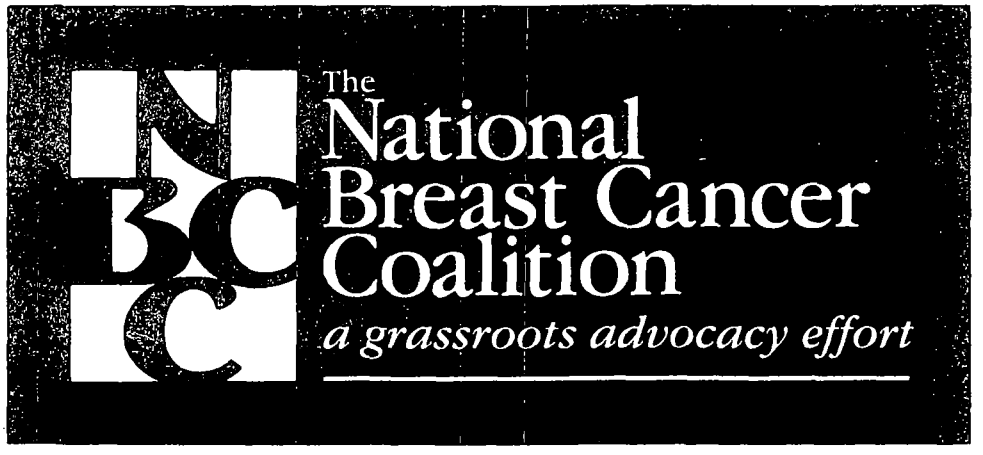
MONDAY, Oct. 18th

Monday 10/18



FUTURE PLANS

May Conference
Plans for our May conference are shaping up. We now anticipate that the advocacy training seminar will take place on Monday, May 3 at the George Washington University conference center. The next morning, we will converge on the Hill to put into practice our newly honed advocacy skills. We plan to hold a fundraising luncheon on Tuesday afternoon. Our plans for Sunday, May 2 are still in the works. **Please hold the dates!** Also, please drop a line to the Coalition at: P.O. Box 66373, Washington, D.C. 20035 and let us know if representatives of your organization are interested in attending.

February Congressional Breakfast
NOTE NEW DATE: On February 3, 1993 the Coalition will host a Congressional breakfast to brief Congressional members and to honor those members who were particularly helpful in our cause this past year. After the breakfast we expect to sponsor our first 1993 lobby day on the Hill to greet the new Congress and to begin advocating for our legislative agenda.

Membership Drive
Our goal is to double our organizational membership over this next year. To that end, we expect to launch a membership drive within the next two months. Contact NBCC if you need a membership application form. If you are aware of organizations that are interested in joining the Coalition, please share this information with them. If you are a member and have not completed a form, please do so as soon as possible. Thanks.

NBCC Search for Major Gifts Director

Due to a generous grant from a supporter of the Coalition, we are in a position to hire a seasoned Major Gifts Fund Raiser. We are looking for an individual with a proven track record and strong fundraising experience in identifying, cultivating and soliciting significant gifts from individuals and corporations ($5,000 - $100,000). We need an excellent planner and implementor, with good oral and written communication skills. Base location and hours are negotiable. If you know of someone who fits this description and is interested in the position, please have her send a cover letter, resume and writing sample to NBCC Search, c/o 612 D St. N.E., Washington, D.C. 20002.

President's Cancer Panel Special Commission On Breast Cancer

Since the inception of this Special Commission in Spring, 1991, the Coalition has protested the makeup of the Commission. The only lay members of the Commission are its chair, Nancy Brinker, of the Susan B. Komen Foundation, and Zora Brown, chair of the Cancer Awareness Program Services (CAPS) and board member of the Komen Foundation. The Coalition demanded grassroots patient advocacy representation on the Commission. As a result, the Commission opened an additional seat for nominations and the Coalition nominated the NBCC president, Fran Visco. We have just learned that the nomination has been approved. The next meeting of the Commission is January 11 and 12 in Atlanta, Georgia, the topic is treatment.

1993 Legislative Agenda

We are in the process of setting the 1993 agenda for the NBCC. While we intend to again fight for more money for breast cancer research, we also want to put together a package of access legislation - dealing with access for all women to high quality screenings, treatment and diagnosis. In addition, we are looking at legislation mandating national tumor registries. Please drop us a line with any suggestions on legislation you would like to see introduced this year.

California Bill

Congratulations to California advocates! The California Personal Income Tax law permits taxpayers to contribute amounts in excess of their liability for the support of specified funds. California recently passed an amendment to allow taxpayers to designate on their tax returns that a specified amount in excess of their tax liability be transferred to the California Breast Cancer Research Fund, created by the bill. The money would be appropriated by the Legislature to be allocated to the State Department of Health Services to make contract or grants to conduct research relating to the prevention, screening, treatment and cure of breast cancer.

Note:
If there is advocacy news you want to share with other members, please drop a note with the text to the Coalition post office box.

P.O. Box 66373
Washington, D.C. 20035
(202) 296-7477

The National Breast Cancer Coalition

a grassroots advocacy effort

Fall, 1992

UPDATE

SUCCESS...SUCCESS...SUCCESS

This has been a phenomenal year! We attained our first year's entire legislative agenda. When the Coalition announced our $300 million more campaign, we were told by many that it was an impossible goal. We were not deterred and we won! For the first time ever, because of the Coalition's work, there is a meaningful appropriation for breast cancer research. We were influential in getting the Mammography Quality Standards Act enacted and we supported the Cancer Registries Act which passed. Thanks to everyone who participated.

WHAT WE DID

$300 Million More: the Story

The story of how the NBCC and its members caused the appropriation for breast cancer research to more than triple in size bears retelling. Of course, the genesis of the "$300 million more" campaign was our commitment to ending the breast cancer epidemic by the year 2000. Recognizing that we needed to develop a plan of how much money would be needed to reach our goal, the Coalition sponsored research hearings in February 1992 at which scientists renowned in the field of breast cancer testified to areas of promising but underfunded research. Based upon these hearings, the Coalition determined that an additional $300 million should be spent on breast cancer research in 1993, for a total of $433 million. "$300 million more" became our rallying cry. We sponsored lobby days in Congress at which busloads of women came in to Capitol Hill to meet with their congressional representatives and lobby for $300 million more. We established a hotline through which mailgrams could be sent to Congress. We sent out the word through our action network and thousands responded by calling the hotline. We sent the telephone and fax numbers of targeted members of Congress to our members with the message to phone, fax and visit to demand that Congress appropriate the funds.

We initially tried to get the entire $433 million from the domestic budget - we were told that the money was not there. Because we did not give up, the House voted to appropriate $180 million, or an additional $47 million, for breast cancer research. The Senate voted for $220 million. We then went to the defense side - we started a campaign based on the theme "1% for Women's Lives - Stop Breast Cancer" - we wanted a transfer of 1 percent of the defense research and development budget of $38 billion--or $380 million--to the domestic side of the budget, $300 million of which would be for breast cancer. Initially, we became part of Senator Harkin's transfer amendment--he wanted to transfer $4.2 billion from the defense budget to domestic, including $200 million for breast cancer research. That amendment, because it would break the budget agreement, needed 60 votes to pass; it failed. Senator D'Amato then introduced our 1% amendment - it also failed although it received more votes than any other transfer amendment.

Sen. Harkin then introduced an amendment to the defense appropriations bill to allocate $210 million of defense dollars to breast

cancer research - this money would not be transferred to domestic and thus would not break the budget agreement. This amendment passed by a vote of 89 to 4 - many senators initially voted no, but when they saw the amendment was going to pass, they changed their votes to yes. Next, the administration tried to block this allocation. The Office of Management and Budget sent a letter to the defense appropriation conference committee stating that OMB would consider the money for breast cancer research domestic, even though the Senate had voted it in the defense budget. This threatened to have the practical effect of killing the allocation - it would break the budget agreement. The Coalition put its action network into high gear. Through our national action network, telephone calls, faxes, and in person visits occurred. We staged a vigil on the Senate steps - we would not leave as long as Congress was in session, until they approved the breast cancer allocation. The Congress did not succumb to the OMB threat, and the $210 million for breast cancer remains in the DOD budget.

We now intend to demand a structure through which we will have a say in how the money is spent - both on the domestic and the defense sides. The Coalition has developed a relationship with the Army officers responsible for oversight of this money and will continue to meet with representatives of NIH and NCI.

This years' allocation for breast cancer research - at least a $287 million increase - is the first meaningful appropriation for this disease. It was accomplished by the hard work and commitment of the members and volunteers of the Coalition.

Mammography Quality Standards Act

The Coalition's advocacy contributed to the passage of the Mammography Quality Standards Act. At our September 9 lobby day, we attracted additional sponsors for this bill. Under the Act, all facilities must have a certificate to operate, which is conditioned on the facility having been accredited and inspected. The accreditation program mandates strict requirements for equipment, personnel experience and training, routine quality control procedures, annual survey by a qualified medical physicist, and peer-review of clinical images. The measure establishes a National Advisory Committee, made up of patient/consumer, medical, and technical representatives, to make recommendations to the Secretary of Health and Human Services on the implementation of the law. The measure also requires a study to determine whether the new program will result in improved quality and access to mammography, and whether the reduced frequency of poor quality mammography will improve the early detection of breast Cancer.

The Cancer Registries Act

The Coalition supported passage of the Cancer Registries Act which has been signed into law. The Act establishes a National Program of Cancer Registries to make grants to States or others designated by a State to operate the State's cancer registry, to support the operation of population-based, statewide cancer registries in order to collect certain data for each form of in situ and invasive cancer (with certain exceptions). The Act also legislates a study in the states of Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont and the District of Columbia for the purpose of determining the factors contributing to the fact that breast cancer rates in those states are elevated compared to rates in other states.

Unfortunately, no funds were appropriated for implementation of this legislation. The Coalition intends to advocate this year for appropriate funding for this Act.

HOW WE DID IT

Lobby Days

Much of our success stems from the lobby days we sponsored this past year. In June, with no more than 48 hours notice, we managed to bring about 70 women to Capitol Hill to meet with their Congressional representatives and to rally outside the room in which the House appropriations subcommittee was meeting. Several Coalition members were in the committee room for the start of the meeting. The Committee voted to proceed in closed session (Rep. Early from Massachusetts was the only member who opposed closure). We then split up into groups and went to visit various legislators.

On September 9, 1992 we held a lobby day in the Senate. At least two hundred women attended. Every Senator was visited and was given a packet of information about the Coalition and the need for more money -- $300 million more -- for breast cancer research and for passage of the Mammography Quality Standards Act.

Hotline

We sponsored a hotline to Congress through Western Union. Through the NBCC hotline, several thousand mailgrams were sent to Congress in support of the appropriations and quality standards bill. We periodically changed the recipient and message as required - initially, the mailgrams were sent to Rep. Natcher, as chair of the House Labor HHS appropriations subcommittee. Subsequently, they were sent directly to the caller's Senators.

Postcard

As part of an internal mailing, postcards containing the message to vote for $300 million more for breast cancer research, to be mailed to the sender's Senators were sent out to 3,000 names and addresses.

Faxes And Telephone Calls

At various points throughout the process, the names, telephone and fax numbers of important committee members were sent out to our grassroots members through the National Action Network with the message to contact those committee members and urge for passage of legislation.

SUCCESS...SUCCESS ...SUCCESS

Our National Action Network has grown to thousands of members. All of this led to our amazing success this past year, but we all recognize how much more there is to do. We have just begun.

RECENT ACTIVITIES

Testimony

The Coalition testified before the Senate Appropriations Subcommittee, the House Subcommittee on Health and the Environment (the Committee on Energy and Commerce), the House Select Aging Committee, Special Hearings on Breast Cancer, and the President's Cancer Panel, Special Commission on Breast Cancer. Our testimony given before the House Select Aging Committee was shown on C-Span and resulted in hundreds of calls to the Coalition with requests for membership applications.

Media Coverage

The NBCC has been quoted or identified in several national newspapers and magazines over the past few months, including The New York Times, The Los Angeles Times, The Philadelphia Inquirer, The Baltimore Sun, The Memphis Daily News, Minneapolis City Paper, Time Magazine, Family Circle and The Soroptimist Magazine. We were featured in Morton Zuckerman's editorial in the November 23 issue of U. S. News and World Report. The Coalition is often featured in the Cancer Letter, the Blue Paper and similar periodicals.

Hillary Clinton Visit

On Wednesday, October 14, 1992, in Williamsburg, Virginia, several members of the Coalition participated in a round table discussion on breast cancer with Hillary Clinton, that was moderated by the NBCC president. Originally, the meeting was set with President-elect Bill Clinton, but due to his having to rest his voice for a debate, Mrs. Clinton participated. It was an exciting afternoon, in more ways than one. The Coalition Board was meeting in Washington, D.C. and planned to take a bus to Williamsburg, leaving at 11:30 a.m. for the 3:30 p.m. round table. At 2:55 p.m., 13 miles outside of Williamsburg, the bus broke down! Undaunted, the fifteen board members on board immediately jumped off the bus, flagged down any vehicles that would stop, and proceeded to the Williamsburg Lodge in a caravan of pick-up trucks, automobiles and sheriff's cars. Board members pulled up in front of the hotel at 3:25, rushed down the hall and were in place moments before Mrs. Clinton appeared. As Linda Byrd Robb, who was also present, said "These are Can Do Women!"

NOTICES

Board Membership

There have been some changes in the makeup of the Working Board. Cancer Care has resigned from the Board, while retaining its membership in the Coalition and on the Access Task Force. The Board approved the board membership applications of Breast Cancer Action of San Francisco, California, 1 in 9 of Long Island, New York, UCLA Breast Center, and approved a seat for a representative of the Washington, D.C. area chapter of the Coalition.

NBCC Computer Network

We now have on-line capability through the Cancer Forum in the CompuServe network. As of January 1, 1993, you can find us in the National Breast Cancer Coalition conference. If you are already on CompuServe, please join us. If you would like to become a member of CompuServe, let us know. We have a number of member packets that can be distributed to our action network.

Year-End Appeal

At our November meeting the Board established the hiring of support staff as a #1 priority. We need your help. Please solicit others and make a year-end contribution to the NBCC at P.O. Box 66373, Washington, D.C. 20035. Let's make this year as successful as the last!

THE CANCER LETTER

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P.O. Box 15189 Washington, D.C. 20003 Telephone 202-543-7665

Breast Cancer Coalition To Congress: 'Find A Way To Fund The War;' Bypass Level Is Not Enough

It looked as though Fran Visco was demanding money for a disease other than cancer.

She did not exchange nods with other cancer activists, did not shmooze with the lobbyists who accompanied them. Instead, Visco sat down with a group of women, several of them wearing ribbons

(Continued to page 2)

In Brief

Sullivan Rejects Oregon Medicaid Rationing Plan; Howe To Head National Marrow Donor Program

OREGON'S MEDICAID rationing plan was rejected this week by HHS Secretary **Louis Sullivan**, who said the controversial program to expand Medicaid services to the poor by excluding some services appeared to violate the Americans with Disabilities Act. Sullivan said the state's decision about which services to exclude "was based in substantial part on the premise that the value of the life of a person with a disability is less than the value of a life of a person without a disability." The plan would have excluded cancer treatment for Medicaid beneficiaries who have less than a 10 percent chance of five year survival (**Cancer Economics**, March 1992). . . . CRAIG HOWE has been named chief executive officer of the Minneapolis-based National Marrow Donor Program. Howe was associate professor of medicine and director of the bone marrow transplant program at Medical College of Virginia. . . . AMERICAN CANCER Society Clinical Research Professorships were awarded to to **Rodney Withers**, Univ. of California (Los Angeles) and **Alan Solomon**, Univ. of Tennessee Medical Center. Each will receive $250,000 for five years. **Dartmouth College** received a $1 million special institutional grant from ACS to establish a Center for Psycho-Oncology Research, under the direction of **Peter Silberfarb**. . . . PACIFIC YEW ACT has passed the Senate by voice vote and awaits signing by President Bush. The House passed the bill on July 7. The act provides for management of the yew tree, the source of the drug taxol. . . . CHILDRENS CANCER Group is seeking a pediatric oncologist-hematologist for the position of associate chairman for group operations. This new position will report to the group chairman and be responsible for operational management of the group and its office in Arcadia, CA, in association with USC School of Medicine. Appropriate clinical activities and academic appointment can be arranged. Experience in cooperative clinical trials required. Prospective applicants may write to: Chairman, Children's Cancer Group, PO Box 60012, Arcadia, CA 91066-6012.

Breast Cancer Coalition Goes Against 'The Rules,' Demands $300 Mil. More

(Continued from page 1)

emblazoned with "$300 million more," the slogan of the Breast Cancer Coalition over which Visco presides.

Taking the stand before Senate Labor, HHS, Education Appropriations Subcommittee, the diminutive 44-year-old Philadelphia trial lawyer and breast cancer survivor assumed the tone unheard of when cancer groups come to ask Congress for money:

"When the men in suits all but destroyed the savings and loan system in this country, the nation's economic stability was threatened and this Congress responded with billions of dollars.

"Because our cities are in danger of extinction, this Congress has found a way to appropriate emergency funds for the urban crisis.

"When this administration decided to wage a war, you found $7.5 billion to fund it.

"Women have declared war on breast cancer and you had better find a way to fund that war.

"Women refuse to fight with other diseases for which no funds are available. That would be going by existing rules, and too many women die under those rules.

"It is not enough that we can all say breast cancer aloud. And it is not enough to say you want to help us.

"We will no longer be passive. We will no longer be polite. We can no longer afford to wait while Congress gets around to significant, decent funding for breast cancer.

"We implore you: you must find a way to appropriate the additional $300 million for breast cancer research now. We can accept to less."

From the perspective of professional societies, NIH and NCI, this is an outlandish figure that would increase spending on breast cancer to $433 million, almost double the bypass budget level of $220 million, which NCI says would meet all opportunities in breast cancer research in FY 1993.

"I think that if they had taken the same tactic, but asked for something more in line with the bypass budget, we would have been more supportive of them," said a lobbyist for one of the professional societies.

With the congressional appropriations cycle half-over, the Breast Cancer Coalition has not been able to bring additional funds into the cancer program. However, this is not to suggest that the coalition has been ineffective. Strapped for funds yet unable to say no to a vocal constituency, Congress has done what it could: mandate a diversion of funds from existing NCI programs.

Last week, the House Appropriations Committee, apparently in response to pressure from the Breast Cancer Coalition and its supporters in the Congressional Caucus for Women's Issues, mandated a $40 million increase in NCI's spending on breast cancer research. Altogether, $70 million was reallocated to breast, cervical, ovarian and prostate cancer programs (**The Cancer Letter**, July 31).

For years cancer researchers looked wistfully at the appropriations hauled in by the politicized AIDS activists. What would happen if cancer patients became as politicized? Would more money suddenly be found for cancer?

Now the time for wondering has passed.

Like it or not, breast cancer patients have moved beyond battling paternalistic surgeons. Politicized and militant, they are taking on Congress, the President and NCI.

From Stop the War to Stop Breast Cancer

It is certainly a phenomenon where political style and political tactics are firmly rooted in demographics: the kids who once opposed the war are starting to get suspicious mammograms.

"The nature of breast cancer is such that it is starting to affect people who grew up in the sixties," Visco said to **The Cancer Letter**. "We are activists. That's our nature."

This shared political temperament made it natural for the new generation of cancer advocates to accept the lessons of AIDS activism.

"From AIDS activists we learned what would happen when you open your mouth and make demands," Visco said. "That's where we are now, and that seems to be what the people in power respond to. We are grateful to AIDS activists for showing this to us."

THE CANCER LETTER

Editor: **Kirsten Boyd Goldberg**
Founder & Contributing Editor: **Jerry D. Boyd**
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The newly politicized stance is reflected in the coalition's rhetoric.

"I recognize how starkly dissimilar my [Senate] testimony was from other testimony given that day," Visco said. "I thought it was time to give this kind of a speech. I thought it was time for them to understand that we are serious, that we mean this, and that we are not going to go away."

The Breast Cancer Coalition was started early in 1991 by leaders of CancerCare, Cancer Patients Action Alliance, Faulkner Breast Center, Mary Helen Mautner Project for Lesbians with Cancer, National Coalition for Cancer Survivorship, National Alliance of Breast Cancer Organizations, Women's Community Cancer Project and Y-ME. Since then, 160 organizations, including the American Cancer Society, joined the coalition.

Last October, the coalition decided to flex its muscles by deluging official Washington with letters demanding additional funds for breast cancer research. The goal was to generate 175,000 letters, one for each woman diagnosed with breast cancer last year.

Instead, over 600,000 letters were generated. About 140,000 letters, addressed and delivered to the White House, are yet to be acknowledged by the Bush Administration, said Sharon Green, head of Y-ME and one of the founders of the Breast Cancer Coalition.

After some negotiations, a White House staff member showed up at the side entrance of the Old Executive Office Building to accept the boxes. According to Green, the staff member stood idly while late stage breast cancer patients were placing the boxes on the conveyor.

"Our feeling was, they are probably on the way to the shredder," Green said to **The Cancer Letter.**

Room for 'Moderates?'

The $300 million figure was derived last February, after the coalition held a conference on prevention, epidemiology, basic and clinical science.

Following the conference, the coalition's "research task force," which includes activists as well as physicians and PhDs, arrived at the number.

Among the recommendations considered was one by Virginia Soffa of Vermont's Breast Cancer Action Group. By comparing incidence vs. federal spending on AIDS and breast cancer, Soffa interpolated that breast cancer research should get $4.3 trillion to reach equivalency with AIDS.

While reasonable to some activists, the $300 million figure amounted to heresy in the eyes of the groups committed to pursuing another ambitious goal: closing the gap between NCI's bypass budget and the funds appropriated to the Institute.

Some patient advocacy groups, most prominently, Nancy Brinker's Susan G. Komen Foundation, chose not to join the coalition. The American Cancer Society, also a supporter of the bypass budget, chose a different strategy.

"We knew from the outset that there would be events in which we would not care to participate," said Joann Shellenbach, spokesman for ACS and a member of the Breast Cancer Coalition board. However, the benefits of being part of an emerging political force outweighed the potential costs, she said.

"We've reached a level of understanding with their national board," Shellenbach said. "It's the local chapters with whom we have problems to iron out."

Along with the National Coalition for Cancer Research, ACS is on record asking for a $170 million increase for the entire NCI in FY93 and is opposed to diverting funds from existing NCI programs.

Later this month, at a meeting in Washington, a group of members of the society's public issues committee will gather to decide the future of ACS membership in the coalition.

"I suspect that we will give it another year," Shellenbach said. "The coalition and ACS have disagreed on certain matters, but we haven't been embarrassed. We've disagreed, we've been comfortable about doing it."

Joanne Howse, the Breast Cancer Coalition's Washington lobbyist and partner in the lobbying firm Bass & Howse, said she would like to see ACS remain in the coalition.

"If they decide to leave, from my perspective it would be a serious loss," Howse said. "But again, they obviously have to be supportive of all cancers and they have their own political considerations."

T-shirts at Rayburn

Earlier this year, under questioning by Rep. William Natcher (D-KY), NIH Director Bernadine Healy said that "despite NIH's enormous support of women's health research, I think it would be destructive to planning and destructive to the broad goals of the NIH to have $500 million [including $300 million for breast cancer] earmarked specifically for women's research."

Similarly questioned by Natcher, NCI Director Samuel Broder asked: "Sir, are you asking me for my professional judgment?"

NATCHER: "Yes, I am."

BRODER: "Our FY 1993 bypass budget request for breast cancer was approximately $220 million."

These statements notwithstanding, Howse said she is convinced that Broder "is not going to turn the money down if it's there."

The infusion of $300 million for breast cancer

research could force NCI to operate more efficiently, she said.

"When they tell us how long it takes to get the grants out, women become very impatient," Howse said to **The Cancer Letter.** "Let's get the money out. Let's not create the kind of bureaucracy that can't get the money out efficiently. Let's do something different."

Visco is similarly confident. "We can show [Broder] that the money would not be wasted," she said.

As the Breast Cancer Coalition stood by its demand, the $300 million figure made its way into a letter signed by 20 members of the Congressional Caucus on Women's Issues. Later, the figure appeared in the NIH reauthorization bill.

Then, as members of the Labor, HHS, Education Appropriations Subcommittee went to a closed session to mark up the FY93 budget, women in T-shirts inscribed with demands for "$300 million more" lined the halls of the Rayburn House Office Building.

"We aren't doing street theater, we aren't interrupting meetings like ACT-UP," said Y-ME's Green. "What we do is line the halls. They knew we were there. We did not have to shout."

Most recently, the coalition's goals got another boost when Democratic presidential contender Bill Clinton told a group of breast cancer patients that he supported the $300 million increase.

Looking for Funds

Howse said she was disappointed to see "one disease played against another disease" in the House report.

"You can't get any money from Labor, HHS," she said. "There isn't any money there. We want to get it elsewhere." Most likely, the group would call for cuts in the defense research and development budget, she said.

"We believe that we don't have to take money from other diseases," Howse said. "We are trying to figure out a way to increase the pie for breast cancer research. What we would like to see is that we increase the pie for everyone, so we are seen as heroines."

So far, attempts to cut the superconducting super collider and the space station have failed in Congress, and if the cuts are made, it is far from certain that in the current fiscal climate Congress would apply the funds to anything other than deficit reduction.

Be that as it may, the Breast Cancer Coalition is preparing for its next political action:

Not revealing the details, Howse says only that a large number of coalition members will come to Washington on Sept. 9, the first day of Senate markup of the HHS budget.

In Congress

House Preserves Space Station; Societies Support $170 Mil. Raise

The cancer program suffered another setback last week as the House voted to preserve funding for the space station. The amendment to kill the $30 billion project was expected to be followed by a move to put about $350 million into health research.

The amendment to kill the $30 billion space station, introduced by Reps. Bob Traxler (D-MI) and Bill Green (R-NY) was rejected by a 237 to 181 vote. It was to be followed by an amendment by Rep. Richard Durbin (D-IL).

In another apparent setback, the Senate Appropriations Committee restored the funds for the $8.25 billion superconducting super collider.

Observers say that even if these or other projects get the ax before the end of the appropriations cycle, it appears doubtful that the funds would be applied to anything other than deficit reduction.

Earlier this year, cancer program lobbyists expressed hopes that Sen. Dale Bumpers (D-AK) would introduce a series of amendments that would cut the defense and space budget and divert a portion of the savings to medical research.

Whatever Bumpers' ultimate plans, the bills Bumpers introduced last month (S 2930 through S 2934) mention no diversion of funds to medical research. The entire $10 billion he proposes to cut from the FY 1993 budget would be applied to deficit reduction.

• • •

Advocates of the cancer program addressed the Senate Labor, HHS Appropriations Subcommittee, reiterating their request for additional $170 million for NCI over the President's FY 1993 budget request.

"The House has recommended the NCI funding level $11 million below the President's request," said Ellen Stovall, executive director of National Coalition for Cancer Survivorship.

"This is most unfortunate since the Congress made progress last year in restoring the funding base of NCI. Overall the House provided an increase of 3.1 percent to the entire National Institutes of Health with only a 2.4 percent increase allocated to the National Cancer Institute. We urge you not to repeat the pattern of NCI receiving an increase below that of the rest of the NIH."

Stovall spoke on behalf of the National Coalition for Cancer Research.

▶Speaking for the American Society of Clinical

Mammography

Q: I am a women who is 42 years old and am concerned about the issues surrounding mammography screening. Under the Health Security Act will it be difficult to get this screening and will I have to pay a lot of money for this service?

A: The Health Security Act is deeply committed to womens' health issues. The plan is designed to work toward ensuring appropriate mammography screening in order to reduce the tragedy of breast cancer. Mammography screening is included for women over the age of 50, at no cost every two years. This recommendation was based on the best scientific literature available today, including the National Cancer Institute. For all other women mammography screening will be covered when it is medically necessary or appropriate. This decision will be made between a women and her physician. For these women, mammography will be covered with the same co-payments, just as any other medical procedure.

BH BASS and HOWES, Inc.

Patti -
I think HRC can do this in Oct.

July 16, 1993

Melanne Verveer
Deputy Chief of Staff to the First Lady
Old Executive Office Building
White House
Washington, DC 20500

Dear Melanne,

I wanted to bring you up to date on the National Breast Cancer Coalition's (NBCC) Campaign to obtain 2.6 million signatures, which represent the number of women who have breast cancer in this country.

The NBCC has asked President Clinton to invite 200 breast cancer activists most responsible for collecting the petitions and others from the scientific community, private industry and the world of public policy to a public ceremony on October 18, 1993 in the Rose Garden where we can present the petitions to him.

We have been working with a number of key individuals at the White House - Carol Rasco, Assistant to the President for Domestic Policy, Doris Matsui, Deputy Assistant to the President (see enclosed letters), and Marcia Hale, Director of Presidential Scheduling to name a few. They have been very supportive of this endeavor, and we are appreciative of their efforts. Anything you can do to help will be greatly most appreciative to make this event happen.

Looking forward to talking with you soon about possible next steps to pursue for this plan of action.

Warmly,

Joanne

Joanne Howes

Enclosure

Kim Tilly

1601 Connecticut Avenue, NW, Suite 801, Washington, DC 20009 Phone: 202-328-2200 Fax: 202-667-0462

BH BASS and HOWES, Inc.

June 25, 1993

Ms. Doris O. Matsui
Deputy Assistant to the President
Deputy director of Public Liaison
White House
Washington, DC 20500

Dear Doris,

As promised, enclosed is a letter to President Clinton requesting that he meet with representatives of the National Breast Cancer Coalition to receive the 2.6 million signatures representing the number of women living in this country with breast cancer.

It is the hope of the NBCC that the 200 breast cancer activists most responsible for collecting the petitions would be invited to participate in a public ceremony at the White House on October 18, 1993. In addition, Members of Congress, public policy makers and scientists could be added to the list.

This is an excellent time to hold this event. Not only is October designated Breast Cancer Awareness Month, but the message will be well timed in the midst of the health care reform debate. Preventing disease is an important way to restrain health care costs. Six billion dollars a year are spent on treating breast cancer; finding the cause of and cure for breast cancer will save dollars as well as lives.

We have had initial conversations with Carol Rasco and Melanne Veveer at the White House, and Sarah Kovner, Special Assistant to Secretary Shalala about developing the national strategy that President Clinton would announced. We will keep you apprised of those developments.

We will be in touch with you shortly to learn how the event is developing on your end.

Warm regards,

Joanne Howes

1001 Connecticut Avenue, NW, Suite 801 Washington DC 20036 Phone 202-328-2200 Fax 202-467-0462

We mean something new, and real, when we talk about a national strategy to end the breast cancer epidemic: a strategy that goes beyond research. This strategy will require a public\private partnership and will only work if every relevant administrative agency and the Congress are also partners in its design and implementation. This is not just an issue for the National Institutes of Health, but also for the Department of Education, Commerce, the Environmental Protection Agency, the Department of Labor, the Department of Defense and others. Most importantly, women with breast cancer and other breast cancer advocates - consumers - must be at the table from day one, involved on an equal basis at every level of the process. We can no longer afford "business as usual." It is time to shake up the system. There are many volunteers within the leadership of the business community who want to be involved in this effort. Let us mobilize these private resources. We must find a way to foster communication and coordination of effort among scientists and medical professionals, to better educate the medical profession, to form partnerships with patient advocates and the scientific community. Any strategy must find ways to remove roadblocks to innovative research, to coordinate and oversee the research performed by private foundations, to inform and educate the public about access and care.

The President should use the fact that he appointed Fran Visco to the President's Cancer Panel and announce that Fran will work with Secretary Shalala or whoever will be chosen within the Administration to lead this effort, to begin pulling together the process for a strategic plan.

EXECUTIVE MANSION
138 Eagle Street
Albany, New York 12202

Telephone: (518) 463-2295
Fax No: (518) 434-9989

TO: Patti Solis for the personal attention of Hillary Clinton

FROM: Matilda R. Cuomo

DATE: October 15, 1993

NUMBER OF PAGES TO FOLLOW: one

MESSAGE:

PERSONAL AND ~~CONFIDENTIAL~~

To elaborate and clarify the very brief note I gave you, please read the following:

FOR OFFICE USE ONLY: **SENT BY:** Ann Smerznak **TIME:** 1pm

The Politics of Breast Cancer

A grass-roots movement consisting mostly of breast cancer survivors persuaded Congress to double funds for the disease; its success is rattling the biomedical research establishment

When Kay Dickersin went to a gathering in Washington in May 1991, she wasn't quite sure what she was getting into. The meeting had been billed as a group of women who wanted to influence government policy on breast cancer research. And that was a subject in which Dickersin had a keen—and keenly personal—interest. Four years earlier she had had surgery after a diagnosis of breast cancer. It struck out of the blue: Dickersin had no family history of breast cancer, nor any of the usual warning signs or symptoms. One thing she did have, though, was knowledge: She was a Ph.D. student in epidemiology at Johns Hopkins when she was diagnosed, and she had "reams of files" on breast cancer, which she had collected out of an interest in the subject. It was the combination of personal experience and expertise that she wanted to put at the service of the informal gathering of women in Washington.

That combination of personal drive and technical knowledge has become a hallmark of the informal group Dickersin joined, which, 1 year later, has become the most visible lobby to stalk the National Institutes of Health (NIH) since the AIDS activist group ACT UP began making a loud noise in the streets of New York. The National Breast Cancer Coalition (NBCC), as it's known, along with other groups, achieved a breathtaking political victory: They lobbied Congress and persuaded it to double the amount of money it spends on breast cancer research. Some of the increase went to the National Cancer Institute (NCI), raising its breast cancer budget from $133 million to $197 million, but by far the larger amount ($210 million) went to the Department of Defense, to be administered by the U.S. Army (*Science*, 30 October 1992, p. 732).

But along with that success has come conflict: between activists, who are demanding a role in deciding how research money should be spent, and scientists, who stoutly defend the existing system. At a recent meeting, for example, Frederick Becker, research chief of the M.D. Anderson Cancer Research Center in Houston, said: "The tidal wave of advocacy...may wash away certain bulwarks of basic science that have been the greatest contributors towards the potential for cancer prevention and cure...." Their chief worry is that popularity rather than quality could become important in determining what gets funded, and that these targeted funds could siphon dollars from other basic research.

And there are conflicts even within the psyches of those who, like Kay Dickersin, are both scientists and breast cancer activists. As a scientist, Dickersin says she finds it "painful" to be identified with a political movement that aims to target research into one area. But she says that experience has shown her that the cancer research program needs shaking up. She agrees with well-known surgeon Susan Love, a fellow NBCC member, who says the coalition wants to break open what it regards as NCI's cliquish inner circle and bring in new faces. "We have to stop business as usual. We have to change the direction and really put our emphasis on basic science and prevention, and not such a large emphasis on treatment," says Love.

Dickersin is also motivated by the fact that two of her sisters have since been diagnosed with breast cancer and the fourth and youngest sister waits, fearing the worst. It's incredibly frustrating, Dickersin says, to think that "we have to sit and wait for each sister to get it, and others have to sit and wait for their daughters to get it," while nothing seems to change. She knows women in NBCC with breast cancer—daughters of women who died of it—who are "getting the same chemo, the same radiation" their mothers got. They fear their daughters will get caught in the same mill. That feeling makes them angry, and it drives their political movement.

Political prowess

Anger, of course, isn't enough on its own to drive a political movement. In NBCC's case, its clout stems from several other factors as well. One is numbers. Breast cancer is one of the commonest cancers, striking 180,000 U.S. women each year, killing 46,000, and leaving in its wake a survivor group of 1.5 million. NBCC established a broad base with captains in every state. A second factor is political know-how, which comes from people like Fran Visco, a litigator for a Philadelphia law firm who is now NBCC's president. Third is a strong dose of scientific and medical expertise, contributed by volunteers like Dickersin and Love, who cochair NBCC's research committee.

But even this constellation of factors might not have been enough if NBCC hadn't hit Washington at a time when its targets were vulnerable to a push in the right direction. NIH had declared that women's health needed more attention. And, in 1992, many senators were trying to overcome the embarrassment of the Clarence Thomas-Anita Hill hearings, proving to constituents that they cared about women's issues. The chairman of the Senate appropriations committee in charge of NIH funding—Senator Tom Harkin (D–IA)—had seen two sisters die of breast cancer and was determined to help the cause.

In exploiting this opening, NBCC president Visco and Joann Howes, a political consultant at the Washington firm of Bass and Howes, say they consciously followed the tactics of AIDS activists. To get their foot in the door, they had to show they had broad support, which they did in the fall of 1991. They solicited written appeals for increased NCI spending on breast cancer, hoping to get 175,000 letters; instead, in 6 weeks they received 600,000. They delivered them to the White House and Congress, then followed up with a technical meeting to establish scientific credibility.

In one of NBCC's key decisions, the group organized its own "research hearings" on Capitol Hill in February 1992. The activists invited top researchers to come and speak, asking whether the field could use more funds. Fifteen spoke, including Marc Lippman of Georgetown University, Maureen Henderson of the Fred Hutchinson Cancer Research

Breast Cancer Research
A Special Report

News editor: Colin Norman
Copy editor: Troy P. Gately
Designer: Diana DeFrancesco

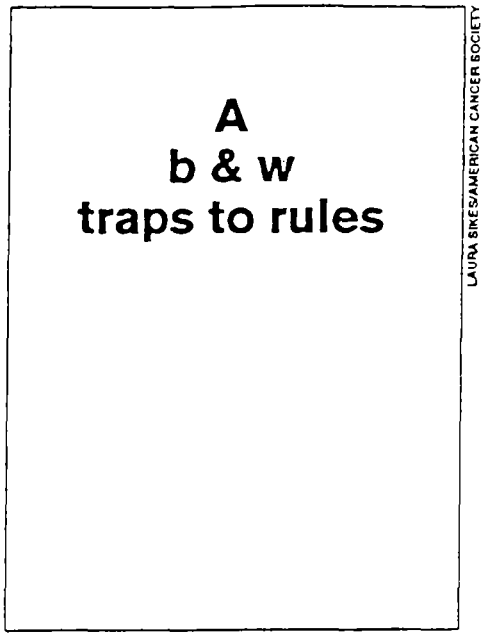
Center in Seattle, Darcy Spicer of the University of Southern California, and Graham Colditz of Harvard. To no one's surprise, they revealed that their work could use additional funding. NBCC came up with a proposed 1993 *increase* for NCI of $300 million, spelling out categories into which it should be put.

The number may have sounded like pie-in-the-sky to many old timers. But, thanks to Senator Harkin's skillful maneuvering, Congress came through with more than two-thirds of the sum the coalition was asking for. Because Congress had agreed to a cap on domestic spending, however, the money ended up in the defense budget. Pentagon defenders like Senator Daniel Inouye (D–HI) objected that it was wasteful and brazenly political to carve up the military budget this way, even for a good cause like medical research. But Harkin pointed to a clause already approved by military stalwarts in the House that earmarked $25 million in Army money for breast cancer research in 1993 and set aside another $7 million for an unnamed "institution in the Northeast." Though no document says so, any appropriations committee aide can tell you the phrase refers to the University of Pittsburgh, whose interests are guarded by two members of the defense appropriations subcommittee: chairman John Murtha (D–PA) and ranking Republican Joseph McDade (R–PA). It became clear that opposition to Harkin's move was not so much a matter of principle as who would get the funds—and how much. Once this became clear, the Senate debate came to an end and Harkin's proposal won.

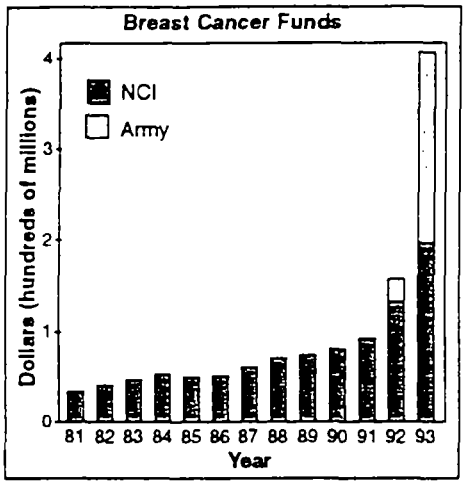
As a result, the Army now has a new mission and $210 million to spend on it. Because it doesn't have a peer-review system comparable to NIH's, the U.S. Army Medical Research and Development Command (USAMRDC) is asking for some help from the Institute of Medicine (IOM). General Richard Travis, USAMRDC's chief, told *Science* in a recent telephone interview that in December IOM agreed to pull together an expert panel that will first, rule on the appropriateness of his strategy for spending the money, and second, advise the Army on how to organize and conduct a peer-review program. Travis says his strategy is to avoid duplicating basic scientific research of the kind done at NCI and to focus instead on "mid-risk, high-payoff" projects. However, if the IOM advisers tell him he should focus exclusively on basic science, he's ready to do that instead. Travis hopes to begin soliciting proposals next spring. The one kind of project he does not intend to fund is the "bricks and mortar" variety.

A seat at the table

Having won money for their cause, the activists are not about to stop there: They want a say in how the funds are spent. At a meeting of NCI's National Cancer Advisory Board (NCAB) on 14 December, NBCC leaders



LAURA SIKES/AMERICAN CANCER SOCIETY



Cause and effect. Activists lobbied for a big *increase; $210 million ended up in the Army.*

Visco and Love laid out a manifesto of proposed changes. Members of the board were shocked to learn how intimately the activists want to become involved.

NBCC wants at least two study sections (volunteer science panels that conduct NIH's peer review) devoted to breast cancer, and they want their own members invited to sit on these panels. This would set a new precedent for NIH, and Samuel Broder, NCI's director, grumbles that people who want to do this just "don't understand how NIH works." By definition, peer review must be conducted by people with expertise in the area under review, Broder says, though he welcomes nonexperts on oversight panels like the NCAB. Here, again, he faces new demands: Cancer activists want a seat on the NCAB, and they also want an NCAB subcommittee devoted exclusively to breast cancer. They would like to be included in groups that monitor data coming in from ongoing clinical trials. They hope to establish a "formal mechanism" through which to exchange information and advice with Broder. And they want every significant subsegment of NCI to have "consumer input."

Some of these requests have upset biomedical leaders such as Becker of the M.D. Anderson Clinic and a member of the NCAB. He says others scientists have told him they agree with an impassioned speech he gave at the advisory board meeting last month, in which he stressed the importance of nontargeted research. He pointed out that some discoveries crucial to understanding breast cancer today—such as information about oncogenes and tumor suppressor genes—came out of highly specialized work on adenoviruses and retinoblastoma. He worries that the trend toward earmarking funds will make it harder to support speculative research.

NCI chief Broder, though he is trying to calm these troubled waters, also is concerned that the emphasis on breast cancer may lead to neglect of basic biomedical science. He notes that "our commitment to breast cancer has increased 177% in recent years" while NCI's overall budget has grown 35%. He worries about the lack of "balance" that's creeping into the budget, citing the cutback this year in NIH's general medical science funds as an indicator of potential trouble in the future. Trying to respond to changing political winds, he worries, could erode the agency's research strategy and deprive esoteric fields of support. Yet Broder agrees that "we have to have an open dialogue" with the patient activists, pointing out that it was he, after all, who invited them to address the NCAB.

Broder has clearly heard the message. Last September, he submitted an NCI budget request for 1994 that seems to go a long way toward doing what the breast cancer lobby would like. The total amount requested for breast cancer research, for example, jumps from the $197 million appropriated this year to $449 million. In addition, NCI is coordinating a new, NIH-wide program to attack breast cancer. It is also launching a series of "specialized programs of research excellence" (SPORES) aimed at getting the latest science into clinical trials and treatment practices as rapidly as possible, the first batch of which will be focused on breast and prostate cancer.

Although Broder says these changes are coming about because "a number of opportunities in breast cancer are unfolding," it's clear that some of them may not be purely scientific opportunities. After meeting with NCI's top brass and reviewing the budget recently, Susan Love says, "They are listening; the dialogue is starting." Broder has proposed an aggressive new plan, which, according to Love, is "exactly the kind of thing we want to see." Now the coalition is gearing up for another lobbying effort in 1993 to make sure that NCI's aggressive plan gets funded.

–Eliot Marshall

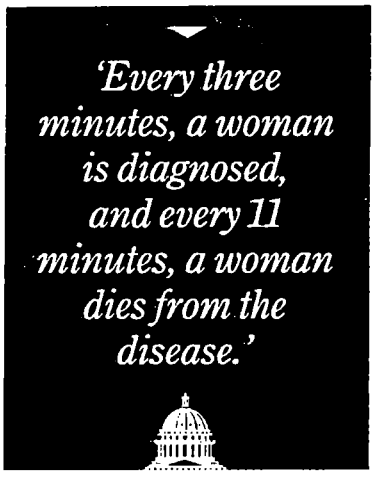
EDITORIAL

BY MORTIMER B. ZUCKERMAN
EDITOR-IN-CHIEF

BATTLING BREAST CANCER

Fran Visco had two full-time jobs at the age of 39—as a commercial trial lawyer and as a wife and mother. Her doctor recommended she have a baseline mammogram even though there was no family history of breast cancer. The mammogram revealed she had the disease. That was five years ago. She has recovered, but she knows that she was lucky and she acknowledges it by throwing herself into a campaign to make the survival of millions of other women more than happenstance.

America is undergoing a breast-cancer epidemic. Every three minutes, a woman is diagnosed, and every 11 minutes, a woman dies from the disease. It strikes 1 in 8 women and kills 46,000 a year. Nearly every woman (and many men, including this writer) has personal knowledge of someone with breast cancer and has witnessed the agonizing medical and emotional struggle to cope with the disease. It is the disease that women fear most, because it also carries with it the fear of disfigurement in a society that places great value on physical appearance. "It's like standing in the midst of a battlefield," says one woman, "with all your friends dropping around you one by one."



The perception is not fanciful. There are 2.8 million victims in America at the moment. It costs the country over $6 billion annually in medical costs and lost productivity—something to bear in mind when the "costs" of a detection program are assessed. Breast cancer has become the leading cause of death for women between the ages of 32 and 52.

This need not be. Fran Visco joined the Linda Creed Foundation, named after a 37-year-old songwriter victim and dedicated to the early detection and treatment of breast cancer. Last year, she became the first elected president of the National Breast Cancer Coalition, which is devoted to changing the rules of research and treatment. The coalition is a model of the American gift for association in action.

A national network of individual members has been formed and now runs into the thousands. In 1991 they set out to collect 175,000 letters representing the number of women who would be diagnosed with breast cancer that year. In six weeks they collected more than 600,000 letters. They organized a conference of renowned scientists in the field, who testified to areas of research that needed more money and concluded that an additional $300 million could realistically be spent annually on breast-cancer research.

With that, women went on the march. Busloads came to Capitol Hill. They set up vigil on the Senate steps. Ultimately, by force of reason and pressure they induced the Congress, and finally the president, to approve a sum of $400 million—nearly a tripling of the previous budget. It was the first meaningful increase in appropriations for the disease. It meant that many projects could be taken up that had been unfunded by the National Cancer Institute because of revenue shortfalls. No longer would women have to pay for breast-cancer research with brownie sales and chili cook-offs.

The money will also go to improving access to high-quality breast-cancer screening, diagnosis and treatment. Mammography is the best way to detect breast cancer in its early stages, when a tumor is small—even too small to be felt—and localized, often confined to the breast or to the milk duct where it arose. It is then particularly amenable to treatment. Appropriate mammography and subsequent treatment can reduce the breast-cancer death rate by as much as one third. The risk in mammography is minimal; radiation doses are low. All doctors should recommend a mammogram.

Until now, however, there has been another snag: Businesses have been slow to include insurance coverage for tests. Remarkably, it has taken a six-year battle to get screening approved as a legitimate Medicare expense. Three quarters of the *Fortune* 500 companies provide insurance coverage for the test, but the provision should be universal.

The NBCC deserves credit for refusing to fight with other medical centers for what little funds were available for medical research and for fighting instead for new money altogether. But where would we be if Fran Visco, and women like her, had not taken up the cause? Their efforts demonstrate how individual enterprise can reawaken a proper sense of national priority. ■

The National Breast Cancer Coalition
a grassroots advocacy effort

P.O. Box 66373
Washington, DC 20035
(202) 296-7477

July, 1993

The President
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President,

Women and men across the country have come together over the past two years to form the National Breast Cancer Coalition with one overriding goal-to eradicate the breast cancer epidemic. Today, the Coalition has more than 185 member organizations and thousands of individual members. We are all volunteers - this movement has grown because of the dedication of women with breast cancer, their families and friends.

The statistics on this disease are staggering: there are 2.6 million women living in this country today with breast cancer; this year an additional 182,000 will be diagnosed and 46,000 will die. In October of 1992 we met with Hilary Rodham Clinton in Williamsburg, Virginia. We wanted to impress upon her the devastating reality and the epidemic proportions of this disease that have escaped the public's awareness for too long. Women's health, and specifically breast cancer, historically have been ignored, by the pubic, by Congress and by past administrations.

We could no longer wait for others to become aware of our issue. Last year, the Coalition through a tremendous grassroots effort was responsible for the first ever meaningful increase in appropriations for breast cancer research. We accomplished this through our grassroots network that has coordinators and members in each state and the District of Columbia.

We cannot afford to see that money wasted. On May 2, 1993 we kicked off our campaign to collect 2.6 million signatures to bring to you in October, asking that breast cancer become a national health priority and that you call for a comprehensive, national strategy to end this epidemic. Over the summer women and men across this country will be involved in this campaign, collecting signatures at town meetings, shopping centers, schools - wherever possible. For many of these individuals, it will be their first experience in the political process, but they are committed to this cause not only for themselves, but for their daughters and granddaughters.

We want to present you with these signatures on Monday, October 18, 1993. We ask that you receive us at the White House on that date and hope that you will respond favorably to the need for a coordinated effort to end the breast cancer epidemic.

Sincerely,

Fran Visco

Fran Visco
President
National Breast Cancer Coalition

THE PROBLEM

Breast cancer is the most common form of cancer in women in the United States.

- **182,000 women will be diagnosed with breast cancer in 1993, and 46,000 women will die from the disease.** Every twelve minutes, another woman dies of breast cancer.
- **Breast cancer is the leading cause of cancer death for African-American women.**
- **Breast cancer is the leading cause of death for women between the ages of 35 and 52.**
- **Every woman is at risk.** The incidence of breast cancer is rising every year and we do not know why. One in eight women will get breast cancer in her lifetime, up from one in twenty in 1960. If these numbers increase at the current rate, by the year 2000, at least one in every seven women can expect to get breast cancer.

There is no known cure for breast cancer. There is no known cause.

The National Breast Cancer Coalition

a grassroots advocacy effort

The voice of women on breast cancer policy and concerns

In the time it takes to read this brochure, another woman in this country will be told she has breast cancer.

The National Breast Cancer Coalition is a grassroots advocacy effort created to focus the nation's attention on the breast cancer epidemic. Conceived in January 1991, the Coalition has grown to more than 170 organizations representing several million patients, professionals, women, their families, and friends.

The Coalition educates the public about breast cancer advocacy and, through its national action network, provides ways for individuals to become actively involved in the fight to stop the breast cancer epidemic.

The mission of the National Breast Cancer Coalition is to eradicate breast cancer by advocating:

- research into the cause of, optimal treatments and cure for breast cancer through increased funding, recruitment, and training of scientists and improved coordination and distribution of research funds.
- improved access to high-quality breast cancer screening, diagnosis, treatment, and care for all women, particularly the underserved and uninsured, through legislation and change in the regulation and delivery of breast health care.
- increased involvement and influence of those living with breast cancer in the areas of legislation, regulatory process, and all aspects of clinical trial design, including access to clinical trials.

The Work of the Breast Cancer Coalition

Legislative Impact. The Coalition initiates new laws and regulations for research budgets, quality of patient care, and regulatory policy.

"[The Coalition's] advocacy is working. The war against breast cancer is a war that must and will be won. Your leadership and advocacy in this fight have set us on the path to victory."—SEN. TOM HARKIN (D-IA)

Grassroots Mobilization. Through phone and fax chains and computer bulletin boards, the National Breast Cancer Coalition has created a network of supporters who mobilize to respond quickly to breast cancer issues that arise.

"By force of reason and pressure [the Coalition] induced the Congress, and finally the president to approve a sum of $400 million — nearly tripling of the previous budget. it was the first meaningful increase in appropriations for [breast cancer]." U.S.NEWS & WORLD REPORT NOV. 23, 1992.

Empowering Women. Faced with the lack of progress in finding the cause and cure, the National Breast Cancer Coalition is asking women to get involved and act to stop breast cancer now.

"I have managed to keep this disease at bay since 1989 and I am now energized by the work of the National Breast Cancer Coalition.... We must continue to bring these issues to legislators, health professionals, and policy makers, who have the power and responsibility to end the breast cancer epidemic." —COALITION MEMBER, N.H.

Media Attention. The Coalition works closely with national and local media to keep breast cancer issues and concerns in front of policy makers and the public.

"Breast cancer is the nations's best kept secret."
—*OTHER VIEWS*, SAN FRANCISCO CHRONICLE, SEPT. 1991

Yes, I want to join the National Breast Cancer Coalition

I want to be part of the national action network determined to fight the breast cancer epidemic.

Here is my contribution of:

___ $20 ___ $25 ___ $35 ___ $50
___ $100 ___ $500 ___ $1,000 ___ Other

My gift is in honor/memory of:

_____

___ Yes, I would like to be an active participant in the Coalition's network.

_____
NAME

_____
ADDRESS

_____
CITY

_____
STATE ZIP

_____ (_____) _____
TELEPHONE HOME

_____ (_____) _____
WORK

_____ (_____) _____
FAX

PLEASE MAKE CHECKS PAYABLE TO AND MAIL TO:

The National Breast Cancer Coalition
P.O. Box 66373
Washington, D.C. 20035

So that NBCC may lobby aggressively on your behalf to increase funding for Breast cancer research your contribution is not tax deductible.

• HISTORY & ACCOMPLISHMENTS

The National Breast Cancer Coalition • *a grassroots advocacy effort*

The National Breast Cancer Coalition is a grassroots advocacy effort conceived in January 1991. Since that time, the Coalition has grown to more than 170 organizations, representing several million patients, professionals, women, their families, and friends. Coalition members include cancer support, information, and service groups, as well as women's, consumer health, and provider organizations.

In just over two years, the NBCC has had a significant impact on general awareness about the breast cancer epidemic, and has had a major influence on public policy. We were able to achieve this success through intensive work and participation on the part of the NBCC Board of Directors, Task Forces, member organizations and our national grassroots action network.

The National Breast Cancer Coalition (NBCC) is now a forceful voice, speaking for women and men across the country, who are demanding victory in the war against breast cancer.

THE MISSION OF THE NATIONAL BREAST CANCER COALITION is to work to eradicate breast cancer, the most common form of cancer among women in the United States, through focusing national attention on breast cancer and by involving patients and caring others as advocates for action, advances and change. The Coalition informs, supports, and directs patients and concerned others in knowledgeable and effective advocacy efforts.

Nationwide, women and men are influencing policy through legislative and regulatory input, promotion of media coverage, and participation in activities such as marches and campaigns.

OUR GOALS ARE:

To promote research into the cause of, optimal treatments and cure for breast cancer through increased funding, recruitment, and training of scientists and improved coordination and distribution of research funds.

To improve access to high-quality breast cancer screening, diagnosis, treatment, and care for all women, particularly the underserved and uninsured, through legislation and change in the regulation and delivery of breast health care.

To increase the involvement and influence of those living with breast cancer in the areas of legislation, regulatory process, and all aspects of clinical trial design, including access to clinical trials.

P.O. Box 66373, Washington, D.C. 20035 • 202-296-7477

ACCOMPLISHMENTS

The NBCC "Do the Write Thing" letter campaign set out in October 1991 to deliver 175,000 letters to Congress and the President — one letter for each projected breast cancer diagnosis that year. In an extraordinary demonstration of the grassroots power of this issue, we delivered more than 600,000 letters. This outpouring of letters plus hard work by NBCC members resulted in an appropriation of $132 million for breast cancer research to the NCI in fiscal 1992 — a gain of almost 50% over 1991 spending.

In February 1992, the NBCC convened Research Hearings in Washington. Fifteen of the nation's most prominent scientists working in the field of breast cancer testified. As a result of the Hearings, the Coalition told Congress that $300 million additional dollars would be needed in 1993 for breast cancer research.

During 1992's Mother's Day weekend, the NBCC coordinated 38 events in 31 states to emphasize the need for more research dollars for breast cancer, quality assurance in mammography, and a national registry system.

In July 1992, the NIH reauthorization bill that included the NBCC's figure of $300 million for breast cancer passed the House and Senate, only to be vetoed by President Bush.

Led by the NBCC, women arrived in Washington by the busload and swamped their members of Congress with calls, faxes, telegrams through the NBCC hotline and constituent visits demanding $300 million more for breast cancer research.

The National Breast Cancer Coalition's demands were met. We won more than $400 million for breast cancer research: $210 million in the Department of the Army and $200 million to the National Cancer Institute. This total appropriation comprises the first-ever significant increase in breast cancer research funding.

We endorsed or supported the Mammography Quality Standards Act of 1992, a Sense of the Senate Resolution Declaring Breast Cancer a Public Health Emergency, the Cancer Registries Act of 1992, and the Breast and Cervical Mortality Prevention Act of 1990.

The Coalition increased the visibility of breast cancer as a national health emergency. NBCC leaders met with Hillary Clinton during the presidential campaign to brief her on breast cancer issues. We appeared on "The Today Show," CNN's "Sonya Live" and the "ABC Nightly News," and were covered by "U.S. News and World Report" and dozens of national and local publications.

On May 2-4 The National Breast Cancer Coalition kicked off its 1993 Campaign to secure 2.6 million letters, postcards, signatures, faxes and mailgrams directed to President Clinton asking that the breast cancer epidemic be declared a National Health Emergency and that we develop a National Strategy to end the epidemic.

WOMEN'S HEALTH

Women are increasingly the victims of life-threatening illness, yet still are at the bottom of our medical research agenda. Funding for research into breast and ovarian cancers, osteoporosis and other diseases remains inadequate. Although women are more likely to use health care than men, they are less likely to have insurance:

- *Women make up a larger portion of the population holding part-time jobs and clerical or sales jobs--jobs which usually don't offer health insurance to employees.*

- *Women tend to live longer and require more long-term and home health services that are often not available or affordable.*

- *Many women must rely on their spouses for health insurance, and risk of being dropped if they divorce or if they are widowed.*

- *From the beginning of the health reform process, women's health and preventive care concerns were at the core of the program. The Health Security plan will emphasize the kinds of care and research that protect women's health and guarantee comprehensive care.*

Comprehensive Benefits

- Under the Health Security plan, all women will be guaranteed coverage regardless of health status, marital status, employment status, or ability to pay.

- Women will be guaranteed a comprehensive package of benefits that will include unprecedented free coverage of a wide range of preventive services, including mammograms, Pap smears, diagnostic services, and prenatal care.

- The plan includes coverage for health services that help prevent unwanted pregnancies.

Preventive Health

- The Health Security plan will cover a schedule of preventive screenings, tests, and checkups covered in only a few of today's health insurance policies. These include regular mammograms for women

with a close family history of breast cancer and will be covered under the regular cost sharing provisions, like other medical procedures.

- The nationally guaranteed comprehensive benefits package will also include free coverage for mammograms every two years for women over age 50 free-of-charge--no matter which plan someone chooses, as an extra incentive for those most at risk.

- Preventive services included in the comprehensive benefits package are provided at ages specified by the report of the U.S. Preventative Services Task Force. These recommendations can be modified by the National Health Board as new information becomes available.

Supports Women's Health Research

- New research initiatives will concentrate on child health (including birth defects, prenatal care, and adolescent health), and illnesses that primarily strike women -- including breast cancer, ovarian cancer, and osteoporosis.

- Medical research initiatives will be expanded to include efforts to isolate and cure diseases such as breast cancer and cervical cancer.

Expansion of Home and Community-Based Long-Term Care Services

- The addition of a new home and community-based long-term care program and the expansion of nursing home coverage will help reduce the undue burden born by many women caregivers.

October 8, 1993

THE PRESIDENT'S CANCER PANEL
SPECIAL COMMISSION ON BREAST CANCER

July 23, 1993

Patti

The Honorable Hillary Rodham Clinton
The White House
Washington, D.C. 20500

Dear Mrs. Clinton:

I am writing at the suggestion of Reed Tuckson, M.D., who serves as a member of the President's Cancer Panel Special Commission on Breast Cancer (SCBC), a federally chartered committee which I chair.

This 19 member Commission is composed of national experts in all aspects of breast cancer research and care and includes three patient advocates. It has held 11 meetings throughout the nation, beginning in May 1992, at which it received testimony on every aspect of the breast cancer problem from over 190 scientists, clinicians, breast cancer survivors, and representatives of relevant government agencies, private sector organizations and businesses.

We are well aware and quite respectful of your interest in health care reform generally, and breast cancer prevention and treatment specifically. All of us were quite moved by your recent speech in Los Angeles on behalf of the Iris Cantor Center for Breast Imaging. Your anecdotes revealed the depth of your personal compassion for the millions of our countrywomen who live with this challenge every day.

Our Commission is completing its final report of findings and recommendations. It is being put together very thoughtfully and with outstanding expertise. We would very much like to provide you with the opportunity to review our report and to use both its release and its substance as part of your health reform campaign. We know that the events surrounding the publication of this document will be of high national interest, particularly in the breast cancer research and advocacy communities. To the greatest extent possible, we would like you to have the benefit of our efforts.

Additionally, I am aware that many members of the Senate have asked the President to convene selected leaders from government, the scientific community, private industry and women with breast cancer to develop and carry out a national strategy to end this disease. Our Commission is a superb group and I am convinced that no more impressive body of experts could be assembled than those from whom we received testimony. The

record of our hearings and the report of findings and recommendations developed by the SCBC based on all this testimony represent a significant investment of time, money and expertise. It is my personal goal to have the report ready by the end of October, which is National Breast Cancer Awareness Month. I hope decisions about future directions and initiatives would not be made until the Administration has had the opportunity to review it and take advantage of all the consultation and hard work that have gone on for over a year.

Given the urgency of time, I and Dr. Tuckson, perhaps along with a few others, would appreciate the opportunity to brief you or your designee about this report and to discuss the next steps. I can be reached at 214/380-9633 or your staff can contact Iris Schneider, the Executive Secretary of the SCBC at the National Cancer Institute at 301/496-5534 look forward to hearing from you soon.

Please accept my deep appreciation for your concern for the health of the Nation and for your interest, in particular, in preventing death and suffering from breast cancer.

Sincerely,

Nancy G. Brinker

Nancy G. Brinker
Chairman
President's Cancer Panel Special
Commission on Breast Cancer

cc:
Dr. Tuckson

The National Breast Cancer Coalition
a grassroots advocacy effort

P.O. Box 66373
Washington, DC 20035
(202) 296-7477

WHY WE NEED A COMPREHENSIVE NATIONAL STRATEGY

The breast cancer epidemic has been called this nation's best kept secret. There are 2.6 million women in America today with breast cancer, one million of whom do not yet know they have the disease. This year 182,000 more women will be diagnosed and 46,000 women will die.

Without a comprehensive strategic plan to end this epidemic, the loss of human and financial resources to this nation, already of staggering proportions, will continue to escalate.

The Problem?

- That we do not know what causes breast cancer, how to prevent it or cure it. That the incidence of breast cancer has been rising since the 1940's and we don't know why.

- That the researchers, the medical community, the government and the women with breast cancer do not work together, do not communicate in the search for answers.

- That 80% of women who are diagnosed with breast cancer fall into no known high risk category. That a significant portion of educational materials on breast cancer are outdated, plainly wrong or duplicative.

- That so little is known about the suspected environmental factors in the development of breast cancer.

- That there has been little progress in methods of detection and treatment over the past twenty years. That too few women have access to high quality care.

- That historically breast cancer has been underfunded and we need to find ways to bring medical professionals and scientists into the field. That we know little about the healthy breast, and fail to educate women, especially young women, in what breast health we do know.

- That breast cancer affects the entire family and too little is done to help those affected by the disease and that fear and cultural mores result in treatment denial or detection that is too late.

- That far too many women die.

Our human resources are too important,
our economic resources too limited, to waste.

We can no longer afford to battle this disease in isolation, not on any level.

The National Breast Cancer Coalition calls for a comprehensive national plan that will:

- Involve all segments of the Administrative branch, from the Environmental Protection Agency, Department of Commerce, Center for Disease Control, National Institutes of Health, National Cancer Institute, to the Department of Defense and the Department of Education.
- Involve leadership from Congress, the scientific community and the private sector.
- Foster communication and coordination of effort among scientists and medical professionals.
- Expedite the approval process for drugs and devices used in the treatment of breast cancer.
- Search for the possible environmental causes of breast cancer.
- Insure that women of all ages are educated about the importance of breast health.
- Provide incentives to attract more scientists to the field of breast cancer research.
- Remove existing roadblocks to innovative research.
- Develop strategies to provide incentives for the private sector to invest in research.
- Insure that the best available information regarding breast cancer is available to medical professionals and the public at large.
- Insure that all women have access to state of the art screening and treatment.
- Find the tools we need, but do not yet have, in the war against this disease.

Our goal is simple: The eradication of breast cancer.

We believe the goal can be achieved. We cannot do it alone. It will take the commitment of the Clinton Administration and the nation. Join the 1993 National Breast Cancer Coalition Campaign.

The National Breast Cancer Coalition
a grassroots advocacy effort

PLEASE NOTE
OUR NEW ADDRESS
P.O. Box 66373
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Summary of Position on Breast Cancer
for the 103rd Congress
Submitted By
The National Breast Cancer Coalition

Breast cancer is an epidemic that has been called this nation's best kept secret. Today, there are 2.6 million women living with breast cancer - 1.6 million who have been diagnosed and an estimated 1 million women who do not yet know they have this disease. This year alone, 182,000 women will be diagnosed with and 46,000 will die of breast cancer. It is the number one killer of women ages 32 to 54. Every three minutes, a woman is diagnosed with breast cancer. Every twelve minutes, a woman dies. Over 120 times a day, someone's wife, someone's mother, someone's best friend dies from this savage disease.

We do not know what causes breast cancer or how to cure it. Breast cancer is a disease with a legacy - a woman who is diagnosed with breast cancer knows that it is likely that her daughters and granddaughters will hear the same diagnosis some day. Yet the vast majority of women who have breast cancer have no family history of the disease. Eighty percent of women who are diagnosed with the disease fall into no known high risk category.

The National Breast Cancer Coalition is a grassroots advocacy effort committed to the eradication of the breast cancer epidemic. We know that we can achieve that goal. We recognize, however, that to do so we must effect fundamental change in all aspects of the fight against this disease. We must not be bound by the status quo, rather we need new ideas and new approaches to address the breast cancer epidemic.

The NBCC asks that this Congress recognize the epidemic of breast cancer and join in our commitment to eradicate the disease. Specifically we ask that Congress:

- Commit to ending the epidemic of breast cancer and to a national plan to combat this disease. Work with the Clinton administration to call together leaders from the Executive branch, the Congress, the scientific community and women with breast cancer and other breast cancer advocates to begin the design and implementation of this plan.

- Enact legislation that will ensure sustained increased levels of funding for breast cancer research.

• Approve a supplemental 1993 appropriation to implement the Cancer Registries Amendment Act and legislation to appropriate a sufficient level of funding in 1994.

• Amend the Mammography Quality Standards Act to strengthen its provisions and approve a supplemental appropriation to support its implementation.

• Mandate a study to determine the feasibility of and to recommend the parameters of a national tissue, tumor and devices bank or banks.

• Ask that the General Accounting Office investigate the structure and process of the National Institutes of Health and recommend changes to facilitate innovative ideas and the entry of new scientists into breast cancer research.

• Devise legislative recruitment and retention strategies that will attract and keep high quality scientists in the field of breast cancer and to support those scientists, entrenched and renowned in other fields, who wish to move to breast cancer research.

• Enact legislation that will provide incentives to the private sector to foster quality private research into breast cancer prevention, detection and treatment.

• Determine and then legislate an appropriate method to oversee and coordinate all federal breast cancer activities including agencies, projects and initiatives. It is vitally important that there be a mechanism through which the exchange of information and data can be accomplished by medical professionals and the lay public.

• Enact health care reform that results in access for all women to appropriate methods of detection and treatment. A woman's survival should not depend upon her economic circumstance. All federally funded education and screening programs must include access to treatment.

• Enact legislation to ensure that access to care will not be denied because of a woman's prior medical history.

The National Breast Cancer Coalition's complete position paper, addressed to President Clinton, follows.

must decide based on their training and experience what is truly known about an agent, which conclusions are too early to make, and, therefore, what data should be made available to a patient. Emerging data are seductive but often subject to various interpretations, as anyone who has attended a National Cancer Institute phase I meeting can readily attest.

The current phase I and phase II trial designs are products of evolution and are widely employed not for their statistical rigor, but because they provide data upon which decisions for future studies can be based. The designs also strike a balance between knowing exactly and unnecessarily treating patients with subtherapeutic doses or inactive drugs. The currently used trial designs are not perfect, and proposals to modify them usually attempt to either improve patient safety or increase the likelihood of response. However, these two elements frequently conflict with one another when a cancer patient is treated with cytotoxic chemotherapy. Many of the proposed modifications to the current phase I and phase II trial designs will shift the balance of these two factors. While a discussion of such proposals may be useful, the feasibility of any new trial design must ultimately be demonstrated by the successful conduct of the clinical study. We can look forward to the investigators at the University of Chicago and other institutions providing us with these reports in the years to come.

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Screening for Breast Cancer: What Should National Health Policy Be?

*Thomas C. Chalmers**

For decades, it has been assumed that the lives of women with breast cancer could be prolonged if their tumors could be diagnosed early, before metastasis to other parts of the body. The addition of effective technology, in the form of radiological mammography, to supplement routine physical examinations and breast self-examination has been viewed as an inherently attractive program, and mammography has become widely used in the last 20 years.

By 1977, there was general agreement that women older than age 50 should have an annual breast physical examination and mammography. This consensus was codified by the National Cancer Institute (NCI) and the American Cancer Society (ACS) (*1*). However, there were serious doubts about the wisdom of encouraging annual mammograms for women younger than 50. Was the apparent lengthening of life merely a shortening of the prediagnosis lead time? Could the exposures to x rays at a younger age be harmful (*2*)? In 1980, undaunted by these worries, the ACS encouraged mammography for women under 50.

In 1988, led by the American College of Radiology, most organizations involved with cancer treatment agreed to a more stringent recommendation, which stated that beginning at age 40, annual or biannual mammography should be performed in addition to a yearly clinical examination. In 1991, the ACS reiterated its support of radiological screening in women under 50.

The landmark Health Insurance Plan (HIP) of New York study that began 30 years ago was the first of eight long-term clinical trials in which women were selected at random or randomly assigned either to a group receiving mammography or to a control group with no mammography. Results of that trial and those from the other six studies, which have been published during the last 8 years, have been combined in a meta-analysis by Elwood et al. (*3*) presented at an international workshop on screening for breast cancer summarized in this issue of the Journal (*4*). A representative of each trial was present and participated in the deliberations.

The charge to the workshop was not to make recommendations regarding mammography, but to seek a consensus on the data from the eight studies for the benefit of an advisory committee of the NCI, which would, in turn, make recommendations. The report from the workshop summarizes data on women aged 40-49 in the trials as follows: "The randomized trials of women ages 40 to 49 are consistent in

*See "Notes" section following "References."

showing no statistically significant benefit in mortality after 10 to 12 years of follow-up . . . . In contrast, results for women ages 50 to 69 in all randomized trials confirmed the disease postponement benefit that was first seen in the HIP trial." All representatives agreed that more randomized control trial data are needed for women who might have their first mammography after the age of 69.

Thus, mammography recommendations with regard to women under the age of 50 seem to have come full circle. However, it is important to point out that there is as yet no basis for denying potential efficacy in younger women. Except for the hard-to-explain shortening of time between random assignment and death from breast cancer found in the Canadian trial, harm has neither been suggested nor proven by the randomized control trial data presented at the workshop. Although mammography's combined effect on mortality from breast cancer in women 40-49 years of age is very close to zero, the 95% confidence interval includes a potentially beneficial lengthening as well as harmful shortening of the time until death from breast cancer of approximately 30%.

This analysis by workshop participants is a good example of how hard it is to prove a negative hypothesis in clinical medicine. The statistical power needed to accomplish that task depends both on the total numbers of study subjects and on the quality of the studies. Although almost half a million young women have been randomly assigned in the eight studies, the number that have had follow-up for 10 years or more is still relatively small, and several studies have found a delay of 8-12 years in the possible effect on mortality.

The quality and applicability of the studies have been vigorously challenged by radiologists, but they are not an unbiased group (*5*). Even so, I believe that there are numerous ways in which flaws in the studies could have resulted in a spurious answer. Randomization was sometimes by clusters of patients rather than by individuals. The technique of mammography was not always what is now considered optimal. The effects of crossovers were not adequately measured (they rarely are). The best of the studies in women aged 40-49 (*6*) is one of two recently reported trials comprising the Canadian National Breast Screening Study (NBSS). This trial was different from most of the others in that the effect of annual mammography and physical examination was compared with that of a single physical examination plus yearly follow-up with a self-administered questionnaire. Over 50000 women were randomly assigned. The risk of death from breast cancer was higher in the mammography group (odds ratio = 1.36; 95% confidence interval = 0.84-2.21)—approximately 35% higher. Even if some beneficial effect begins to appear in the next 5-10 years for women aged 40-49 at the start of the study, it is extremely unlikely that the observed trend will be completely reversed. For the second NBSS trial, involving women aged 50-59 (*7*), annual mammography combined with breast physical examination had produced no effect after 7 years compared with physical examination alone. Considering the NBSS trials, the apparent trend toward a good effect of mammography in the past studies in women of all ages could be attributed to awareness stemming from an annual examination rather than a specific effect of mammography.

So the pooled results of the definitive trials on mammography in women aged 40-49 are unimpressive for mortality efficacy, as pointed out in the accompanying article by Fletcher et al. (*4*). It is important to emphasize that we are discussing routine preventive measures for breast cancer in the general population, not for patients at high risk, such as those with a strong family history.

What should those individuals responsible for public health policy now recommend? I believe that after wallowing in the data for almost a year, I can answer that question with respectable credibility.

I propose two measures: First, because of the annoying uncertainty regarding the benefit of mammography for women aged 40-49, another study that corrects a major defect in all the studies reported to date should be conducted immediately. This defect is the relative crudeness and insensitivity of determining effects by decade rather than individual years of age at the time of randomization. We can remedy this problem by obtaining from all of the investigators all of the individual patient data on age and menopausal status at the time of randomization and timing of all events and compliance after randomization. Menopausal status is especially important because many bits of data suggest that cancer of the breast acts differently before and after menopause. Perhaps menopausal status is the critical cutoff point rather than the age of 50.

The NCI should see that such a "mega-analysis" is undertaken. A precedent has been set by the National Heart, Lung, and Blood Institute. Individual data on all patients randomly assigned to coronary artery bypass surgery in seven trials started over 10 years ago are about to be published.

If such a study does not yield a satisfactory conclusion in 6-12 months and if the data from other trials now under way do not suggest a clear answer to the question, a large-scale international trial designed to avoid all past mistakes should be undertaken. This trial would, I hope, be sized to supplement the available information rather than test the null hypothesis as if no prior information existed.

My second proposal concerns third party reimbursement for mammography in women under the age of 50—or in premenopausal women, if menopause proves to be the critical cutoff point. I recommend that third parties pay for mammography in these women only if the women are randomly assigned in a peer-reviewed study. The point here is that it is foolish for some third parties to continue to pay for mammography in younger women as if it has been proven to be effective and for other third parties not to pay for mammography as if it has been proven ineffective. A board of experts could authorize exceptions such as geographic inaccessibility or other contraindications.

A policy of supporting needed clinical trials and not paying for unproven diagnostic and therapeutic interventions should be a cornerstone of any health care reform, because such a policy will improve quality while at the same time saving money. Mammography for younger women would be a great place to start.

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Deficiencies in the Analysis of Breast Cancer Screening Data

*Edward A. Sickles, Daniel B. Kopans**

Breast cancer is a major, and increasing, public health problem in the United States and most other industrialized countries. Since there is not yet an established means of preventing breast cancer, efforts to combat the disease have focused on early detection through screening to increase the success of existing treatment. There is general consensus that screening is both safe and effective in women aged 50 and older, but considerable controversy remains over the utility of screening women aged 40-49.

The report by Fletcher et al. published in this issue of the Journal (*1*) is a summary of a breast cancer screening workshop convened by the Early Detection Branch of the National Cancer Institute in February 1993. The vast majority of data presented at the workshop involved only the eight randomized controlled trials of breast cancer screening, despite the availability of an abundance of additional evidence. The article by Fletcher et al. (*1*) reflects this bias by discounting the importance of nonrandomized controlled trial data. Screening data from the eight randomized controlled trials are discussed for women aged 40 and older, with special focus on women in the specific age group 40-49, the period during which screening is most controversial.

Fletcher et al. briefly cite many of the problems that have been raised concerning the validity and applicability of the screening data presented at the workshop. However, the reader is left with the implication that these problems are relatively unimportant, when in fact they severely limit both statistical validity and clinical applicability. In this editorial, we present a much more critical analysis of available screening data and also provide what we believe to be a more balanced overview of current knowledge on the strengths and limitations of screening. Paralleling the article by Fletcher et al. (*1*), we concentrate on the evidence from randomized controlled trials of breast cancer screening in women aged 40-49. The major problems concerning the randomized controlled trial data for this age group include lack of statistical power, other flaws in experimental design, and technical deficiencies in implementation of study protocols. Some specific problems are common to all randomized controlled trials, others to individual randomized controlled trials.

Statistical Power

A randomized controlled trial of breast cancer screening must involve sufficient numbers of women who develop sufficient numbers of breast cancers resulting in sufficient numbers of breast cancer deaths, such that a reduction in the number of deaths by screening can be demonstrated with statistical validity. In designing a trial, planners make a calculation of statistical power that estimates how large the study and control populations should be to demonstrate the anticipated benefit. The smaller the expected benefit, the larger the number of women needed in the trial; conversely, if the number of women in the trial is small, only a very large benefit can be demonstrated. If the number of women is too small to begin with, or if dilution effects from noncompliance (refusal of screening) or control group bias (screening in control group) are not accounted for by increasing the number of women studied, then the ability of the trial to demonstrate a benefit is compromised (*2*).

With the exception of the National Breast Screening Study of Canada (NBSS) (*3,4*), for which only preliminary data are available, the randomized controlled trials were designed to evaluate screening in women aged 40 and older as a single

*See "Notes" section following "References."

NCI Proposes New Breast Cancer Screening Guidelines

In a much anticipated move, the National Cancer Institute announced its intention to revise guidelines for breast cancer screening.

Institute officials presented the suggested revisions last month to a subcommittee of the National Cancer Advisory Board. During October and November, NCI planned to circulate the draft guidelines to various public and private agencies for review and comment, with a target date of early December for a final decision.

The most contested part of the proposed changes centered around recommendations for women ages 40 to 49. NCI's proposed guidelines state that women ages 40 to 49 should talk to a health professional about the advisability of screening with mammography, taking into account family history of breast cancer and other risk factors. NCI had been recommending mammography every 1 to 2 years for this age group.

Dr. Peter Greenwald

Peter Greenwald, M.D., Dr.P.H., director of NCI's Division of Cancer Prevention and Control, explained that "for women age 40 to 49, there is uncertainty about the effectiveness of screening mammography for women who have no symptoms." After years of research that does not show a benefit, NCI could not continue recommending that all healthy women without symptoms receive mammograms between the ages of 40 and 49, he said.

1 to 2 Years

In the proposed guidelines, NCI also recommended that asymptomatic women age 50 and older be screened every 1 to 2 years with mammography and receive an annual clinical breast examination. NCI had been recommending annual mammography.

Because studies have shown screening with mammography at intervals from 12 to 33 months to be effective, NCI opened the interval from yearly to every 1 to 2 years. The proposed guidelines continue to include annual clinical breast examination for women ages 40 and older, and monthly breast self-examination for all women as prudent practices.

"Our best evidence for women age 50 and older is that screening with mammography at regular intervals is effective in reducing breast cancer mortality," explained Edward Sondik, Ph.D., deputy director of NCI's Division of Cancer Prevention and Control. "But the data don't determine exactly which interval is best. We're proposing to change the guidelines to reflect the information we have."

Medicare, the government-funded insurance for older people, currently reimburses for screening mammograms every other year in asymptomatic women.

NCI's proposed changes are based on the summary of the International Workshop on Screening of Breast Cancer, held in Bethesda, Md., last February (see News, March 17, 1993) . Workshop participants reviewed the results of 30 years of screening trials and a panel wrote a summary statement, which appears in this issue (see page 1644).

The workshop panel determined that for women age 40 to 49, "it is clear that in the first 5 to 7 years [after screening] there is no reduction in mortality from breast cancer that can be attributed to screening. There is an uncertain, and, if present, marginal reduction in mortality at about 10 to 12 years."

Dr. Thomas C. Chalmers

The panel also found that more than 30 years of controlled, randomized trials have strengthened the conclusion that women age 50 to 69 benefit greatly from regular mammograms. "Current scientific evidence strongly reinforces the value of screening mammography for women age 50 and older," said Greenwald. About three-quarters of all breast cancers are found in women over age 50.

For women age 70 and older, the International Workshop panel said data were "inadequate to judge the effectiveness of screening," and due to the increased risk of breast cancer in this age group, randomized trials would probably not be feasible.

NCI does not propose to have an upper age limit at which to stop screening. "Older women should make screening decisions jointly with their physicians," said Sondik, "and the decision should reflect a consideration of other health-related issues."

Gathering Comments

NCI will be gathering commentary on the proposed changes from various organizations, including the 11 agencies that had been in agreement on the current screening guidelines. At least two of these organizations — the American Cancer Society and the American College of Radiology — are expected to register some level of dissent with the proposed changes.

"We would like to see the NCI and ACS guidelines as close as possible, so as to not send a mixed message to the public," explained Harmon Eyre, M.D., deputy executive vice president for Medical Affairs and Research at ACS, the largest non-profit advocacy group focused on cancer issues. He added that "ACS has taken no action in changing its guidelines in response to NCI's proposed changes."

Eyre said that ACS agrees with the findings of the International Workshop, but disagrees on the recommendations to make from these data. "We will continue to monitor the situation," he said, "and we recognize the continuing controversy over the lack of perceived benefit of mammography for women 40 to 49," noting that ACS has long recommended that women discuss the need for mammography with their physicians.

The first major breast cancer screening trials to include women age 40 through 49 were not planned to enable a separate analysis of results in this age group. Evaluation of data from these trials show clear benefits for screening women age 50 and older, but less clear or no real benefit for younger women. Studies have not clarified this issue, and experts have not reached a consensus on the effectiveness of mammographic screening of asymptomatic women in this age group.

Edward A. Sickles, M.D., of the University of California, San Francisco, and Daniel B. Kopans, M.D., of Harvard Medical School, Boston, register their critical comments on the workshop report, mainly about the conclusions for woman 40 to 49, in an editorial in this issue (see page 1621).

"The Fletcher Report involves a one-sided analysis of the facts, ignoring

NCI's Proposed Breast Cancer Screening Guidelines

The following is a brief version of the National Cancer Institute's proposed guidelines for breast cancer screening and a summary of the proposal process.

Ages 50 and older: NCI recommends women be screened every 1 to 2 years with mammography and receive an annual clinical breast examination. Women ages 70 and above should be screened unless otherwise indicated by health status.

Ages 40 to 49: NCI recommends women discuss with a health professional the advisability of breast cancer screening with mammography, taking into account family history of breast cancer and other risk factors. NCI also recommends annual clinical breast examination as a prudent practice for this group.

Breast self-examination: NCI recommends as prudent practice monthly breast self-examination for all women, along with consultation with a health professional on proper breast self-examination techniques.

The full text of the proposed guidelines and a copy of the report on the International Workshop on Breast Cancer Screening were disseminated to the 11 agencies involved in the first set of guidelines and to professional, voluntary and advocacy groups.

These groups will comment on the draft guidelines at the Oct. 21 meeting of the Board of Scientific Counselors for the NCI's Division of Cancer Prevention and Control. The draft guidelines will also be reported to the National Cancer Advisory Board in November. A final decision by the NCI Executive Committee is slated for December.

— *Kara Smigel*

TO: Bill Grigg, Director, News Division
Office of the Assistant Secretary for Health

THROUGH: Anne Thomas, Acting Associate Director for Communications, NIH

NCI is planning to hold a press conference to announce the results of the work of the President's Cancer Panel Special Commission on Breast Cancer. The Commission met 11 times between May 1992 and July 1993 and heard testimony from 190 individuals: scientists, clinicians, patient advocates, third party payers, relevant DHHS components, biotechnology and pharmaceutical companies, the news media, scientific, professional and voluntary organizations and others.

Pursuant to Executive Order 12838, the Commission went out of existence on September 30, 1993. Their completed report will be published by NCI.

At the press conference, Mrs. Nancy Brinker, the Commission chair and a former member of the President's Cancer Panel, would like to present the Commission's findings to the Government during a press conference in Washington, D. C.

Featured speakers representing the Commission at the press conference would be Mrs. Brinker and Dr. Harold Freeman, the current chair of the President's Cancer Panel. The Commission would like to present their report to Secretary Shalala or another top figure in the Clinton Administration, who could use the occasion to announce the new HHS Breast Cancer Action Plan initiative. The Secretary will chair a special meeting December 14 at NIH. This meeting is a springboard for coordinating Federal activities to implement the Commission's recommendations.

Possible dates for a press conference would depend on the Secretary's schedule, but it is hoped that it can be held in October, which is National Breast Cancer Awareness Month. Mrs. Brinker is not able to be in Washington October 13, 14, 19, 21 or 22. We are tentatively planning to hold the press conference in the HHS auditorium.

Please let me know if you have any questions. I look forward to hearing from you and working with you.

Eleanor Nealon

Eleanor Nealon

- The ability to purchase health insurance, either [illegible] funded care is critical for access to care. Exclusion of preexisting conditions leaves women previously diagnosed with breast cancer without coverage in the event of a recurrence. Women who have been diagnosed with breast cancer cannot change jobs because future treatment for breast cancer would be excluded from coverage. Women with no coverage or inadequate insurance often experience delays in diagnosis and treatment.

- Affordability of care and of health insurance is an important issue. In small companies, breast cancer patients may be discriminated against and feel guilty if the costs of their care lead to a large insurance premium increase for their co-workers. Increased premiums and patients' out-of-pocket costs for breast cancer care can affect family resources and cause the breast cancer survivor to feel guilty.

- There is a very specific problem with regard to reimbursement for mammography. While the current recommended guidelines of the National Cancer Institute, the American Cancer Society, and other professional organizations recommend annual mammograms for women 50 and older, Medicare provides reimbursement every other year for women 65 and older and does not provide any coverage for breast clinical examination.

RECOMMENDATIONS

National Legislation

- New funds should be appropriated to support the President's Cancer Panel Special Commission on Breast Cancer's recommended program at a level no less than $500 million per year until breast cancer prevention and cure are achieved. This research effort should be under the leadership of the National Cancer Institute.

State Legislation

- Support state legislation to provide quality assurance for mammography and insurance coverage for screening, diagnostic tests, treatment, and patient care costs of clinical trials.

Payment Policies

- Decisions about health care coverage in this country should involve all members of our society and take into consideration the society as a whole, government responsibilities, and the concerns of business.

- Increase access to affordable health care coverage by:

  - Eliminating pre-existing condition clauses.

  - Providing a universal health care package regardless of financial status or job or career changes.

  - Utilizing and adequately reimbursing primary care physicians and other providers such as nurse-practitioners and physician assistants.

JOURNAL OF THE NATIONAL CANCER INSTITUTE

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MEMORANDUM FOR: Science Writers and Editors on the Journal Press List

From: Julianne Chappell, Managing Editor 301/496-6975

Subject: Highlights from October 20 Issue, No. 20
(EMBARGOED FOR RELEASE 6 P.M. EST OCTOBER 19)

Review Finds No Breast Cancer Death Reduction From Mammography Guidelines Screening of Women in Their 40's

Medicare 1st year covers—

Amid discussion of possible revisions in breast cancer screening guidelines for women aged 40-49, Suzanne W. Fletcher, M.D., American College of Physicians, and other participants in a February 1993 National Cancer Institute (NCI) International Workshop on Screening for Breast Cancer report the Workshop findings in the October 20 Journal of the National Cancer Institute.

Convened to review current worldwide clinical trial data on breast cancer screening and identify future research issues, the Workshop focused principally on the 8 randomized controlled trials (RCTs) of screening mammography conducted in nearly 500,000 women aged 40-74 in the U.S., Sweden, Great Britain, and Canada over the past 30 years. Published and unpublished data were presented by study representatives, as was a 6-study combined (meta-)analysis of RCT data, excluding the newest results.

The data consistently confirmed earlier evidence that screening women aged 50-69 reduces breast cancer mortality; a 30 percent benefit was apparent 5-7 years after entry into the trials. For women aged 40-49, however, the Workshop concluded that the RCTs showed no screening benefit 5-7 years after study entry, with only marginal and uncertain mortality reductions apparent after 10-12 years of followup. A combined analysis of the Swedish studies showed a statistically insignificant 13 percent mortality decrease

at 12 years. The only trial with followup exceeding 12 years showed a 25 percent mortality decrease (of disputed statistical significance) at 10-18 years. The meta-analysis estimates showed no significant effect of screening, but with a wide range of uncertainty in both directions (from a 15 percent mortality decrease to a 39 percent mortality increase). Despite their high breast cancer risk, too few women over age 70 were included in the trials to assess screening effectiveness.

The authors acknowledge difficulties in drawing firm conclusions from the data--study designs differed and each trial experienced problems: insufficient statistical power for valid age subgroup analyses; possible randomization problems; control group screening outside of the study; different screening intervals (12-33 months) and procedures (mammography, clinical breast examination, and breast self-examination alone or in combination); variations in mammography image quality and procedures (one- versus two-views per breast); inconsistent screening participation levels; and followup and outcome classification variations. Still, they believe, the RCT data provide stronger evidence on breast cancer screening effectiveness than is available for any other cancer.

Workshop participants made no recommendations regarding current NCI/American Cancer Society mammography screening guidelines (i.e., mammography at 1-2 year intervals for women aged 40-49, annually thereafter), but suggested future research questions. Specifically, studies are needed to determine the age at which screening becomes beneficial and the age after which it may no longer be useful; determine intermediate screening sensitivity and specificity measures; assess the added value of two-view versus single-view mammography; and determine the most effective screening modality and screening intervals by age group. A new randomized trial under way in the United Kingdom should determine if newer mammography techniques translate into mortality reductions in women beginning screening in their early 40's. Further, they say, continued followup of the current RCT studies is needed to see if screening benefit in younger women emerges in later years and to clarify worrisome issues in some of the trials; a second meta-analysis may be useful when more data are available. Finally, quality control procedures and standardized reporting should be developed for RCTs, and screening benefit for older women should be investigated.

Two editorials accompany the report by Fletcher, et al. Thomas C. Chalmers, M.D., Medical Research Consulting (West Lebanon, New Hampshire), an expert on meta-analysis, writes that while the 8 RCTs represent a significant body of data, methodological differences, study problems, and issues these create for aggregating data and generalizing findings make it impossible to preclude potential screening benefit in younger women. He believes two more studies are needed: First, an NCI-supported "mega-analysis" of individual patient data from all 8 studies should assess whether factors other than age (e.g., menopausal status) determine when screening effectively reduces breast cancer mortality. Second, if this effort or new data from ongoing breast screening RCTs does not provide answers, a large international trial that avoids past mistakes should be conducted to supplement existing information. In the interim, he notes, third party payors

could support the research efforts and save health care dollars by reimbursing mammography screening of younger women only when they participate in a randomized, peer reviewed study. This approach would also further a policy to support clinical trials and not pay for unproven diagnostic and therapeutic interventions.

In the second editorial, two radiologists--Edward A. Sickles, M.D. University of California, San Francisco (UCSF), and Daniel B. Kopans, M.D., Massachusetts General Hospital--maintain that the Workshop findings minimize or ignore the RCTs' significant methodological and statistical problems to reach unsupportable conclusions regarding screening benefit for women aged 40-49. Most importantly, they say, the RCTs were not designed to prove efficacy in age subgroups and included too few women at each age to do so. Moreover, the conclusions ignore non-randomized trial findings showing screening benefit (e.g., lower tumor grade/size, less frequent lymph node involvement) among screened women in whom breast cancer was found. Sickles and Kopans express special concern that poor mammography image quality provided in the RCTs masked screening benefit, and stress that modern mammography, which vastly improved imaging of younger women's breasts, renders the RCT mammography results irrelevant to current screening policy decisions.

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October 4, 1993, Monday, BC cycle

HEADLINE: RULING ON LESBIAN ADOPTION GIVES CHILD TWO MOTHERS
BYLINE: By Sasha Cavender

Katie Love-Cooksey may not choose to follow in the footsteps of her mother, nationally acclaimed breast surgeon Dr. Susan Love. But the five-year old girl is already famous as the child in a landmark legal decision which allowed a lesbian couple to adopt her.

On Sept. 10 Love and her longtime companion Dr. Helen Cooksey, also a surgeon, were the first gay couple to win such a ruling from the Massachusetts Supreme Court after a long-running court battle closely monitored by both the homosexual and legal communities.

"We're thrilled and excited the court has decided to validate our family," said Love. "This has been dragging on for years."

For Katie it simply means she has two mothers- something she accepts as perfectly natural. She calls Love "Mommy" and Cooksey "Mama."

"I can't see any problem with it," Love said in an interview. "There are so many children that are abused and abandoned, to criticize the makeup of someone's family life is presumptuous."

The couple, who lived in Cambridge, Mass., for many years and taught at Harvard Medical School, were anxious to have a child with biological ties to both of them. Cooksey tried first to conceive by artificial insemination with sperm from Love's brother. When this was unsuccessful, Love later conceived with sperm from Cooksey's cousin.

"Katie knows who her father is," said Love, who is well known for her candor with her patients and treats her daughter the same way.

She said she, Cooksey and Katie all view the father as part of their extended family, though he waived any adoption rights.

"What we told (Katie) is we love each other and we wanted to have a family and we asked her father to help us. He was willing to give us a seed," said Love, adding that Katie has asked to hear the story over and over again.

The couple has shared Katie's upbringing from birth. Both are financially responsible for her, both volunteer at her school and spend weekends with her.

During the prolonged battle to adopt the little girl, a nun and a priest testified that the family was close, loving and church-going. Teachers, colleagues, mental health professionals, neighbors and relatives all testified that "the three form a healthy, happy and stable family unit."

Educators who know Katie described her as an "extremely well-adjusted, bright, creative, cheerful child who interacts well with other children and adults." Neighbors testified they would have no hesitation in leaving their own children in the care of Love or Cooksey.

Last year the family moved from Cambridge to Los Angeles, where Love is director of the Breast Center at the University of California at Los Angeles. Cooksey, a general surgeon, is currently a full-time mother helping Katie adjust to life in a new city.

UCLA treated Love's recruitment to the university "like any other academicrecruitment," said Dr. Michael Zinner, chief of general surgery. "We discussed her family's needs in moving here, a UCLA preschool for daughter, health benefits."

But officials were not so matter-of-fact four years ago when they tried to bar Love and Cooksey from taking Katie on a trip out of the country, demanding that the child must have her father's permission to leave.

The couple contacted attorney Katherine Triantafillou and the long struggle to win Katie's legal adoption began.

The case was the first in Massachusetts, though New York, California, Vermont, Oregon, Alaska and the nation's capital, Washington- have had court rulings allowing similar adoptions.

"This is not just a gay rights case," Triantafillou said of the precedent-setting Massachusetts court ruling. "It allows heterosexual, unmarried couples to adopt too. Clearly the time has come to acknowledge that many, if not most of us, do not live in so-called traditional families and the court's opinion reflects that reality."

Love has a number of 'firsts' to her credit. She was the first female surgeon appointed to the staff at Beth Israel, a Harvard teaching hospital. And in 1988 she founded the Faulkner Breast Center, the first in the United States to have five female surgeons and an all-female medical, nursing and support staff.

"She changed the way other doctors do business," said Dr. Deborah Prothrow-Smith, an assistant dean at Harvard School of Public Health and a former Massachusetts health commissioner.

But so far Katie has no interest in becoming a doctor like both her mothers. She wants to be a ballerina.

"I hope breast surgeons are obsolete by the time she grows up," said Love.