pharmaceutical companies for use in survey mailings and management and, with assistance from NABCO and NBCC, mailed 60 industry surveys, 515 cancer center surveys, and 900 consumer group surveys.
- ✓ *Entered and analyzed data* from 186 consumer group and 193 cancer center surveys that were completed and returned. A draft report on the results was prepared as a foundation for future Working Group initiatives.

NAPBC Grants Program

In 1997, the *National Action Plan on Breast Cancer Compendium of Grants* was prepared. In addition to providing contact information, the compendium summarized each grant's purpose and accomplishments.

Highlights of Upcoming Activities

Substantial progress was made in implementing NAPBC activities in 1997. Highlights of some

of the upcoming NAPBC activities for 1998 include the following:

- ✓ Three research articles generated from the Etiology Working Group's Workshop on Physical Activity and Breast Cancer will be submitted for publication.
- ✓ A genetics leadership meeting will be convened in spring/summer 1998 to educate advocate speakers on diverse genetics topics.
- ✓ Several activities will be conducted concerning multicultural aspects of breast cancer etiology. The scientific literature will be summarized, and organizations active in this area will be identified. In addition, a workshop will be convened to review and discuss the current state of knowledge about this topic and to make recommendations for future research priorities and study designs.
- ✓ Planning will begin for a workshop on hormone (estrogen) metabolizing genes, carcinogen metabolizing genes, and their relationship to environmental influences on breast cancer.
- ✓ The Breast Cancer Core Questionnaire will continue to undergo refinement. All modules, as well as a long and a short core questionnaire, will be completed. The questionnaire and an accompanying interviewer's manual will be available on the Web site in late 1998.
- ✓ Links to Internet resources concerning areas with elevated breast cancer rates will be placed on the NAPBC Web site.
- ✓ An initiative to design and produce a toolkit to encourage communities to build Web sites about local breast cancer resources will be explored.
- ✓ Fact sheets on individual accomplishments and a final report of the National Biological Resource Banks Working Group will be prepared.
- ✓ In a continuation of efforts to identify barriers to participation in clinical trials, three focus groups with people diagnosed with cancer are planned for early January 1998.
- ✓ Two papers on participation in clinical trials will be submitted for publication in spring 1998—one on healthcare provider-based barriers to patient participation and the other on patient barriers to participation and strategies to overcome these barriers.
- ✓ The Hereditary Susceptibility Working Group will continue to facilitate the advancement of policies to prevent workplace discrimination based on genetic information.

Outline for Breast Cancer Report

Pre-Report

Letter from Secretary Shalala and possibly other Cabinet Secretaries to place at the front of the report. (This should include a brief synopsis of the highlights, which should refer to the increases in funding under the Clinton Administration.)

Report

1. Profile of Breast Cancer Statistics: Relatively brief discussion of where we are on breast cancer -- mortality rates, incidence rates, etc.
2. Science: A chapter, with a more objective tone, that describes in some detail the advances that have been made in breast cancer over the last several years, in terms of both treatment and prevention. Throughout this chapter, there should be connections (albeit somewhat subtle) between these advances and the Administration's actions (e.g. FDA approval of breast cancer drugs, new investments in research).
3. The Changing Nature of Breast Cancer (or some other catchall). This chapter should in some way address:
 - quality of life issues
 - outreach
 - coordination of efforts
 - minority women
 - older womenAgain, we should also highlight all the Administration had done on these issues, and this may be even more like an accomplishments document than the rest of the report. For example, it would be good to highlight in some way how we have made so much progress on the National Action Plan. At the end of this section, there should be some discussion about the attempts to find a cure.
4. Challenges Ahead: This chapter should discuss how with all our progress, we have now have new challenges in front of us. These challenges should represent some kind of consensus between the federal agencies and activists.