

MAMMOGRAMS

MASTECTOMY

BREAST CANCER EVENT
FUNDING
GENETIC

Medicare Coverage of Mammography

- o Currently, Medicare covers mammograms on a bi-annual basis for elderly women (the periodicity varies by age) and requires a co-payment.
- o In recent two year period, about 7 million Medicare beneficiaries had a mammogram or about one in three of the nearly 22 million women on Medicare. Clearly, this rate needs to be improved in order to detect and treat breast cancer as early as possible.
- o The President's budget proposal would cover mammograms on an annual basis and would eliminate the co-payment. Research has indicated that the co-payment reduces Medicare beneficiaries' access to mammograms.
- o Under the President's budget proposal, female Medicare beneficiaries could receive a mammogram every year without a co-payment. (About 10% of Medicare beneficiaries rely on Medicare alone: consequently, 2 million women are currently liable for the co-payment when they get mammograms. Other beneficiaries have Medicaid or Medigap insurance which fills in the co-payment.)
- o In addition to better insurance coverage, this Administration has sponsored a public awareness campaign to increase utilization of mammography. For example, the First Lady urged women, last Mother's Day, to get a mammogram.

DATA: The number of women on Medicare will grow to nearly 25 million by 2005.

Source: Health Care Financing Administration

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Source: Health Care Financing Administration



A Message From The Administrator

Get a Mammogram....A picture that can save your life

Dear Colleague:

We hope you will join us in a campaign to encourage more women age 65 and older to protect themselves by obtaining mammography screenings. Although Medicare covers screening mammograms for the early detection of breast cancer, Medicare data indicate that more than 60 percent of older women do not take advantage of this benefit. A successful campaign can prevent thousands of unnecessary deaths.

The Health Care Financing Administration (HCFA) is undertaking the mammography campaign as the second step in the agency's "Consumer Information Strategy." This national strategy will help Medicare and Medicaid beneficiaries participate with their physicians in making decisions on prevention and treatment options.

Preventing breast cancer deaths with timely mammograms is a prime target for our attention. Breast cancer will affect one of every eight women born in the United States. The risk of breast cancer increases with age. National data show that in 1994, approximately 50 percent of new cases of breast cancer were in women age 65 and older; and about 56 percent of the deaths from breast cancer were in women age 65 and older. For women age 65 or older, getting a mammogram every two years can save lives.

We need your assistance in publicizing the life-saving value of mammograms and Medicare coverage of this procedure.

The following materials should be helpful to you:

- Medicare claims data showing 1992 - 1993 mammography utilization rates by state and by race;
- A HCFA brochure, in English and Spanish, telling older Americans about the benefits of the Medicare-covered mammograms;
- Posters encouraging regular mammograms;
- A fact sheet on HCFA's Consumer Information Strategy;
- A HCFA fact sheet on the Medicare mammography benefit; and
- A Woman's Guide on Quality Mammograms from the Agency for Health Care Policy and Research.

We look forward to working with you. If you need additional information, please call HCFA's Office of Public Liaison at (202) 690-6616. For information about HCFA's state and county mammography utilization data, please call (410) 597-3933.

Sincerely,



Bruce C. Vladeck, Ph.D.
Administrator
Health Care Financing Administration



Fact Sheet

Get a Mammogram....A picture that can save your life

MEDICARE COVERAGE OF MAMMOGRAMS

Medicare is a federal health insurance program for people 65 and older and certain individuals with disabilities or end stage renal disease (ESRD). It is run by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services.

Screening Mammograms:

Since January 1, 1991, Medicare has covered mammography screening for the early detection of breast cancer. Screening mammograms, together with a physician's interpretation of the results, are covered by Medicare. The following table describes the conditions under which Medicare will pay for screening mammograms.

AGE	MEDICARE COVERAGE FOR SCREENING MAMMOGRAMS
Under 35	No Coverage
35 to under 40	Only One Screening Mammogram
40 to under 50	One Screening Mammogram Every 2 Years
40 to under 50*	One Screening Mammogram Every Year
50 to under 65	One Screening Mammogram Every Year
65 and above	One Screening Mammogram Every 2 Years

*Women with a high risk of developing breast cancer (for example, a woman with a mother, sister or daughter who has had breast cancer).

Medicare also covers diagnostic mammograms when the patient shows signs or symptoms of having breast disease. Medicare will cover these diagnostic mammograms for Medicare beneficiaries when the patient's physician has a specific reason for ordering the test, no matter what the age of the patient.

Payment for Screening Mammograms:

In 1995, a beneficiary's share of the costs will vary depending on the type of mammogram, whether her physician's Medicare claim is assigned or unassigned, and whether her Part B deductible has been met.

MORE



HCFA FACT SHEET (cont.)

For screening mammograms, Medicare will pay a maximum of 80 percent of the 1995 Medicare approved amount (that is, $\$60.88 \times .80 = \48.70). A physician who does not accept assignment of a Medicare claim may charge a beneficiary no more than 115 percent of the Medicare approved amount.

For diagnostic mammograms, Medicare will pay a maximum of 80 percent of the fee schedule amount. The fee schedule amount is approximately \$67.16. The exact amount varies based on location and whether a physician is a Medicare participating physician. A physician who does not accept assignment of a Medicare claim may charge a beneficiary no more than 115 percent of fee schedule amount.

Quality Standards

The Mammography Quality Standards Act (MQSA) of 1992 went into effect on October 1, 1994, requiring all mammography facilities seeking Medicare payment for mammography screening to meet quality standards defined by regulations of the Food and Drug Administration (FDA). To lawfully perform either screening or diagnostic mammography under MQSA, facilities must obtain a certificate from the FDA by meeting quality standards for personnel, equipment, quality assurance and record keeping and must display its FDA certificate.

To retain the certificate, a facility must successfully complete an annual inspection by an MQSA inspector trained by the FDA. HCFA has ceased performing inspections. Instead, HCFA has agreed to accept FDA's certification as evidence that the facility is qualified for Medicare reimbursement, thereby minimizing duplication of inspections.

Statistics



The American Cancer Society (ACS) estimates there will be 182,000 new cases of invasive breast cancer in 1995 and that 93,700 of these cases will be in women age 65 and older.



ACS estimates there will be 46,000 deaths in females from breast cancer in 1995 and that 25,700 of these deaths will be in women age 65 and older.

For More Information call...

1-800-4-CANCER (1-800-422-6237)
(Breast cancer/mammograms)

1-800-638-6833
(Medicare coverage)



Beneficiary Newsletter

Get a Mammogram....A picture that can save your life

**MAMMOGRAMS SAVE LIVES!
THE FACTS ABOUT OLDER WOMEN AND BREAST CANCER**

The Health Care Financing Administration (HCFA), the federal agency responsible for the Medicare and Medicaid programs, is conducting a nationwide public information campaign to encourage women age 65 and older to get screening mammograms. A mammogram can find breast cancer that is too small for a woman, her doctor or nurse to feel during regular physical breast exams. Mammograms can detect breast cancer early when it can be treated. Mammograms save lives.

Breast cancer will affect one of every eight women born in the United States, and the risk increases with age. Breast cancer is the most commonly diagnosed cancer and the second leading cause of death among women. Breast cancer is most common among women over age 65. National data show that in 1994, approximately 50 percent of new cases of breast cancer were in women age 65 and older; and about 56 percent of the deaths from breast cancer were in women age 65 and older.

Although Medicare covers screening mammograms for the early detection of breast cancer, Medicare data indicate that more than 60 percent of older women do not take advantage of this benefit. Rates for African American women are even lower.

For women age 65 and older, Medicare helps pay for one screening mammogram every two years. Medicare's interval for screening is consistent with the National Cancer Institute (NCI) statements. It is important for women age 65 and older to return for a mammogram every two years (sooner if symptoms develop), because cancer can show up at any time. For women who are younger than age 65 and are covered by Medicare, the age and risk of the patient determine how often screening mammograms should be done. Medicare does not cover screenings for women under age 35.

Medicare covers diagnostic mammograms when a woman shows any signs of breast disease. For Medicare eligible women of any age, diagnostic mammograms are covered when ordered by their doctors.

Individuals who are Medicaid eligible should contact their state or local medical assistance (Medicaid) agency, social services office, or welfare office to find out about Medicaid coverage of mammography screenings.



CONSUMER Information Strategy

Get a Mammogram....A picture that can save your life

OVERVIEW



The Health Care Financing Administration's (HCFA) Consumer Information Strategy will help Medicare and Medicaid beneficiaries stay healthy. Using information from a variety of sources, the initiative encourages greater use of health care services and assists beneficiaries in making informed choices about health care.



Medicare and Medicaid data on the use of services and patterns of care are the primary source of information for the initiative. Medicare alone pays more than 700 million claims a year for services to beneficiaries. Data on patterns of care can provide useful information on treatment options. Analysis of claims data can also identify underserved localities to which special outreach efforts may be targeted.



HCFA plans to use its network of communications with consumers and physicians to promote use of important existing Medicare benefits and to help consumers choose wisely among alternative treatments. The first full scale campaign in 1994 promoted use of covered flu shots.



Screening mammography is the second campaign. Later campaigns will help beneficiaries choose among treatment options for localized prostate cancer and early stage breast cancer. All campaigns make use of HCFA's claims data to highlight current practice and to monitor effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

MEMORANDUM FOR KITTY HIGGINS

Subject: Hearings on Mammography; Wednesday, February 5, 1997

On Wednesday, February 5, Dr. Richard Klausner, Director of the National Cancer Institute (NCI), and Dr. Susan Blumenthal, Assistant Secretary for Women's Health, will testify on mammography before the Senate Appropriations Subcommittee on Labor/HHS/Education.

The hearing was called to review the findings of a National Institutes for Health Consensus Conference on mammography screening of women ages 40 to 49, which was held at NIH from January 21-23. The panel stated that the available scientific data do not warrant a singular recommendation for annual mammography for all women in their forties, but that each woman should weight the costs and benefits and decide for herself whether to undergo mammography. For women in their forties who choose to have a mammogram, the panel recommended that insurers *should* cover the procedure. Dr. Klausner issued a statement that, while he agreed with the panel's conclusions, the report understated the benefits of mammography and overstated the risks and thus, did not present a balanced statement to the public.

Dr. Klausner's testimony will review the science that provides the basis for current screening practices, the controversy surrounding the 40-49 age group, and the information women need to make an informed decision.

Dr. Blumenthal's remarks will focus on the progress of Departmental initiatives to ensure that mammography is of the highest quality, and that women have increased access to this lifesaving technology. She will describe other initiatives that are underway to improve diagnostic screening. These include evaluation of novel technologies, such as magnetic resonance imaging and positron emission technology, and the transfer of imaging technologies from the defense, space, and intelligence communities. She will also discuss other Departmental activities in this area.

William V. Corr

To be Released Upon Delivery

Statement of
Richard D. Klausner, M.D.
Director, National Cancer Institute
on Screening Mammography

Before the
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Senator Arlen Specter, Chairman
February 5, 1997

Good morning, Senator. I am Richard Klausner, Director of the National Cancer Institute. I am here to talk about mammography screening for women ages 40-49. I want to thank you for your interest in this important issue. Two weeks ago, a conference was held at the NIH that brought together experts in all aspects of mammography and an independent consensus panel to address the often confusing and sometimes contentious debate that surrounds the question of the age at which a woman should begin regular mammography. On behalf of the NCI, I had asked for the conference in response to reports of new data, primarily from Sweden, that addresses the great gap in our knowledge concerning the potential benefit of population screening of women age 40-49 and, as hoped, the conference successfully stimulated the presentation and discussion of new and updated data.

From a scientific point of view, the value of any screening test used in a healthy population depends on the incidence of the disease, the mortality associated with that incidence as well as on the performance characteristics, shortcomings, and risks of the screening procedure. A woman's risk of breast cancer does not suddenly change at a particular age but gradually and steadily rises. It is not surprising therefore that the value of widespread screening follows a similar pattern. There is general agreement that the population of women between the ages of 50-69 benefits from regular mammography. While breast cancer does occur in very young women, there is general agreement that, because of its low incidence in this population, screening for all women in their 20's or 30's is not warranted. So we are left with the issue of women age 40 to 49. As a woman enters her forties, she is beginning to move from a time when regular population screening is not warranted to one where it is proven to be beneficial. The question is where that line is crossed. Is it age 40? Age 42? Age 46? Or Age 50?

Rather than concluding that there is only one right answer to the question, the Panel concluded that each woman should make an informed decision in the transition decade of her forties that is the right answer for her. Despite some press accounts, I stated at the end of the conference that I agreed with this conclusion of the Panel. My concern was with the balance and tone of the discussion in the Panel's draft report. It is my opinion that the draft report of the Panel overly minimizes the benefits and overly emphasizes the risks for this population. A balanced statement of the pros and cons of screening is essential for a woman to make an informed decision whether to initiate regular mammography in her forties.

Do we now have evidence that would support a woman's decision if she decides to begin screening mammography in her forties? The best data we have is from 8 randomized clinical trials involving about 180,000 women, including the 5 Swedish studies. Few trials have enough instances of death from breast cancer to achieve statistical significance, but analyzed all together, by a procedure called meta-analysis, there is about a 15 percent reduction in mortality. The meta-analysis included eight

randomized clinical trials that were conducted over the past 30 years from the United States, Sweden, Canada and Great Britain. I would be happy to discuss the interpretation of these studies in the question period. What does this mean to an individual woman? In general, a woman in her forties has a 1 in 66 chance of being diagnosed with breast cancer and about 1 chance in 190 of dying of breast cancer that develops in that decade. A 15 percent reduction would lower these odds of dying to about 1 in 220.

What does this mean? This year, over 30,000 women in their forties will be diagnosed with breast cancer and a 15 percent reduction in mortality would mean over 1600 lives saved. This year, about 27,000 women in their fifties will be diagnosed with breast cancer and over 3300 lives would be predicted to be saved via mammographic screening in that age group.

Why would a woman choose not to have a mammogram? What are the limitations and downsides of mammography? The first relates to false positives and the medical procedures involved in follow-up of the false positives. If women were to receive yearly mammograms for 10 years, it is estimated that as many as 30 percent of all women will have an apparent abnormality detected. An estimated one-fourth of these will result in biopsies and, for women in their 40's, only about one-fourth of these biopsies will prove to be cancer. In other words, most abnormal mammograms do not signify cancer. Beyond false positives, mammography may miss up to 25 percent of breast cancer in young women, a percentage that falls to 10-15 percent in older women (i.e., women over age 50).

What about the risks of radiation? This is a theoretical concern, but it is based largely on exposure to very high doses of radiation and in much younger women. While the risks of radiation should not be completely dismissed, there is no direct evidence that exposure of women in their 40's to the levels of radiation used in mammography causes breast cancer or poses any other health risk.

Where then do we go from here?

The National Cancer Advisory Board will discuss the issue of screening mammography of women in their forties in order to provide guidance to the NCI concerning how we move forward with information, education and research. We must provide information to every woman and her physician or caregiver and to ensure that such information is accurate, current and user-friendly.

The NCI has long funded vigorous programs in digital mammography, in image analysis, and in non-ionizing approaches to cancer imaging such as ultrasound, MRI, optic scanning, microwaves, and other technologies. Dr. Blumenthal will describe some of these efforts in her opening statement.

The NCI will continue its long-standing commitment to support research in new modalities of imaging and molecular detection, and we must strive to enhance the value and reduce the limitations and problems of current mammography. The NCI, CDC and DoD are supporting the Breast Cancer Surveillance Consortium, a national mammographic screening and outcome database which, by the year 2000, will include over 1.8 million screened women and provide valuable data to improve the practice, interpretation, delivery and follow-up of mammography in this country.

Mammography is not a cure for breast cancer. Better screening methods will not ever replace the need to find real preventions and curative therapies.

Mammography has an important place in our current approach to breast cancer, but we tend to overestimate its benefits. We must remember that 70 percent of breast cancer deaths in women over 50 will still occur even with regular mammography. We must be relentless in our search for a cure.

Women deserve to be active and educated participants in their own health care decisions, and we cannot produce certainty where it doesn't yet exist. Physicians and scientists must be active partners with consumers to use both the best evidence and the best judgment to help each woman reach a decision that is right for her. Based on current evidence, we must inform women about the pros and cons for initiating screening in their forties. We must be wholeheartedly committed to helping each woman weigh these pros and cons as a critical part of her health care.

Thank you. I would be pleased to answer any questions.

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Divider Title: Admin. Information

MEMORANDUM

TO: Interested Parties

January 8, 1997

FR: Chris J.

RE: Medicare Q&As and Breast Cancer Patient Protection Act

Attached is a one-page set of Q&As that was prepared for Erskine today. They were drafted (and cleared by Gene) to help respond to likely questions that will emerge from continuing leaks/speculation about our Medicare proposal.

As you will note, we are avoiding any discussion about specific provisions/numbers that will be in the budget. However, we are attempting to provide filler language to deal with Democrats' concerns about the aggregate number and a defense of the home health care proposal, based on our position on this issue in last year's proposal.

In addition, I am enclosing a stop-gap answer for "Drive-By-Deliveries" Part II legislation -- a bill aimed at preventing women who have undergone mastectomies from being prematurely being released. We are reviewing the legislation now to see if it has any budgetary impact before taking any final position.

Please call if you have any questions (6-5560).

MEDICARE QUESTIONS

Q. Will your budget have in excess of \$124 billion over 6 years?

A. I will not go into specifics about particular Medicare savings numbers. Those figures are for the President to present. The savings number will not be exactly the same as last year's proposal. However, I can assure you that the proposal will be very consistent with the approach, policy, and values that were included in our last balanced budget proposal.

Q. Can you tell us whether the \$100 billion in savings over 5 year number reported today is accurate? Have you ruled out a high income premium increase?

A. Once again, I will not go into specifics about numbers or policy. I will tell you that our entire Medicare proposal will meet four basic principals: First, it will extend the life of the Medicare Trust Fund until the middle of the next decade. Second, it will protect and be consistent with our fundamental commitment to the Medicare program and its beneficiaries. Third, whatever Medicare savings number we send up will be based on real, scorable reductions to the program. And fourth, as our proposal strengthens the Trust Fund, it will also make policy defensible contributions to balance the budget by 2002.

Q. Is the home health care transfer gimmick going to be in the budget? How can you possible defend it?

A. As you know, we -- and the Republicans in the House -- advocated for this proposal in recent budget proposals. Without commenting on our future proposal, I will say that the home health care initiative we proposed last year was good, defensible policy that focused on the portion of this benefit that is out-of-control -- home health services in excess of 100 visits. Payment for more than 100 visits should not be in Part A of the program, which is the part of Medicare that pays for acute -- not long-term -- services. In fact prior to 1980, that is how Medicare allocated the payment for these services. Finally, our home care proposal last year included a brand new prospective payment system for home health services, as well as a fraud and abuse component, which would reduce excess utilization and achieve scorable savings for the program.

Q. If you did this proposal again, would you include the new expenditures in the Part B side of the program in the calculation of the premium?

A. Neither the Republicans nor the Administration included this in the premium calculation previously. We were and always will be concerned about program changes that increase costs for beneficiaries. Having said this, I won't comment beyond this.

BREAST CANCER PATIENT PROTECTION ACT OF 1997

Q. Do you support the breast cancer patient protection act of 1997 introduced by Representative DeLauro?

A. We are extremely concerned about reports that some women who have received mastectomies may be prematurely discharged from the hospital. The President and his Administration has a long track record of challenging health plans to be accountable for coverage of medically appropriate services. We are reviewing the legislation introduced by Representatives DeLauro, Dingell, and Roukema. We look forward to working with Congress on this matter.

40-49



DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

Phone: (202) 690-7850

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To: Rahm Emanuel
Bruce Reed
Chns Jennings

Fax: _____ Phone: _____

Date: 3/6 Total number of pages sent: 3

Comments:

F4I - Here are a couple of Q+As on mammography we did a quick turn-around on yesterday, in response to a request from Cabinet Affairs.

Mammography Qs & As

3/5/97

Q: Why should women wait two months for the National Cancer Advisory Board to come to a conclusion about the value of mammography for women age 40-49?

A: This Administration has done everything it can to be sure women in America receive the best information and services to help them in the fight against breast cancer. Funding for breast cancer research, prevention and treatment has almost doubled since 1993, from \$276 million to \$541 million in 1997. The FDA is also working to ensure that women have access to high quality mammography services with its quality standards for equipment and personnel.

Our commitment also extends to supporting the very best research at NCI. As NCI has said since 1993, a woman in her forties, in consultation with her health care provider, should decide for herself when to begin mammography screening. Some factors a woman should consider when making a decision include whether or not she has a personal or family history of breast cancer; whether she has signs or symptoms of menopause; and whether or not she has a personal history of benign breast disease, such as atypical hyperplasia. That advice has not changed.

What has changed is that new information has come in that has to be reviewed carefully. The NCAB is now reviewing new information from Swedish screening studies which may show a consistent benefit of mammography screening to women in their forties that had not been seen before. Because this is an important and complex issue, the Board wants to be sure it takes a careful and deliberative approach in reaching a conclusion. It is important to provide women with the best possible information as they decide when to begin mammography screening and the NCAB will work as quickly as it can to make an informed decision.

Q: Why won't you direct all federal health programs to pay for mammograms for women in their forties?

A: They do. For women age 40-49, Medicare covers one screening mammogram every two years. For women with a high risk of developing breast cancer (for example, a woman with a mother, sister or daughter who has had breast cancer), Medicare covers one screening mammogram every year. Under Medicaid, a mammogram needed for diagnostic purposes for women in their forties is a mandatory service and is covered in every state.

Background

If the mammogram is being used as a screening tool, it is an optional Medicaid service. States have the flexibility to choose to cover screening under optional services categories such as preventive care, screening services or clinic services. Most states cover screening mammograms in fee-for-service Medicaid. In addition, virtually all Medicaid coordinated care plans offer preventive services, including mammography, to their enrollees.

For further information about all aspects of breast cancer, including screening, a woman can also call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER.

MEDICARE COVERAGE OF MASTECTOMY AND LYMPH NODE DISSECTION FOR THE TREATMENT OF BREAST CANCER

What is being proposed under the Breast Cancer Patient Protection Act of 1997?

- The Breast Cancer Patient Protection Act of 1997 (H.R. 135), introduced on January 7th by Representative John Dingell and Representative Rosa DeLauro (D-CT), would prohibit health insurance plans (not just managed care plans) that provide coverage for a hospital stay in connection with a mastectomy or lymph node dissection from restricting inpatient benefits to less than 48 hours and 24 hours, respectively. However, the patient, in consultation with her doctor, could decide to be discharged earlier.
- The decision whether to have the mastectomy or lymph node dissection on an inpatient or outpatient basis would be made by the patient and her physician. Plans would not be required to cover these benefits on an inpatient basis.
- The bill utilizes the health plan definitions included in the Health Insurance Portability and Accountability Act (HIPAA). The applicability of HIPAA's provisions to Medicare fee-for-service and Medicare managed care plans is ambiguous. According to the Office of General Counsel (OGC), the bill's provisions would not apply to Medicare fee-for-service but would apply to managed care plans contracting with Medicare.

What are the concerns associated with the Breast Cancer Patient Protection Act of 1997?

- While the Administration and Congress have already supported this legislative approach for "drive through deliveries," federal legislation on a procedure by procedure basis is not an appropriate mechanism to resolve potential quality of care issues.
- The Congress clearly cannot legislate standards for every procedure. Such legislation would lock into place standards which could become out-of-date as a result of changes in medical practice or technological advances.
- Such legislation could have unintended consequences. For example, the Breast Cancer Patient Protection Act could create incentives for managed care plans to cover the majority of mastectomies and lymph node dissections on an outpatient basis in order to avoid the minimum lengths of stay requirements for inpatient treatment, thereby reducing beneficiary choice.

Are the protections that would be offered under the Breast Cancer Patient Protection Act of 1997 available to women under Medicare?

- Beneficiaries in Medicare are not guaranteed a minimum 48 hour inpatient stay following mastectomy as individuals in private health plans would be under the Breast Cancer Patient Protection Act.

- However, we believe the Medicare program offers beneficiaries broader protections than those afforded under the Breast Cancer Patient Protection Act. For example, if a beneficiary required an inpatient stay greater than 48 hours and was facing being discharged prematurely by a hospital, she could appeal to the Peer Review Organization (PRO) for immediate consideration.

Is there a need in Medicare for the Breast Cancer Patient Protection Act of 1997?

- HCFA has not received any indications from the Peer Review Organizations (PRO) or the Center for Health Dispute Resolution (CHDR), which handles HMO appeals, that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections in the Medicare fee-for-service or managed care programs.
- HCFA is currently conducting an analysis of fee-for-service claims to determine if rates of outpatient mastectomies and lymph node dissections have increased and to determine the impact (if any) on patient outcomes. Claims data are not available for a similar analysis for the Medicare managed care program.
- Attached is a description of the procedural protections available to Medicare beneficiaries in fee-for-service Medicare and in managed care.

Could protections similar to those included in the Breast Cancer Patient Protection Act be extended to Medicare patients using administrative authority?

- A minimum 48 hour inpatient stay for mastectomies and a 24 hour stay for lymph node dissection would require legislation.
- An expedited appeals process would offer significant protections to beneficiaries enrolled in managed care plans. HCFA is currently developing interim-final regulations to require Medicare managed care plans to establish such a process.

Is there a cost to the Medicare program associated with the Breast Cancer Patient Protection Act of 1997?

- Since Medicare pays managed care plans a capitated payment amount (based on Medicare's fee-for-service costs) and this bill does not apply to Medicare fee-for-service, there would be no financial impact on the Medicare program.

What is current Medicare policy?

• FEE-FOR-SERVICE MEDICARE

- ▶ Medicare covers mastectomy and lymph node dissection for the treatment of breast cancer both on a hospital inpatient or outpatient basis (e.g., hospital outpatient department, ambulatory surgical centers).
- ▶ The decision whether to have a mastectomy or lymph node dissection on an inpatient or outpatient basis is made by the patient and her physician.
- ▶ In 1995, the average length of stay associated with DRGs for mastectomies and lymph node dissections ranged from 1.6 days to 2.8 days.
- ▶ If a beneficiary believes she is being discharged prematurely from a hospital, the beneficiary's appeal will receive immediate consideration by the PRO and the hospital cannot discharge the beneficiary before a decision is reached by the PRO.
- ▶ If the beneficiary disagrees with the physician's assessment that a mastectomy or lymph node dissection be performed on an outpatient basis, the beneficiary could choose to receive care from another physician who would recommend the procedure be performed on an inpatient basis.

• MEDICARE MANAGED CARE

- ▶ Managed care plans must provide all medically necessary benefits covered under Medicare. Medicare does not, however, dictate the managed care plan's specific coverage policies (e.g., whether a benefit must be provided on an inpatient or outpatient basis, lengths of stay for treatment provide on an inpatient basis).
- ▶ The beneficiary enrolled in a managed care plan has several mechanisms to appeal a managed care plan's coverage and payment decisions including those related to the treatment of breast cancer.
- ▶ Like their fee-for-service counterparts, Medicare beneficiaries enrolled in managed care plans can report their concerns regarding early discharge from the hospital to the PROs for immediate consideration and the hospital cannot discharge the beneficiary before a decision is reached by the PRO.
- ▶ Beneficiaries can also file complaints with the PRO regarding the quality of care provided by the managed care plan. PROs must review every beneficiary complaint.
- ▶ Finally, at the request of the enrollee, the managed care plan must reconsider any determination (e.g., the plan would not cover an inpatient hospital stay for a

mastectomy) within an appropriate period of time but not more than 60 days. If the plan upholds its initial decision, the appeal is then forwarded to the an independent, third party expert for review, the Center for Health Dispute Resolution (CHDR). If the plan's decision is still upheld, the beneficiary may continue to appeal the plan's decision through the same process available to beneficiaries in the fee-for-service program. HCFA is currently developing an interim-final regulation to establish an expedited review process for time-sensitive cases.

Is there a problem with the current Medicare policy?

- No. HCFA has not received any indications from PROs that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections in Medicare fee-for-service.
- Similarly for the Medicare managed care program, HCFA has not received any indications from PROs or CHDR that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections
- HCFA does believe, however, that appeal rights need to be strengthen and for this reason is developing an interim-final regulation on expedited appeals and a proposed regulation which would make other improvements to the appeals process.

MEDICAID COVERAGE OF MASTECTOMY AND LYMPH NODE DISSECTION FOR THE TREATMENT OF BREAST CANCER

What is current Medicaid practice regarding coverage of certain treatments for breast cancer?

Like all other covered services under Medicaid, amount, duration and scope of services for mastectomies and lymph node dissections performed for the treatment of breast cancer is determined by the State. The Medicaid statute provides each State with the authority to define medical necessity for Medicaid covered services. As a result, coverage and payment for mastectomies and lymph node dissections for the treatment of breast cancer varies from State to State.

Under Medicaid managed care, plan contracts with State Medicaid agencies must define the amount, duration, and scope of services to be provided --the State, however, has the ultimate authority for determining medical necessity, not the plan.

States define the basis for paying hospitals. States can adopt the Medicare unit of payment and reimburse based on diagnosis related groups, pay for a day of care, pay based on admissions or discharges, or select a daily rate based on case mix. Based on 1993 state reported data, 21 states use the Medicare DRG for payment for acute care hospital services.

Is there a problem with current Medicaid policy?

The Medicaid Bureau is unaware of any beneficiary complaints regarding Medicaid coverage for services relating to mastectomies or lymph node dissections for the treatment of breast cancer. There have been no complaints regarding the quality of care received under Medicaid for services related to these treatment options.

If there was a problem with coverage for services relating to mastectomies or lymph node dissections, a beneficiary has the right to file a grievance or appeal regarding the plan's coverage decision. Furthermore, the beneficiary and/or her provider can appeal the coverage decision to State.

Grievance requirements are general under Medicaid and vary from State to State. Federal regulations require contracts to have internal appeals and grievance procedures but we do not mandate the actual procedure or process that must be in place. Furthermore, we do not mandate a specific appeals process for a beneficiary to appeal to the State --the State is just required to have a process in place.

There is nothing in the Medicaid statute or our regulations that would keep a patient in the hospital while she is appealing a coverage decision. Some States may require provision of services during an appeals process, others may not.

What is being proposed?

The "Breast Cancer Patient Protection Act of 1997" introduced on January 7, 1997 with 62 cosponsors (55 Dems., 1 Rep., 1 Ind.), requires group health plans and health insurance issuers offering group health insurance coverage to cover minimum hospital stays for mastectomies (48 hours) and lymph node dissections (24 hours) for treatment of breast cancer as of January 1, 1998. This bill only addresses inpatient services for mastectomies and lymph node dissections --not outpatient services.

The exception to this requirement is if the attending provider, in consultation with the patient, decides to discharge the patient earlier. Furthermore, these Federal requirements will not apply to plans in states where there is a State law with the same requirements and exception.

The definition of plans and insurers subject to these requirements is the same as under the Kassebaum/Kennedy bill and the 48 hour hospital maternity stay law.

There is no specific language pertaining to Medicaid, however, it is assumed that managed care plans contracting with State Medicaid programs will be subject to the new coverage requirements. This would be consistent with the 48 hour maternity stay law --it applies to Medicaid managed care plans, not to FFS.

There is no executive order or administrative action we could take, absent specific legislation to require states to provide 48 hour coverage for mastectomies.

Is there a cost?

On the FFS side, the cost impact would be minimal. As mentioned above, 21 states make payments to hospitals based on Medicare's DRG for mastectomies which is based on a 2 day hospital stay. Nineteen states make acute care hospital payments based on per diem costs. Since 48 hour and 24 hour hospital stays are the standard of care for these treatments, the additional cost of the bill would basically be if patients disagree with provider determinations that the patient can be discharged early.

On the managed care side, we do not have information indicating costs would increase. We do not have any information indicating plans are currently providing inadequate coverage for mastectomy or lymph node dissection services.

Since States base capitation rates on FFS payments, we assume that coverage for 48 hours and 24 hours respectively is already incorporated in the capitation payment.

The provisions of this bill, however, could provide an incentive for managed care plans to shift some patients from inpatient care to outpatient care for treatment to save costs.

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Medicaid will only pay for surgeries designated as medically necessary. States have the authority for determining medical necessity. Reconstructive surgery is standard practice after a mastectomy and is generally regarded as medically necessary --however, each State has the authority to make this determination.

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Divider Title: Medicare Mastectomy



Office of Managed Care
Director's Office
Washington, D.C. 20201

FROM: Bruce Merlin Fried *BMF*
DATE: February 12, 1997
SUBJECT: Medicare Managed Care Plan's Health Services and Benefits Policies
TO: Addressees

The Health Care Financing Administration holds managed care plans accountable for providing the highest quality care. A number of safeguards are currently in place to assure that plans or physicians do not inappropriately withhold medically necessary care. For example, a physician providing care to a Medicare beneficiary under the terms of a risk or cost contract may not be limited in counseling or advising the beneficiary of a medically necessary treatment option that may be appropriate for the individual's condition or disease.

Medicare managed care plan enrollees have the right to an appeal of any benefit decision by a provider or a plan, including the length of time pre-authorized for a hospital stay. In addition, beneficiaries have the right to an expedited review by the PRO if they feel they may be discharged prematurely from a hospital; during this time the beneficiary may remain in the hospital and the plan will assume financial liability.

Occasionally, specific issues arise of sufficient concern to the public that further guidance is required to our contractors. Such guidance should, and will be, based on the best medical evidence available. The attached OPL is based on an extensive literature review and is HCFA's guidance with regard to surgical interventions for treatment of breast cancer.

Addressees: C.E.O.s - Medicare Managed Care Plans;



Office of Managed Care
Director's Office
Washington, D.C. 20201

Office of Managed Care
Operational Policy Letter
OPL 97.049

Date: February 12, 1997

Subject: **Medicare Managed Care Plans' Benefits and Coverage of Certain Surgical Interventions for Treatment of Breast Cancer**

Question: May a Medicare managed care plan require that enrollees obtain services related to certain surgical interventions (including mastectomy and/or lymph node dissections) for treatment of breast cancer on an outpatient basis or establish a maximum length of stay for treatment as a hospital inpatient?

Answer: No. A managed care plan's coverage policies, disease management protocols, or utilization review criteria that impose such limits are not supported by the available medical evidence and do not take into account individual patient circumstances.

In OPL 96.046 (December 19, 1996), HCFA clarified that managed care plans must make decisions about the coverage of health care services pursuant to an objective, evidence-based process. We also made it clear that medical necessity decisions on the appropriate care for an individual patient must take into account the specific circumstances and needs of that individual. In addition, in OPL 96.044 (November 25, 1996), HCFA stated that a managed care plan may not restrict a physician in providing advice and counseling on what medically necessary treatment is most appropriate for an individual patient's condition or disease.

For Medicare beneficiaries, advanced age, increased risk of post-surgical complications, presence of significant comorbidity, impaired functional status, and lack of social support may put them at increased risk if this surgery is performed in an outpatient setting or with an insufficient hospital length of stay. The more extensive the surgical intervention (e.g., radical mastectomy), the more likely the patient is to be at increased risk from the procedure in the outpatient setting or from shortened lengths of stays. Given the current available evidence, it is not acceptable practice for managed care plans to adopt policies, applied indiscriminately to all Medicare enrollees, mandating surgical interventions for treatment of breast cancer in an outpatient setting or setting a maximum length of stay as an inpatient.

In certain circumstances, with carefully selected patients, an outpatient setting or limited hospital stay may be appropriate. However, these practices may only be used when they have been

determined to be appropriate by the patient and her physician, after assessment of the patient's individual circumstances. Assuring the availability of all medically necessary covered benefits to Medicare enrollees will continue to be a focus of HCFA's routine oversight of contracting managed care organizations.

Contact:

HCFA Regional Office Managed Care Staff

cc: OMC Management Team
RO Managed Care Contacts
PASS
Policy and Program Improvement Team



Office of Managed Care
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MEDICARE COVERAGE OF MASTECTOMY AND LYMPH NODE DISSECTION FOR THE TREATMENT OF BREAST CANCER

What is being proposed under the Breast Cancer Patient Protection Act of 1997?

- The Breast Cancer Patient Protection Act of 1997 (H.R. 135), introduced on January 7th by Representative John Dingell and Representative Rosa DeLauro (D-CT), would prohibit health insurance plans (not just managed care plans) that provide coverage for a hospital stay in connection with a mastectomy or lymph node dissection from restricting inpatient benefits to less than 48 hours and 24 hours, respectively. However, the patient, in consultation with her doctor, could decide to be discharged earlier.
- The decision whether to have the mastectomy or lymph node dissection on an inpatient or outpatient basis would be made by the patient and her physician. Plans would not be required to cover these benefits on an inpatient basis.
- The bill utilizes the health plan definitions included in the Health Insurance Portability and Accountability Act (HIPAA). The applicability of HIPAA's provisions to Medicare fee-for-service and Medicare managed care plans is ambiguous. According to the Office of General Counsel (OGC), the bill's provisions would not apply to Medicare fee-for-service but would apply to managed care plans contracting with Medicare.

What are the concerns associated with the Breast Cancer Patient Protection Act of 1997?

- While the Administration and Congress have already supported this legislative approach for "drive through deliveries," federal legislation on a procedure by procedure basis is not an appropriate mechanism to resolve potential quality of care issues.
- The Congress clearly cannot legislate standards for every procedure. Such legislation would lock into place standards which could become out-of-date as a result of changes in medical practice or technological advances.
- Such legislation could have unintended consequences. For example, the Breast Cancer Patient Protection Act could create incentives for managed care plans to cover the majority of mastectomies and lymph node dissections on an outpatient basis in order to avoid the minimum lengths of stay requirements for inpatient treatment, thereby reducing beneficiary choice.

Are the protections that would be offered under the Breast Cancer Patient Protection Act of 1997 available to women under Medicare?

- Beneficiaries in Medicare are not guaranteed a minimum 48 hour inpatient stay following mastectomy as individuals in private health plans would be under the Breast Cancer Patient Protection Act.

- However, we believe the Medicare program offers beneficiaries broader protections than those afforded under the Breast Cancer Patient Protection Act. For example, if a beneficiary required an inpatient stay greater than 48 hours and was facing being discharged prematurely by a hospital, she could appeal to the Peer Review Organization (PRO) for immediate consideration.

Is there a need in Medicare for the Breast Cancer Patient Protection Act of 1997?

- HCFA has not received any indications from the Peer Review Organizations (PRO) or the Center for Health Dispute Resolution (CHDR), which handles HMO appeals, that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections in the Medicare fee-for-service or managed care programs.
- HCFA is currently conducting an analysis of fee-for-service claims to determine if rates of outpatient mastectomies and lymph node dissections have increased and to determine the impact (if any) on patient outcomes. Claims data are not available for a similar analysis for the Medicare managed care program.
- Attached is a description of the procedural protections available to Medicare beneficiaries in fee-for-service Medicare and in managed care.

Could protections similar to those included in the Breast Cancer Patient Protection Act be extended to Medicare patients using administrative authority?

- A minimum 48 hour inpatient stay for mastectomies and a 24 hour stay for lymph node dissection would require legislation.
- An expedited appeals process would offer significant protections to beneficiaries enrolled in managed care plans. HCFA is currently developing interim-final regulations to require Medicare managed care plans to establish such a process.

Is there a cost to the Medicare program associated with the Breast Cancer Patient Protection Act of 1997?

- Since Medicare pays managed care plans a capitated payment amount (based on Medicare's fee-for-service costs) and this bill does not apply to Medicare fee-for-service, there would be no financial impact on the Medicare program.

What is current Medicare policy?

• **FEE-FOR-SERVICE MEDICARE**

- ▶ Medicare covers mastectomy and lymph node dissection for the treatment of breast cancer both on a hospital inpatient or outpatient basis (e.g., hospital outpatient department, ambulatory surgical centers).
- ▶ The decision whether to have a mastectomy or lymph node dissection on an inpatient or outpatient basis is made by the patient and her physician.
- ▶ In 1995, the average length of stay associated with DRGs for mastectomies and lymph node dissections ranged from 1.6 days to 2.8 days.
- ▶ If a beneficiary believes she is being discharged prematurely from a hospital, the beneficiary's appeal will receive immediate consideration by the PRO and the hospital cannot discharge the beneficiary before a decision is reached by the PRO.
- ▶ If the beneficiary disagrees with the physician's assessment that a mastectomy or lymph node dissection be performed on an outpatient basis, the beneficiary could choose to receive care from another physician who would recommend the procedure be performed on an inpatient basis.

• **MEDICARE MANAGED CARE**

- ▶ Managed care plans must provide all medically necessary benefits covered under Medicare. Medicare does not, however, dictate the managed care plan's specific coverage policies (e.g., whether a benefit must be provided on an inpatient or outpatient basis, lengths of stay for treatment provide on an inpatient basis).
- ▶ The beneficiary enrolled in a managed care plan has several mechanisms to appeal a managed care plan's coverage and payment decisions including those related to the treatment of breast cancer.
- ▶ Like their fee-for-service counterparts, Medicare beneficiaries enrolled in managed care plans can report their concerns regarding early discharge from the hospital to the PROs for immediate consideration and the hospital cannot discharge the beneficiary before a decision is reached by the PRO.
- ▶ Beneficiaries can also file complaints with the PRO regarding the quality of care provided by the managed care plan. PROs must review every beneficiary complaint.
- ▶ Finally, at the request of the enrollee, the managed care plan must reconsider any determination (e.g., the plan would not cover an inpatient hospital stay for a

mastectomy) within an appropriate period of time but not more than 60 days. If the plan upholds its initial decision, the appeal is then forwarded to the an independent, third party expert for review, the Center for Health Dispute Resolution (CHDR). If the plan's decision is still upheld, the beneficiary may continue to appeal the plan's decision through the same process available to beneficiaries in the fee-for-service program. HCFA is currently developing an interim-final regulation to establish an expedited review process for time-sensitive cases.

Is there a problem with the current Medicare policy?

- No. HCFA has not received any indications from PROs that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections in Medicare fee-for-service.
- Similarly for the Medicare managed care program, HCFA has not received any indications from PROs or CHDR that there are quality problems or beneficiary complaints associated with mastectomies or lymph node dissections
- HCFA does believe, however, that appeal rights need to be strengthen and for this reason is developing an interim-final regulation on expedited appeals and a proposed regulation which would make other improvements to the appeals process.

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What is current Medicaid practice regarding coverage of certain treatments for breast cancer?

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Divider Title: Rosa-Delauco-Dingell



U.S. Congresswoman
Rosa DeLauro

NEWS RELEASE

436 Cannon

Washington, DC 20515

202/225-3661

For Release: Immediately
Tuesday, January 7, 1997

Contact: Stacy Beck
Phone: (202) 225-3661

DELAURO ASKS CONGRESS TO PROTECT BREAST CANCER PATIENTS
Bill Requires Longer Hospital Stays

WASHINGTON -- Saying that women's health issues will be a top priority for her in the 105th Congress, Congresswoman Rosa DeLauro (D-3) today introduced the Breast Cancer Patient Protection Act of 1997.

"Beginning on the first day of the 105th Congress, with this bipartisan bill, we can ensure that women with breast cancer receive the best treatment and coverage available," said DeLauro. "We can also ensure that crucial health care decisions are left in the hands of doctors, not accountants."

DeLauro's legislation would require longer hospital stays for women undergoing breast cancer treatments, such as mastectomies and lymph node dissections. Over the past ten years, the length of hospitalization for these surgeries has dwindled significantly, as doctors and hospitals, under pressure from Health Maintenance Organizations (HMOs) to cut costs, have had to perform lymph node dissections and even mastectomies as outpatient surgery. DeLauro's bill would require a minimum hospital stay of 48 hours for mastectomies and 24 hours for lymph node removals.

Some HMO's now send women home just hours after breast cancer surgery, with patients groggy from anaesthesia, in pain, and with drainage tubes still in place. Others even deny women hospitalization on the day of their surgery, forcing doctors to choose between giving patients the quality care they need or being penalized by the HMO for not following their guidelines.

A Connecticut general surgeon, Dr. Kristen Zarfes, first brought the problem to DeLauro's attention last year. Since then, DeLauro has worked closely with Dr. Zarfes and others in the medical community to develop a legislative remedy to the problem. DeLauro introduced a similar bill at the end of the last session of Congress.

The DeLauro-Dingell-Roukema Breast Cancer Patient Protection Act is a bipartisan bill with 50 original co-sponsors. Senate Minority Leader Tom Daschle (D-SD) is planning to introduce a companion bill in the U.S. Senate. "This is legislation that should receive broad bi-partisan support in both the House and the Senate," said DeLauro. "It is too important to fall victim to partisan politics. With one in every eight women developing breast cancer, virtually every family in America is vulnerable to this disease."

This year alone, approximately 184,300 grandmothers, mothers and daughters will be diagnosed with invasive breast cancer. Another 44,300 women will die from this disease.

DeLauro's legislation enjoys strong support from the National Breast Cancer Coalition, the National Association of Breast Care Organizations, the Y-Me National Breast Cancer Organization, the Families USA Foundation, the Women's Legal Defense Fund, and the American Society of Plastic and Reconstructive Surgeons.

The Hartford Courant

Monday, January 27, 1997

Surgeon's fight for one patient becomes a catalyst for change

By STACY WONG
Courant Staff Writer

MIDDLETOWN — The clock seemed to tick more quickly than usual that Friday in August, when Middletown surgeon Kristen Zarfos made a last, anxious phone call to ConnectiCare.

She hoped to persuade the health maintenance organization to approve a one-night hospital stay for her patient, 40-year-old Carolyn Hart, who faced mastectomy surgery Monday.

Without approval that afternoon, Hart would spend an uncertain weekend — wondering whether she would have to leave the hospital after her breast was removed, with drains in her body letting out blood, returning to a loving husband who nevertheless felt unsure about her care.

Zarfos had reached a critical point. Believing a medical decision was being compromised, she made her own decision: "This was a line I couldn't cross."

That afternoon, after she and Hart's family had placed nine phone calls over two days, Zarfos finally got approval from ConnectiCare. That afternoon, she decided not to remain silent about HMO

payment practices.

"I was driven by outrage," Zarfos said. "I wanted to be a faceless voice, but I never dreamed it would go as far as it did."

Her story about Hart's case, the result of new payment guidelines advocating outpatient mastectomies, sparked outrage across the country and became a pivotal issue for health insurers and their patients.

Zarfos found herself propelled into the spotlight by local and national news media for taking her stand, one that has already prompted changes in the volatile, evolving relationship among HMOs, doctors and patients.

Having just faced the same issue for hospital maternity stays, legislators began looking for a better way to regulate managed care to avoid legislating the length of hospital stays for every situation.

Managed care companies, believing they had been unfairly vilified, took several steps of their own to improve communication with doctors and patients, and to incorporate physicians more in the

Please see Surgeon's, Page A7

Continued from Page 1

process.

"She's been the catalyst for a renewed effort on our part to involve doctors on medical management issues," said Dr. Paul A. Bluestein, ConnectiCare's senior vice president and chief medical officer. "She's bright and articulate. She's a point of view. It may be different from mine, but I'd rather have it than someone who is disinterested."

'meek' woman

A few outside Middlesex County heard of Dr. Kristen Zarfos, 43, before the autumn of 1986. A slim, 5-foot-6 woman with brown hair cut stylishly short, Zarfos was not a ve-maker.

She devoted her professional life to her surgical practice, and to the presidency of the Middlesex County Medical Society.

She devoted her personal life to her husband, William Vasilou, and her 10-year-old son, Michael Wayland; her colonial home in Deep River; soccer games, church, hiking, gardening and trying recipes from Appetit.

She was the only child of a Maryland couple of Pennsylvania Dutch stock, was a good student with a quiet, serious bent, graduating summa cum laude from Hood College in Frederick, Md., before getting her medical degree at the University of Maryland Medical School.

Zarfos described herself as "meek" until she entered surgical residency.

"You can't be a surgeon and sit back when there's a need for action," she said.

Like other doctors, Zarfos became increasingly concerned about HMOs. Not only did HMOs regulate medical treatment, they also supervised patients — and income — to doctors.

HMOs do track us economically. All physicians are concerned about being decertified by HMOs," Zarfos said.

It was she who was compelled to speak after new managed care guidelines developed by the actuarial firm of Millman and Robertson, took effect in July. Among other things, the guidelines said some doctors could have outpatient mastectomies.

Zarfos surveyed 226 of her past mastectomy patients and found 100 women outraged that anyone would think of booting them out of hospital after such surgery.

Later that summer, Hart became the first mastectomy patient after the new guidelines went into effect. Hart, a Middletown mother, 42, had just had her first mammogram, recommended for women over 40.

The mammogram showed two lumps. A second mammogram showed four lumps. At that point Hart opted for a mastectomy.

It was scheduled for surgery on Monday, Aug. 5. The week before, Zarfos and Hart's husband began to pressure ConnectiCare to secure a hospital stay.

Because not all mastectomies are

the same, some women may prefer outpatient procedures. However, such mastectomies tend to occur under ideal conditions and among younger women, and not every woman meets the criteria, physicians say.

"The problem is, you have to fight tooth and nail for those people who can't go home," Zarfos said.

Hart said she was determined to stay even if ConnectiCare refused to pay. "It's your health," she said. "You have to do what you have to do."

ConnectiCare paid more than \$8,000 in bills. At home, Hart's teenage daughter helped care for her, and a visiting nurse paid for by the HMO came to inspect the bandage and record vital signs.

Even with family support, a visiting nurse, and faith in God, Hart found it tough. "It would be more difficult for someone on their own, or much older," she said. "And that's just the physical (aspect). . . . Mentally, you have to deal with that, too."

While Hart recuperated, Zarfos searched for a way to bring the issue to public attention. Eventually, she contacted U.S. Rep. Rosa L. DeLauro, D-3rd District, a survivor of ovarian cancer, as well as state Rep. Edith Prague, D-Columbia.

By Aug. 8, Hart's story had broken in newspapers and on television. DeLauro promised to introduce legislation mandating minimum two-day hospital stays for mastectomies, unless a patient and physician decide less hospital time is appropriate.

By Aug. 15, other legislators had seized the issue and called for reforms in the managed care industry. The story picked up more steam in September, when physicians, HMO officials and business people spoke passionately for and against the need for industry reforms at a hearing before the General Assembly's program review and investigations committee.

National spotlight

By November, "60 Minutes," "Dateline NBC," and "Good Morning, America" had called Zarfos, though not all of them broadcast stories. Nationally syndicated columnist Ellen Goodman wrote a piece on the issue, and stories and editorials ran in places such as Chicago, Philadelphia and Washington.

Alarmed by the growing negative publicity, the American Association of Health Plans issued a statement saying its members will pay for overnight hospital stays for any mastectomy as long as patients and their doctors decide it is necessary.

"We really have been pilloried in the press, attacked by anecdote," said Mickey Herbert, co-chief executive officer of the Connecticut-based Physicians Health Services and chairman of the American Association of Health Plans. "We need to take a much more aggressive role than we do in telling people about the good things we are doing for patients and doctors."

In December, the association launched a campaign called "Pa-



Stephan Dunn / The Hartford Courant

■ Middletown surgeon Kristen Zarfos found herself in the national spotlight last summer, going public about HMO payment practices after she had to battle for an overnight hospital stay for a mastectomy patient. "I was driven by outrage," she said.

lients First" designed to improve communication with patients and physicians, streamline administrative procedures and initiate more research on the outcomes of care provided in health plans.

Member health plans will also have to adhere to a code of conduct. The code stipulates that HMOs will not have gag clauses barring physicians from revealing financial strictures to patients. The code also requires members to communicate so subscribers and physicians understand the basis for payment decisions.

Meanwhile, Zarfos became a hero of sorts to patients and physicians struggling with the world of

managed care.

"She is a surgeon, as I am. We've been taught to operate," said Dr. Michael M. Deren, president of the Connecticut State Medical Society. "In this day and age, more importantly, we have to advocate for patients in other ways, and she's done that very nicely."

Zarfos' husband and friends encouraged her in the turbulent months after the story broke. At one point, Zarfos stood up in St. John's Episcopal Church in Essex and thanked her fellow parishioners for their support.

"I'm really proud of her, as a committed Christian and as a person of

integrity who would always do the right thing," the Rev. Hope Eakins said. "She trusted God, and guess what? It all fell into place. Goliath fell to David. . . . A strong underpinning provided her with the courage and strength to do what needed to be done and take on a giant."

ConnectiCare opened discussions with Zarfos on ways doctors could be more involved in setting payment guidelines. The HMO has since enlisted its physicians to review the new guidelines to see where they might differ from actual experience.

The core of the HMO's role, though, remains the same.

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(203) 378-8005



UNITED STATES
HOUSE OF REPRESENTATIVES

ROSA L. DELAURO

30 DISTRICT, CONNECTICUT

CHIEF DEPUTY WHIP
COMMITTEE ON NATIONAL SECURITY
SUBCOMMITTEES:
MILITARY PROCUREMENT
MILITARY PERSONNEL

January 27, 1997

Mr. Rahm Emmanuel
Assistant To the President
Director of Special Projects
The White House
1600 Pennsylvania Ave, NW
Washington, D.C. 20502

Dear Rahm:

Last week I spoke with you about working with the White House on legislation guaranteeing minimum hospital stays for women undergoing mastectomies and lymph node dissections.

You requested information on how many women would be affected by this legislation. Attached is a fact sheet that outlines estimates of how many women are enrolled in managed care organizations and how many women undergo mastectomies.

Please contact Lissa Topel in my office at 225-3661 if you have any questions.

Thank you for your help.

Sincerely,


ROSA L. DELAURO
Member of Congress

RLD/lt

Attachments

**Facts on the Number of Women Affected
by the DeLauro-Dingell-Roukema
Breast Cancer Patient Protection Act**

- o According to the Group Health Association of America, approximately 51 million Americans were enrolled in HMOs in 1994. According to the American Association of Health Plans, in 1994, approximately 53 percent of HMO enrollees were women. Therefore, approximately 27 million women were enrolled in HMOs in 1994.
- o An HCIA study, cited in a November 6, 1996 Wall Street Journal article, estimates that 110,400 mastectomies were performed on breast cancer patients in 1995.
- o In 1995, HCIA estimates that 8,390 mastectomies (7.6 percent) were done on an outpatient basis. In 1991, HCIA estimates that only 1.6% of all mastectomies were done as outpatient surgery.
- o The American Cancer Society estimates that 180,200 women will be diagnosed with breast cancer in 1997; another 43,900 will die from the disease this year.

DRAFT

THE WOMEN. . . THEIR STORIES

Judy Willis

In September of 1994, Judy Willis of Virginia underwent a bilateral mastectomy with expander implants (implants that are gradually filled with saline as the wounds heal). She was admitted into the hospital around 1:00 pm and released from the hospital at around 8:00 am the next day (19 hours later) -- without even getting a meal! She had not been told that she would be released that soon. In fact, the doctor told her that she would probably be in the hospital for a few days. Her sister was very surprised when Judy told her to come pick her up that early the next day.

She was discharged 19 hours after being admitted, and sent home with 3 drainage tubes sticking out of her chest. She had to empty and measure the fluid draining out. She had little use of her arms (women have to do exercises to regain mobility), which made this task very difficult to perform. She could not get out of bed on her own and going to the bathroom was also difficult - cooking meals were out of the question.

For Judy Willis, undergoing an outpatient mastectomy was both physically and emotionally devastating. She knows that others in her health plan have undergone the same treatment and she wants it to stop.

Sharon Faucher

In February of 1996, Sharon Faucher of Connecticut was admitted to the hospital for a mastectomy at 8:00 a.m. Since outpatient surgery is defined as a hospital stay of 23 hours or less, by 6:00 a.m. the next morning, 22 hours later, a nurse woke her up and told her that she should get dressed because she was being discharged. She had been given morphine for her pain, so she could barely stand. She also had been vomiting. She asked to stay, but the nurse told her she had to leave.

She left with drainage tubes and bandages. No oncology nurse was sent to talk to her about her surgery. No wheelchair was sent to carry her out of the hospital. On her way home from the hospital, less than 24 hours after her surgery, she vomited three times.

Sharon hopes that no woman ever has to endure the physical and emotional pain she went through after such a humiliating experience.

**PRESS RELEASE****VIEWERS STAND WITH LIFETIME TELEVISION AND LINDA ELLERBEE AGAINST "DRIVE-THROUGH" MASTECTOMIES****More Than 10,000 Viewers Sign Network's Internet Petition on Lifetime Online:
Names And Numbers To Be Sent to Congress**

ANAHEIM, CA., December 12, 1996 — In a span of two weeks, more than 10,000 viewers of LIFETIME Television have responded to journalist/breast cancer survivor Linda Ellerbee's commentary on "drive-through" mastectomies currently being debated among politicians, medical professionals and health maintenance organizations (HMOs). The Ellerbee short segment premiered on Sunday, Nov. 24, on "Perspectives on Lifetime," the Network's award-winning vignette series.

In the 60-second segment, which has aired only once each day, Ellerbee argues that a mastectomy is more complex than "getting a tooth pulled." However, she tells viewers how some health care groups are treating mastectomies with outpatient treatment, a controversial step for such a physically and emotionally challenging procedure. Ellerbee urges viewers and on-line users to sign an on-line petition at www.lifetimev.com which will be sent to congressional representatives to lobby for a law mandating a 48-hour hospital stay. The spot will air through December 8.

Amy Langer, Executive Director of the National Alliance of Breast Cancer Organizations (NABCO) said, "NABCO, along with breast cancer survivors across the country, applaud Lifetime's efforts to alert their viewers of this alarming trend and urge them to participate in this petition."

Meredith Wagner, LIFETIME's Senior Vice President of Public Affairs said, "It is extremely rewarding to know that so many of our viewers and online users are responding to our outreach efforts. Lobbying for legislation that will keep women well cared for after breast surgery is not a typical effort for a cable network to take, but it is something that Lifetime feels is crucial for the health of women nationwide."

LIFETIME Television is available on more than 8,300 cable systems and alternative delivery systems nationwide, serving 66.7 million households. Learn more about LIFETIME Television on the Lifetime Online web site at <http://www.lifetimev.com>.

#

Contact: Brett Henne, LIFETIME Television 212/424-7120



NABCO

NATIONAL ALLIANCE
OF BREAST CANCER
ORGANIZATIONS

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December 23, 1996

Hon. Rosa DeLauro
United States Congress
House of Representatives
436 Cannon House Office Building
Washington, DC 20515

Dear Congresswoman DeLauro:

Thank you for your leadership in initiating Federal legislation protecting women from inappropriate post-mastectomy hospital stays under managed care. As the leading non-profit information resource on breast cancer and a network of 375 organizations across the country, the National Alliance of Breast Cancer Organizations has been increasingly concerned about the impact that managed care will have on the treatment and quality of life of women with breast cancer and their families.

In recent conversations with Lissa Topel, we mentioned that Lifetime Television has also taken a stand on this issue. Lifetime has been working with NABCO and other breast cancer organizations for the past three years as the network has become active in the fight against breast cancer. As the enclosed press release dated December 12 explains, more than 10,000 Lifetime viewers have signed an on-line petition expressing concern about "drive through" mastectomies.

After Congress reconvenes, NABCO and Lifetime would like to explore ways to join with you in calling attention to the issue, perhaps including the delivery of the 10,000 petitions at a press event. Please contact my office to discuss your thoughts on next steps, including the involvement of your Congressional colleagues and other national organizations.

Information about NABCO is enclosed, along with the Lifetime press release. I'll look forward to your call, and wish you a happy and healthy New Year.

Very truly yours,

Amy S. Langer
Executive Director

encs.

cc: Kim Calder, NABCO
Marcy Haley, Lifetime
Lissa Topel

The Honorable Rosa L. DeLauro

Introduction of the Breast Cancer Patient Protection Act of 1997

Extension of Remarks

January, 7 1997

Mr. Speaker, I rise today to introduce the bipartisan Breast Cancer Patient Protection Act of 1997. I want to thank my colleagues Representatives Dingell, Roukema, Sanders, Foglietta, Moran, Lowey, Pallone, Meek, Pelosi, Nadler, Eshoo, Maloney, Norton, Clayton, Slaughter, Frank, Towns, Rahall, Gordon, Ackerman, Mink, Sherrod Brown, Clement, McDermott, LaFalce, Rindee, Olver, Oberstar, Morella, Corrine Brown, Payne, Hinchey, Valazquez, Frost, Evans, Gejdenson, Farr, Patrick Kennedy, Bentsen, DeFazio, Kennelly, Gonzalez, and Conyers for joining me as original cosponsors.

As an active participant in the fight for health care reform, I continue to believe that we must reform the health care system to provide quality care for all Americans. Particularly important is ensuring that women receive equitable treatment in our nation's health care system.

This year, approximately 184,300 mothers, daughters, and grandmothers will be diagnosed with invasive breast cancer. Another 44,300 women will die from this disease. With one every in eight women developing breast cancer, virtually every family in America is vulnerable to this disease. That's why today I am filing a bill that sets a minimum length hospital stay for patients undergoing breast cancer treatment. This bill would require a minimum hospital stay of 48 hours and 24 hours for lymph node removals.

Standard surgical treatment for breast cancer includes mastectomy, lymph node dissection, and lumpectomy. Over the last ten years, the length of hospitalization for patients undergoing mastectomies has dwindled significantly from 4-6 to 2-3 days. Patients undergoing lymph node dissections generally were hospitalized for 2-3 days. Hospitalization is essential for pain control and for the management of fluid drainage from the operative site. The less tangible, but still important benefit of hospitalization is to provide a supportive surrounding for the patient to address the psychological and emotional reactions inherent with having breast cancer, such as depression, anxiety, and hostility.

Now, under incessant pressure from managed care organizations to reduce costs, surgeons have had to perform lymph node dissections and even mastectomies as outpatient surgery. Some HMO's send their patients home a few hours after their surgery groggy from anaesthesia, in pain, and with drainage tubes still in place. Others even deny women hospitalizations on the

Congress of the United States

Washington, DC 20515

December 20, 1996

**SUPPORT A BI-PARTISAN BILL TO PROTECT
WOMEN WITH BREAST CANCER**

Dear Colleague:

We are writing to urge you to become an original co-sponsor of legislation to guarantee that women who must undergo surgery for the treatment of breast cancer get the hospital stay they need and deserve. The DeLauro-Dingell-Roukema Breast Cancer Patient Protection Act of 1997 guarantees a minimum hospital stay of 48 hours for a woman having a mastectomy and 24 hours for lymph node removal for the treatment of breast cancer. Our bill, modeled after the law protecting mothers from "drive-through" deliveries, ensures that women and their doctors, not insurance companies, would determine if a shorter stay is needed.

Under pressure from managed care organizations (HMOs) to reduce costs, doctors across the country have had to perform mastectomies and lymph node dissection as outpatient surgery. This has resulted in women being sent home groggy from anaesthesia, in pain, and with drainage tubes still in place. Doctors who believe it would be more appropriate and better for their patients to stay in the hospital longer are forced to choose between giving their patients the individual care they need or being penalized by the HMO for not following their guidelines.

Please join us in working to ensure that women with breast cancer receive treatment determined by doctors who want to provide good health care for their patients -- and not by insurance companies who are motivated solely to lower costs. Please contact one of us or Lissa Topel in Rep. DeLauro's office at 5-3661 by January 6th to sign on or if you have any questions.

Sincerely,


ROSA L. DeLAURO
Member of Congress


JOHN D. DINGELL
Member of Congress


MARGE ROUKEMA
Member of Congress

105TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURIO (for herself, [insert names of cosponsors shown on attached list]) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act and Employee Retirement Income Security Act of 1974 to require that group and individual health insurance coverage and group health plans provide coverage for a minimum hospital stay for mastectomies and lymph node dissections performed for the treatment of breast cancer.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the "Breast Cancer Patient
5 Protection Act of 1997".

1 SEC. 2. COVERAGE OF MINIMUM HOSPITAL STAY FOR CER-
2 TAIN BREAST CANCER TREATMENT.

3 (a) GROUP HEALTH PLANS.—

4 (1) PUBLIC HEALTH SERVICE ACT AMEND-
5 MENTS.—(A) Subpart 2 of part A of title XXVII of
6 the Public Health Service Act, as amended by sec-
7 tion 703(a) of Public Law 104-204, is amended by
8 adding at the end the following new section:

9 "SEC. 2706. STANDARDS RELATING TO BENEFITS FOR CER-
10 TAIN BREAST CANCER TREATMENT.

11 "(a) REQUIREMENTS FOR MINIMUM HOSPITAL STAY
12 FOLLOWING MASTECTOMY OR LYMPH NODE
13 DISECTION.—

14 "(1) IN GENERAL.—A group health plan, and a
15 health insurance issuer offering group health insur-
16 ance coverage, may not—

17 "(A) except as provided in paragraph

18 (2)—

19 "(i) restrict benefits for any hospital
20 length of stay in connection with a mastec-
21 tomy for the treatment of breast cancer to
22 less than 48 hours, or

23 "(ii) restrict benefits for any hospital
24 length of stay in connection with a lymph
25 node dissection for the treatment of breast
26 cancer to less than 24 hours, or

1 “(B) require that a provider obtain author-
2 ization from the plan or the issuer for prescrib-
3 ing any length of stay required under subpara-
4 graph (A) (without regard to paragraph (2)).

5 “(2) EXCEPTION.—Paragraph (1)(A) shall not
6 apply in connection with any group health plan or
7 health insurance issuer in any case in which the de-
8 cision to discharge the woman involved prior to the
9 expiration of the minimum length of stay otherwise
10 required under paragraph (1)(A) is made by an at-
11 tending provider in consultation with the woman.

12 “(b) PROHIBITIONS.—A group health plan, and a
13 health insurance issuer offering group health insurance
14 coverage in connection with a group health plan, may
15 not—

16 “(1) deny to a woman eligibility, or continued
17 eligibility, to enroll or to renew coverage under the
18 terms of the plan, solely for the purpose of avoiding
19 the requirements of this section;

20 “(2) provide monetary payments or rebates to
21 women to encourage such women to accept less than
22 the minimum protections available under this sec-
23 tion;

24 “(3) penalize or otherwise reduce or limit the
25 reimbursement of an attending provider because

1 such provider provided care to an individual partici-
2 pant or beneficiary in accordance with this section;

3 "(4) provide incentives (monetary or otherwise)
4 to an attending provider to induce such provider to
5 provide care to an individual participant or bene-
6 ficiary in a manner inconsistent with this section; or

7 "(5) subject to subsection (c)(3), restrict bene-
8 fits for any portion of a period within a hospital
9 length of stay required under subsection (a) in a
10 manner which is less favorable than the benefits pro-
11 vided for any preceding portion of such stay.

12 "(c) RULES OF CONSTRUCTION.—

13 "(1) Nothing in this section shall be construed
14 to require a woman who is a participant or bene-
15 ficiary—

16 "(A) to undergo a mastectomy or lymph
17 node dissection in a hospital; or

18 "(B) to stay in the hospital for a fixed pe-
19 riod of time following a mastectomy or lymph
20 node dissection.

21 "(2) This section shall not apply with respect to
22 any group health plan, or any group health insur-
23 ance coverage offered by a health insurance issuer,
24 which does not provide benefits for hospital lengths

1 of stay in connection with a mastectomy or lymph
2 node dissection for the treatment of breast cancer.

3 “(3) Nothing in this section shall be construed
4 as preventing a group health plan or issuer from im-
5 posing deductibles, coinsurance, or other cost-shar-
6 ing in relation to benefits for hospital lengths of stay
7 in connection with a mastectomy or lymph node
8 dissection for the treatment of breast cancer under
9 the plan (or under health insurance coverage offered
10 in connection with a group health plan), except that
11 such coinsurance or other cost-sharing for any por-
12 tion of a period within a hospital length of stay re-
13 quired under subsection (a) may not be greater than
14 such coinsurance or cost-sharing for any preceding
15 portion of such stay.

16 “(d) NOTICE.—A group health plan under this part
17 shall comply with the notice requirement under section
18 713(d) of the Employee Retirement Income Security Act
19 of 1974 with respect to the requirements of this section
20 as if such section applied to such plan.

21 “(c) LEVEL AND TYPE OF REIMBURSEMENTS.—
22 Nothing in this section shall be construed to prevent a
23 group health plan or a health insurance issuer offering
24 group health insurance coverage from negotiating the level

1 and type of reimbursement with a provider for care pro-
2 vided in accordance with this section.

3 “(f) PREEMPTION; EXCEPTION FOR HEALTH INSUR-
4 ANCE COVERAGE IN CERTAIN STATES.—

5 “(1) IN GENERAL.—The requirements of this
6 section shall not apply with respect to health insur-
7 ance coverage if there is a State law (as defined in
8 section 2723(d)(1)) for a State that regulates such
9 coverage that is described in any of the following
10 subparagraphs:

11 “(A) Such State law requires such cov-
12 erage to provide for at least a 48-hour hospital
13 length of stay following a mastectomy per-
14 formed for treatment of breast cancer and at
15 least a 24-hour hospital length of stay following
16 a lymph node dissection for treatment of breast
17 cancer.

18 “(B) Such State law requires, in connec-
19 tion with such coverage for surgical treatment
20 of breast cancer, that the hospital length of
21 stay for such care is left to the decision of (or
22 required to be made by) the attending provider
23 in consultation with the woman involved.

1 “(2) CONSTRUCTION.—Section 2723(a)(1) shall
2 not be construed as superseding a State law de-
3 scribed in paragraph (1).”.

4 (B) Section 2723(c) of such Act (42 U.S.C.
5 300gg-23(c)), as amended by section 604(b)(2) of
6 Public Law 104-204, is amended by striking “sec-
7 tion 2704” and inserting “sections 2704 and 2706”.

8 (2) ERISA AMENDMENTS.—(A) Subpart B of
9 part 7 of subtitle B of title I of the Employee Re-
10 tirement Income Security Act of 1974, as amended
11 by section 702(a) of Public Law 104-204, is amend-
12 ed by adding at the end the following new section:

13 **“SEC. 713. STANDARDS RELATING TO BENEFITS FOR CER-**
14 **TAIN BREAST CANCER TREATMENT.**

15 “(a) REQUIREMENTS FOR MINIMUM HOSPITAL STAY
16 FOLLOWING MASTECTOMY OR LYMPH NODE
17 DISECTION.—

18 “(1) IN GENERAL.—A group health plan, and a
19 health insurance issuer offering group health insur-
20 ance coverage, may not—

21 “(A) except as provided in paragraph
22 (2)—

23 “(i) restrict benefits for any hospital
24 length of stay in connection with a mastec-

1 tomy for the treatment of breast cancer to
2 less than 48 hours, or

3 "(ii) restrict benefits for any hospital
4 length of stay in connection with a lymph
5 node dissection for the treatment of breast
6 cancer to less than 24 hours, or

7 "(B) require that a provider obtain author-
8 ization from the plan or the issuer for prescrib-
9 ing any length of stay required under subpara-
10 graph (A) (without regard to paragraph (2)).

11 "(2) EXCEPTION.—Paragraph (1)(A) shall not
12 apply in connection with any group health plan or
13 health insurance issuer in any case in which the de-
14 cision to discharge the woman involved prior to the
15 expiration of the minimum length of stay otherwise
16 required under paragraph (1)(A) is made by an at-
17 tending provider in consultation with the woman.

18 "(b) PROHIBITIONS.—A group health plan, and a
19 health insurance issuer offering group health insurance
20 coverage in connection with a group health plan, may
21 not—

22 "(1) deny to a woman eligibility, or continued
23 eligibility, to enroll or to renew coverage under the
24 terms of the plan, solely for the purpose of avoiding
25 the requirements of this section;

1 “(2) provide monetary payments or rebates to
2 women to encourage such women to accept less than
3 the minimum protections available under this sec-
4 tion;

5 “(3) penalize or otherwise reduce or limit the
6 reimbursement of an attending provider because
7 such provider provided care to an individual partici-
8 pant or beneficiary in accordance with this section;

9 “(4) provide incentives (monetary or otherwise)
10 to an attending provider to induce such provider to
11 provide care to an individual participant or bene-
12 ficiary in a manner inconsistent with this section; or

13 “(5) subject to subsection (e)(3), restrict bene-
14 fits for any portion of a period within a hospital
15 length of stay required under subsection (a) in a
16 manner which is less favorable than the benefits pro-
17 vided for any preceding portion of such stay.

18 “(c) RULES OF CONSTRUCTION.—

19 “(1) Nothing in this section shall be construed
20 to require a woman who is a participant or bene-
21 ficiary—

22 “(A) to undergo a mastectomy or lymph
23 node dissection in a hospital; or

1 “(B) to stay in the hospital for a fixed pe-
2 riod of time following a mastectomy or lymph
3 node dissection.

4 “(2) This section shall not apply with respect to
5 any group health plan, or any group health insur-
6 ance coverage offered by a health insurance issuer,
7 which does not provide benefits for hospital lengths
8 of stay in connection with a mastectomy or lymph
9 node dissection for the treatment of breast cancer.

10 “(3) Nothing in this section shall be construed
11 as preventing a group health plan or issuer from im-
12 posing deductibles, coinsurance, or other cost-shar-
13 ing in relation to benefits for hospital lengths of stay
14 in connection with a mastectomy or lymph node
15 dissection for the treatment of breast cancer under
16 the plan (or under health insurance coverage offered
17 in connection with a group health plan), except that
18 such coinsurance or other cost-sharing for any por-
19 tion of a period within a hospital length of stay re-
20 quired under subsection (a) may not be greater than
21 such coinsurance or cost-sharing for any preceding
22 portion of such stay.

23 “(d) NOTICE UNDER GROUP HEALTH PLAN.—The
24 imposition of the requirements of this section shall be
25 treated as a material modification in the terms of the plan

1 described in section 102(a)(1), for purposes of assuring
2 notice of such requirements under the plan; except that
3 the summary description required to be provided under the
4 last sentence of section 104(b)(1) with respect to such
5 modification shall be provided by not later than 60 days
6 after the first day of the first plan year in which such
7 requirements apply.

8 “(e) LEVEL AND TYPE OF REIMBURSEMENTS.—
9 Nothing in this section shall be construed to prevent a
10 group health plan or a health insurance issuer offering
11 group health insurance coverage from negotiating the level
12 and type of reimbursement with a provider for care pro-
13 vided in accordance with this section.

14 “(f) PREEMPTION; EXCEPTION FOR HEALTH INSUR-
15 ANCE COVERAGE IN CERTAIN STATES.—

16 “(1) IN GENERAL.—The requirements of this
17 section shall not apply with respect to health insur-
18 ance coverage if there is a State law (as defined in
19 section 731(d)(1)) for a State that regulates such
20 coverage that is described in any of the following
21 subparagraphs:

22 “(A) Such State law requires such cov-
23 erage to provide for at least a 48-hour hospital
24 length of stay following a mastectomy per-
25 formed for treatment of breast cancer and at

1 least a 24-hour hospital length of stay following
2 a lymph node dissection for treatment of breast
3 cancer.

4 "(B) Such State law requires, in connec-
5 tion with such coverage for surgical treatment
6 of breast cancer, that the hospital length of
7 stay for such care is left to the decision of (or
8 required to be made by) the attending provider
9 in consultation with the woman involved.

10 "(2) CONSTRUCTION.—Section 731(a)(1) shall
11 not be construed as superseding a State law de-
12 scribed in paragraph (1).".

13 (B) Section 731(c) of such Act (29 U.S.C.
14 1191(c)), as amended by section 603(b)(1) of Public
15 Law 104-204, is amended by striking "section 711"
16 and inserting "sections 711 and 713".

17 (C) Section 732(a) of such Act (29 U.S.C.
18 1191a(a)), as amended by section 603(b)(2) of Pub-
19 lic Law 104-204, is amended by striking "section
20 711" and inserting "sections 711 and 713".

21 (D) The table of contents in section 1 of such
22 Act is amended by inserting after the item relating
23 to section 712 the following new item:

"Sec. 713. Standards relating to benefits for certain breast cancer treatment."

24 (b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B
25 of title XXVII of the Public Health Service Act, as amend-

1 ed by section 605(a) of Public Law 104-204, is amended
2 by inserting after section 2751 the following new section:

3 "SEC. 2752. STANDARDS RELATING TO BENEFITS FOR CER-
4 TAIN BREAST CANCER TREATMENT.

5 "(a) IN GENERAL.—The provisions of section 2706
6 (other than subsection (d)) shall apply to health insurance
7 coverage offered by a health insurance issuer in the indi-
8 vidual market in the same manner as it applies to health
9 insurance coverage offered by a health insurance issuer
10 in connection with a group health plan in the small or
11 large group market.

12 "(b) NOTICE.—A health insurance issuer under this
13 part shall comply with the notice requirement under sec-
14 tion 713(d) of the Employee Retirement Income Security
15 Act of 1974 with respect to the requirements referred to
16 in subsection (a) as if such section applied to such issuer
17 and such issuer were a group health plan.

18 "(c) PREEMPTION; EXCEPTION FOR HEALTH INSUR-
19 ANCE COVERAGE IN CERTAIN STATES.—

20 "(1) IN GENERAL.—The requirements of this
21 section shall not apply with respect to health insur-
22 ance coverage if there is a State law (as defined in
23 section 2723(d)(1)) for a State that regulates such
24 coverage that is described in any of the following
25 subparagraphs:

14

1 “(A) Such State law requires such cov-
2 erage to provide for at least a 48-hour hospital
3 length of stay following a mastectomy per-
4 formed for treatment of breast cancer and at
5 least a 24-hour hospital length of stay following
6 a lymph node dissection for treatment of breast
7 cancer.

8 “(B) Such State law requires, in connec-
9 tion with such coverage for surgical treatment
10 of breast cancer, that the hospital length of
11 stay for such care is left to the decision of (or
12 required to be made by) the attending provider
13 in consultation with the woman involved.

14 “(2) CONSTRUCTION.—Section 2762(a) shall
15 not be construed as superseding a State law de-
16 scribed in paragraph (1).”.

17 (2) Section 2762(b)(2) of such Act (42 U.S.C.
18 300gg-62(b)(2)), as added by section 605(b)(3)(B) of
19 Public Law 104-204, is amended by striking “section
20 2751” and inserting “sections 2751 and 2752”.

21 (c) EFFECTIVE DATES.—(1) The amendments made
22 by subsection (a) shall apply with respect to group health
23 plans for plan years beginning on or after January 1,
24 1998.

- 1 (2) The amendment made by subsection (b) shall
- 2 apply with respect to health insurance coverage offered,
- 3 sold, issued, renewed, in effect, or operated in the individ-
- 4 ual market on or after such date.

01/24/97 14:12

JOHN D. DINGELL
16TH DISTRICT, MICHIGANRANKING MEMBER
COMMITTEE ON COMMERCE

MEMBER

OFFICE OF TECHNOLOGY
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CONSERVATION COMMISSION

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January 23, 1997

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mrs. Clinton:

I want to thank you for taking the time out of your busy schedule to speak with me this morning. Your assistance is greatly appreciated.

I am respectfully requesting your support for legislation, which I have introduced with Representatives Rosa DeLauro and Marge Roukema, that guarantees a minimum hospital stay of 48 hours for women having a mastectomy and 24 hours for lymph node removal for the treatment of breast cancer. H.R. 135, the Breast Cancer Patient Protection Act is modeled after the law protecting mothers from "drive-through" deliveries. It ensures that women and their doctors, not insurance companies, would determine if a shorter stay is needed. Senator Tom Daschle has introduced the companion bill in the Senate. You should also be aware that Senator Al D'Amato and Representative Susan Molinari are planning to introduce similar legislation; however, I have serious concerns with the substance of their proposal and the political reality of passing it. It would be splendid if the President would highlight his support for this bill in his upcoming State of the Union address.

Largely because of pressure from HMOs, women across the country are being discharged early after mastectomies and lymph node dissections, sometimes in pain with drainage tubes still in place. H.R. 135, which is structurally similar to the new law which ended the practice of drive-through deliveries, would require HMOs to cover the costs of mastectomy patients remaining in the hospital for a minimum of 48 hours after surgery. The bill provides that the attending health care provider does not need to obtain authorization from a health insurer to ensure coverage for this hospital stay. The legislation requires that this critical health care decision be made exclusively by the attending physician and the woman.

January 23, 1997
Page Two

As per our conversation, I have enclosed a memo outlining the specifics of this bill. If you have any further questions or require more information, please do not hesitate to contact me. I have always enjoyed working with you and your support is again appreciated.

With every good wish,

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'John D. Dingell', written over a large, loopy initial 'J'.

John D. Dingell
Member of Congress

JOHN D. DINGELL
16TH DISTRICT, MICHIGAN

RANKING MEMBER
COMMITTEE ON COMMERCE

MEMBER
OFFICE OF TECHNOLOGY
ASSESSMENT

MIGRATORY BIRD
CONSERVATION COMMISSION

Congress of the United States
House of Representatives
Washington, DC 20515-2216

MEMORANDUM

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TO: Mrs. Hillary Rodham Clinton

FROM: Congressman John D. Dingell JDD

DATE: January 24, 1997

RE: H.R. 135, the Breast Cancer Patient Protection Act.

*** Required Coverage for Minimum Hospital Stay For Certain Breast Cancer Treatment.**

It states that the minimum hospital stay for a woman is 48 hours following a mastectomy and 24 hours following a lymph node dissection treatment. The decision to discharge a patient prior to the minimum length of stay be made by the attending physician in consultation with the woman.

A group health plan may not deny a woman eligibility to enroll or renew coverage for the purposes of avoiding the requirements of this legislation and a health plan may not offer monetary incentives to the woman or her physician to avoid the requirements of the bill. Furthermore, the legislation would prohibit health plans from penalizing physicians for providing care consistent with this legislation.

Ensures that no additional deductibles, or coinsurance payments are required in connection with the extended hospital stay.

It does not preempt state law which meets the requirements of this legislation.

*** Current Cosponsorship**

H.R. 135:

Rep. Andrews	Rep. Clayton	Rep. Farr	Rep. Gonzalez
Rep. Ackerman	Rep. Clement	Rep. Fazio	Rep. Gordon
Rep. Allen	Rep. Conyers	Rep. Filner	Rep. Green
Rep. Barrett (WI)	Rep. DeFazio	Rep. Foglietta	Rep. Gutierrez
Rep. Bentsen	Rep. Delahunt	Rep. Fox	Rep. Hinchey
Rep. Boucher	Rep. Dellums	Rep. Frank (MA)	Rep. Hinojosa
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Rep. Brown (OH)	Rep. Evans	Rep. Furse	Rep. Kaptur
Rep. Carson	Rep. Faleomavaega	Rep. Gejdenson	Rep. Kennedy (MA)

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Rep. Lowey	Rep. Millender-McDonald	Rep. Pelosi	Rep. Tauscher
Rep. McCarthy (NY)	Rep. Mink	Rep. Pickett	Rep. Thurman
Rep. McCarthy (MO)	Rep. Moakley	Rep. Quinn	Rep. Towns
Rep. McDermott	Rep. Moran	Rep. Rahall	Rep. Velazquez
Rep. McGovern	Rep. Morella	Rep. Rangel	Rep. Woolsey
Rep. McHugh	Rep. Murtha	Rep. Rivers	Rep. Yates
Rep. McNulty	Rep. Nadler	Rep. Roukema	
Rep. Maloney (NY)	Rep. Neal	Rep. Roybal-Allard	
Rep. Maloney (CT)	Rep. Norton	Rep. Romero-Barcello	

Cosponsorship S. 143:

Sen. Daschle	Sen. Mosely-Braun	Sen. Murry	Sen. Ford
Sen. Hollings	Sen. Boxer	Sen. Johnson	Sen. Lautenberg
Sen. Kennedy	Sen. Feinstein	Sen. Bryan	
Sen. Levin	Sen. Inouye	Sen. Sarbanes	

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FAX: 456-7431
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FROM: Kristin Bass PHONE: 778-8504
DATE: _____ TIME: _____

TOTAL # OF PAGES (including cover page): 10

MESSAGE Enclosures: 1) NRC transcript on Hopkins program on outpatient mastectomy 2) AAHP talking points, including summary of research documenting outcomes (faster recovery; lower infection rates) 3) AAHP Board statement. (Given advances in medical treatment, it makes no sense for the President to go down the road of calling for legislation on this and other issues — especially when the industry has rallied to address concerns. Why not have him include a call to the industry to solve this problem, if such a problem exists?)

K



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Transcript

DATE January 2, 1997
TIME 4:00-6:00 PM (ET)
NETWORK National Public Radio
PROGRAM All Things Considered

Robert Siegel, host:

There have been a number of news stories about insurance companies and HMOs pressuring doctors to release women from the hospital the day after having a mastectomy or even the same day. Federal and state legislatures are considering bills that would require health plans to cover at least a two-day stay. But as NPR's Joanne Silberner reports, some doctors and patients have found that it can be better for a woman to recover at home.

Joanne Silberner reporting:

Surgeons at Johns Hopkins Hospital have been doing mastectomies and sending the patients home the same day for the last three years. An important part of the procedure comes before the actual operation.

Nurse Alison Schuler (sp) and breast cancer patient Lea Cluvarius (sp) and her husband are talking in a small examining room at the Johns Hopkins Outpatient Center. Nurse Schuler is explaining how to take care of the tubes that will be temporarily sewn into Mrs. Cluvarius' chest. The tubes are put there to drain the fluids that will collect after her breast has been removed.

Cluvarius has traveled to Hopkins from her home in Italy because of the hospital's reputation, but she didn't realize her surgeon would want to send her back to her hotel just a few hours after the mastectomy. She's worried about emptying the drainage tubes. Schuler tells Mrs. Cluvarius that a visiting nurse will come to her hotel room the night after the surgery and again the next morning. Schuler is convinced that the hospital is not the ideal place for women the night after their surgery.

Alison Schuler (Nurse, Johns Hopkins): What they don't realize is that they're gonna be the least sick patient on that unit. So, they're gonna get the least amount of attention from any nurse or anyone else on that unit. And the other thing is that nursing is required while the patients are admitted to monitor vital signs and to check on them throughout the night, so the patients don't get a

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very good night's sleep.

Silberner: It used to be that mastectomy patients stayed in the hospital for a week or so until they had gotten over the pain of the operation and also had their drainage tubes removed. But in the last ten years, says surgeon William Dooley (sp), director of the Johns Hopkins Breast Center, things changed. Insurance companies began pressuring the hospital to send patients home with their drains in just a couple days after surgery. So Dooley and others began trying to make it easier on the patients. They developed better anesthesia and anti-nausea regimens. That reduced discomfort so much that the women only needed pain pills, not intravenous medications after the surgery.

Dr. William Dooley (Director, Johns Hopkins Breast Center): About three and a half years ago, a patient called me at eleven o'clock at night from their hospital bed and said, you know, I feel perfectly fine, and I'm not getting any sleep in the hospital, it's too noisy, I want to go home, which prompted us to then look- is this something we ought to be thinking about.

Silberner: And he developed an education program so women would know what to do. Dooley always gives his mastectomy patients a choice and only offers the outpatient option to women who are healthy enough to take care of themselves and have a partner, friend or relative willing to go through the educational session with them and help with the post-op care. His patients seem to like the idea. About ninety percent go home the same day. One patient even decided to have the operation itself done with just localized numbing rather than be put to sleep.

But many doctors aren't sold on same-day mastectomies. Surgeon Christin Zarfus (sp) practices in Middletown, Connecticut, where women generally stay in the hospital for two to four days.

Dr. Christin Zarfus (Surgeon, Middletown, Connecticut): Most women do not want to go home with their drains in place. Despite any education from me and nurses, they're very fearful that the drains are going to fall open, drain blood or they're going to get an infection, which studies show that they do not have an increased risk of developing infection. Nevertheless, the women are very fearful of these drains.

Silberner: Zarfus brought the issue of outpatient mastectomies to the media's attention over the summer, when she heard that two Connecticut HMOs were going to start requiring it. Zarfus surveyed her patients, and they were angry, too, asking how anyone could ignore the pain they were in or their emotional and psychological needs.

But Dooley at Johns Hopkins says going home quickly

can help the patient by taking some of the fearsomeness out of a cancer diagnosis.

Dooley: Patients have, in their mind, that I'm having this huge operation, I'm going to be very sick, I have this dreaded disease, I'm supposed to behave like a sick person. And we began to think maybe this is the wrong psychological mindset for our patients to have.

Silberner: A few days after her operation, Lea Cluvarius, who had such misgivings, was glad she chose the outpatient option.

Lea Cluvarius (Mastectomy Patient): After the surgery, I felt normal and, I mean, I really felt like I didn't have surgery. I had no pains, I felt in full control of myself.

Silberner: Her husband changed the drains until she returned to the hospital to have them removed a few days later. She said he was an excellent nurse.

Cluvarius: I feel that I probably recovered faster being outside of the hospital than being inside. I was not a sick person any more. I was going back to normal life. In a hospital, you can't walk around, you can't go out for lunch, you can't go to the aquarium and look at something that's soothing. You are a sick person in the hospital. When you go out, you become a normal healthy person.

Silberner: It's not clear how frequently insurers pressure doctors to send their patients home the day of surgery or the day after. Two breast cancer advocacy groups say that following several news stories this fall, they received calls complaining about short stays after mastectomies, but not from anybody who had it happen to them.

Several surgeons have told NPR that they've had to convince insurers when they wanted to keep their patients in the hospital for more than one night. In mid-November, the nation's HMOs pledged not to force women to leave the hospital if they don't want to have the procedure done on an outpatient basis. Even with that commitment, several members of Congress plan to introduce legislation requiring insurers to allow at least a two-day stay, something they did last year for new mothers.

The Connecticut surgeon, Dr. Zarfus would like to see the bill pass.

Zarfus: Unfortunately, in this day and age in the United States, that's the only way to protect women who've just had a baby or women who've just had a mastectomy. Most hospitals in this country, certainly under the constricted reimbursement that they have now, don't have the resources to create such a wonderful program that Dr. Dooley does.

VIDEO MONITORING SERVICES OF AMERICA, LP

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Silberner: Cancer specialist Andrew Selner (sp) has followed the outpatient mastectomy issue closely as head of the Connecticut chapter of the American Cancer Society. He says congressional micro-management of what's in insurance policies may be humane but not practical, since there are thousands of reasons for hospital stays.

Andrew Selner (Connecticut Chapter, American Cancer Society): I really feel that the legislature's time is better used at a higher level, looking in general, at managed care companies and how responsive they are to the needs of patients and members and the health care provider, as opposed to exploring every specific medical situation.

Silberner: Like how long a woman should be able to stay in the hospital after a breast reconstruction or abdominal surgery or a heart bypass. Hopkins surgeon William Dooley says what's really important is how good the care is and how satisfied the patient is and that's hard to legislate, because it's harder to measure than just by days in the hospital.

This is Joanne Silberner reporting.

#

DRAFT

American Association of
HEALTH PLANS

Mastectomy Length of Stay Should be Based on Shared Decision Making by Patients and Physicians

Issue: Press reports about mastectomies performed on an outpatient basis have raised concerns about the care provided to breast cancer patients in HMOs and other network-based plans. These anecdotes have resulted in legislative proposals to mandate that such plans provide coverage for a minimum inpatient hospital stay for women receiving a mastectomy. Such proposals are based on assumptions that outpatient mastectomies are the result of overly aggressive efforts to contain costs and that they are always medically unsound.

Evidence shows that many outpatient mastectomies are performed on women with fee-for-service coverage, including fee-for-service Medicare. Moreover, women enrolled in HMOs are no more likely than women in fee-for-service plans to have a mastectomy on an outpatient basis. This pattern demonstrates that physicians -- not health plans -- are deciding whether care should be provided in an inpatient or outpatient setting.

Such decisions reflect the fact that there are different types of mastectomies¹ and that research conducted at respected academic medical centers shows that outpatient mastectomies can produce better outcomes than inpatient care for some women. Legislation governing clinical practice fails to take into account the varying severity of breast cancer and the intensities of its treatment and will discourage treatments tailored to each patient's individual needs and preferences.

With their proven track record on the early detection of breast cancer, HMOs and other network-based plans have demonstrated their commitment to promoting women's health and treating this serious condition. AAHP and its member plans have proactively addressed the issue of mastectomy length of stay by issuing a statement reinforcing the policy that mastectomy length of stay decision should be made by the physician and the patient and should be based on the best available scientific information and the unique characteristics of the patient.

- Whether a woman has an outpatient mastectomy is determined by her physician -- not by the type of insurance she has. Fee-for-service patients, in both private plans and traditional Medicare, account for a large proportion of outpatient mastectomies. Women in HMOs are no more likely than women in FFS plans to have outpatient mastectomies.

¹Lumpectomies remove only the tumor and some adjacent breast tissues; segmental or partial mastectomies remove the tumor and the lobe in which the tumor is growing; simple or total mastectomies remove the entire breast; modified radical mastectomies remove the entire breast and the lymph nodes under the arm; and radical mastectomies remove the breast, underarm lymph nodes, and part of the underlying chest muscles.

- + At the national level, HCIA Inc, a Baltimore research company specializing in health care, analyzed 110,000 mastectomies covered by Medicare, the large majority of which were reimbursed on a fee-for-service basis, and found that 7.6% were performed on an outpatient basis. This analysis was performed for the Wall Street Journal.
- + Data from the New York State Department of Health found that the majority of outpatient mastectomies performed in 1995 were performed on Medicare fee-for-service beneficiaries. Of the 124 outpatient mastectomies performed in New York State in 1995, 72 were performed on women in Medicare fee-for-service and 19 were performed on women in HMOs.
- + AAHP commissioned the MEDSTAT Group, a health care data analysis firm, to analyze outpatient mastectomy rates for privately insured women in 1993 and 1994. Rates were analyzed for three types of mastectomy: (1) partial mastectomy with lymphadenectomy, (2) simple mastectomy, and (3) modified radical and radical mastectomy. All three health plan categories examined -- FFS, PPOs/Point of Service (POS), and HMOs/Other Capitated Plans -- "had fairly consistent rates of mastectomy procedures performed in the outpatient setting." Based on a sample of 2.5 million individuals for each year, the only statistically significant differences were as follows:
 - * For simple mastectomies, there was a statistically significant difference in outpatient procedure rates during 1993. FFS plans had the highest rate of outpatient procedures -- 26%. PPO/POS plans had the lowest rate -- 11%. HMOs were in between with 17% of simple mastectomies performed in outpatient settings.
 - * In 1994, the rate of modified radical and radical mastectomies performed on an outpatient basis differed somewhat by type of plan. PPO/POS had the highest outpatient percentage (12%) and HMOs had the lowest outpatient percentage (5%). FFS plans were in between (9%). However, when 1993 and 1994 data were combined, there was not a statistically significant difference in outpatient rates by type of plan.
- The incidence of outpatient mastectomies in both network-based and FFS plans reflects growing recognition that such an approach is appropriate in certain cases. At least five recent studies conducted at academic medical centers have shown that outpatient mastectomies on women who have met certain medical criteria indicating a low risk of complication result in equal or better medical outcomes and/or patient satisfaction than inpatient mastectomies. Creating unfounded concerns about outpatient mastectomy could actually harm women by causing them to avoid considering an alternative that can reduce infections and accelerate recovery.
- + The Johns Hopkins Breast Center in Baltimore, which has gradually eliminated hospital stays for some women undergoing certain types of mastectomies, has found lower infection rates and high levels of satisfaction among women.

- + A 1996 study of 525 women who underwent outpatient mastectomies at Henry Ford Hospital in Michigan reported accelerated physical recovery, earlier return to occupational activities, and numerous psychological advantages, such as control, independence, and strong family interactions. (*The American Surgeon*, Feb. 1996; vol 62)
- + A 1995 study of 133 women who underwent outpatient partial mastectomies with lymph node removal and 45 women who had the surgery on an inpatient basis at the New Jersey College of Medicine showed that the outpatient group had a lower rate of post-operative infection and reported a high level of satisfaction. (*International Surgery*, 1995; vol 80)
- + A 1994 study of 118 women who underwent outpatient mastectomies at St. Peter's Medical Center in New Jersey reported accelerated healing and recovery at home and a high level of satisfaction. (*The American Surgeon*, Dec. 1994; vol 60)
- + A 1993 study of 221 women who underwent outpatient mastectomies and partial mastectomies with lymph node removal at the Comprehensive Breast Care Center in Florida found that the women experienced no serious complications, no readmissions, and high patient satisfaction. (*Archives of Surgery*, Oct. 1993; vol 128)
- **The occurrence of outpatient mastectomies in both network-based and FFS plans also reflects the diversity of cases and currently available treatment options. A clinical mandate for mastectomy length of stay will stifle further medical innovation and discourage individualized treatment tailored to a patient's specific needs.**
 - + Mastectomy refers to a spectrum of breast cancer treatments that ranges from lumpectomies which only remove the tumor to radical mastectomies which remove the breast, underarm lymph nodes, and part of the underlying chest muscles. Legislation governing clinical practice fails to take into account the varying severity of breast cancer and the intensities of its treatment and will discourage treatments tailored to each patient's individual needs and preferences.
 - | The past decade has brought us more effective medicines, safer anesthesia, expanded home care options, and improved surgical techniques. *Even as the debate over mastectomy care began, the Journal of the American Medical Association reported in its December 11, 1996, issue, a new mapping technique which allows physicians to determine the extent of the cancer while performing much less extensive surgery on many women than has been standard practice. Legislation that defines medical practice will eliminate incentives to further innovate and improve care.*
- **Network-based health plans have been at the forefront of encouraging prevention and early detection of cancer in women - activities that have made a significant contribution to a reduction in cancer mortality.**

- + Several studies have documented HMOs' success in early detection of breast cancer in women. The Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics found that women in HMOs are more likely to obtain mammograms and clinical breast exams than women in old-style fee-for-service plans. In fact, the Physician Payment Review Commission (PPRC) recently found that 62% of women enrolled in Medicare HMOs had mammograms compared to 39% in the fee-for-service sector. The gap between HMOs and FFS plans was greatest among low income and African-American women, indicating that network-based plans may significantly improve access to mammograms among vulnerable populations.
- + In addition, the Health Care Financing Administration (HCFA) showed that 12 different types of cancer, including breast cancer, are diagnosed significantly earlier in Medicare HMOs patients than in Medicare fee-for-service.
- + HMOs have developed expertise in using a variety of outreach techniques designed to increase awareness of their cancer prevention and screening services and encourage more women to receive appropriate breast exams. For example, one plan uses a postcard reminder program to encourage women to receive a free mammogram and a special streamlined referral program which allows women to go directly to a radiology center to receive their mammogram. Another plan uses an automated tracking and reminder system that ensures routing and repeat mammograms and facilitates follow-up appointments.
- + Evidence suggests that this emphasis on prevention has contributed to reduced mortality. In November, 1996, The American Cancer Society announced that death rates from cancer declined for the first time. Breast cancer mortality rates declined 6.3%. This decline was attributed to the "cumulative effects of prevention, early detection, and treatment."
- A key public policy issue not addressed by the mastectomy length of stay issue is the failure of uninsured women and of a high proportion of women in fee-for-service plans to receive appropriate breast exams which can detect and trigger treatment of breast cancer at an early stage when it is more curable and treatable with less extensive surgery.
- AAHP and its member health plans have been proactive in addressing the mastectomy length of stay issue and in assuring patients of the high quality care delivered through health plans.
- | In November, 1996, AAHP's Board of Directors issued a policy statement on mastectomy:

"It is the policy of the American Association of Health Plans that the decision about whether outpatient or inpatient care best meets the needs of a woman undergoing removal of a breast should be made by the woman's physician after consultation with the patient. Health plans do not and should not require outpatient care for removal of a breast. As a matter of practice, physicians should make all medical treatment decisions based on the best available scientific information and the unique characteristics of each patient."



American Association of
HEALTH PLANS

Press Release

Not for release until:
November 14, 1996, 1:30 p.m.

Contact: Don White
202-778-3274

Health Plans Should Not Require Outpatient Mastectomy *AAHP Takes Decisive Action Regarding Hospital Stays*

Washington, D.C. -- Decisions about a hospital stay following mastectomy should be made by a woman's physician in consultation with the patient herself, according to a policy statement adopted by the American Association of Health Plans Board of Directors.

Public attention has recently been focused on the question of whether or not mastectomies can or ought to be performed on an outpatient basis. Accounts by prominent news organizations suggest that mastectomy patients are being denied overnight hospital stays, even when a woman's physician believes hospitalization is the best option for her.

Before making the policy announcement, AAHP canvassed member plans and found that the standard practice is for physicians and their patients to determine the best care following mastectomy, including whether to stay in the hospital or return more quickly to their homes and families.

Because of the importance and sensitivity of the issue, and to alleviate the concerns of patients facing this difficult surgery, the AAHP Board of Directors decided to formally adopt this policy.

"Our members believe it is time to speak out on this important women's health issue, and to send a clear message about what constitutes good health plan practice," said AAHP President Karen Ignagni.

Today's announcement reinforces the association's Philosophy of Care emphasizing the importance of physicians and their patients making decisions about the best care.

The American Association of Health Plans (formerly GHAA/AMCRA) represents more than 1000 HMOs, PPOs, and similar plans. AAHP's member companies are dedicated to a philosophy of health care that puts the patient first; together they care for more than 100 million Americans nationwide.

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Clinton Presidential Records Digital Records Marker

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This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: Breast Cancer Death Rates Fall

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, May 7, 1996

Contact: NCI Press Office
(301) 496-6641

NCI Reports Improvements in Breast Cancer Death Rate

The National Cancer Institute announced today that the breast cancer death rate in American women continued to decline through 1993, a finding that suggests improved breast cancer management from early detection to treatment is having a beneficial effect.

Breast cancer mortality trends for white women in the United States have improved markedly in the 1990s compared with the 1980s. For black women, increases in mortality persist, especially among older women, but the overall increase has slowed significantly.

During the most recent 5-year period of available data, 1989 to 1993, the age-adjusted breast cancer mortality rates fell approximately 6 percent in white women and rose about 1 percent in black women. By comparison, from 1980 to 1989, rates increased 3 percent in white women and 16 percent in black women, according to data from the National Center for Health Statistics.

"These findings are good news, but not good enough," said HHS Secretary Donna E. Shalala. "The Clinton Administration will keep pursuing every opportunity for prevention, early detection and treatment, and an effective research agenda to fight breast cancer."

NCI Director Richard Klausner, M.D., said "The data suggest the trend is starting to move in a positive direction for African-American women as well as white women. Rates have

(more)

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declined among younger black women, although they are still higher than those of white women and are improving more slowly."

The overall rate in U.S. women has fallen about 5 percent in recent years, dropping from 27.5 per 100,000 women in 1989 to 25.9 in 1993. This year, an estimated 44,300 women will die of the disease nationwide, but that estimate could prove to be too high if the trend continues.

In both white and black women, the greatest improvements in mortality during the recent 5-year period were seen in younger age groups, but the changes were more modest in blacks than in whites of all ages.

- Among white women, death rates declined for all decades of age from 30 to 79 years;
- Among black women, rates were down for all decades from 30 to 69 years;
- For women aged 30 to 39 years, rates dropped about 13 percent in whites and 5 percent in blacks;
- For women aged 40 to 49 years, rates dropped 9 percent in whites and 2 percent in blacks;
- For women aged 50 to 59 years, rates declined 9 percent in whites and less than 1 percent in blacks;
- For women 60 to 69 years old, rates declined 6 percent in whites and less than 1 percent in blacks;
- For women 70 to 79 years old, rates increased 5 percent in blacks and decreased 3 percent in whites;
- For women 80 years and older, rates increased 5 percent in blacks and 2 percent in whites.

The median age at death for white breast cancer patients is 68 years and for black breast cancer patients 62 years.

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Experts believe the recent decline in breast cancer mortality is partly a result of mammography screening, which rapidly increased in the United States during the 1980s and resulted in a shift toward the detection of breast cancer at earlier, more curable stages. But they say screening cannot explain all of the decline.

"Such changes in mortality trends across a wide age range usually indicate improvements in medical interventions, and examination of stage-specific breast cancer incidence rates and survival rates suggests that both earlier detection and improved treatment are likely contributing to the recent declines in breast cancer mortality," said Robert Tarone, Ph.D., of the National Cancer Institute's Biostatistics Branch.

"Further study is required to determine the relative contribution of early detection and improved treatment to the recent declines in breast cancer mortality," added Brenda K. Edwards, Ph.D., director of NCI's Cancer Control Research Program. "Research is now under way to investigate the impact of adjuvant therapy on mortality rates."

Health authorities in the United Kingdom have also reported a steep decline in the breast cancer death rate among women aged 55-69 during roughly the same time period. The mortality rate in this group dropped 12 percent from 1987 to 1994. This trend began at the same time as the introduction of the U.K. breast screening program, but researchers there have concluded that it occurred too soon to be entirely a result of screening. Instead, they attribute much of the decline to more effective treatment, particularly the widespread adoption of tamoxifen therapy. These results add weight to the evidence for a similar beneficial effect of treatment advances on breast cancer mortality in U.S. women.

Breast cancer mortality rates vary fairly widely among racial and ethnic groups in the United States. Hispanic, Chinese, Filipino, and Japanese women have annual rates at or below 15 per 100,000; while black, white, and Native Hawaiian women have rates above 25 per 100,000.

Edwards said the racial differences in mortality rates depend on several factors including risk of developing breast cancer, access to screening and early detection, treatment and medical follow-up, and supportive care. NCI is investigating differential risk factors, patterns of care, and clinical and biological prognostic factors for survival, she said, adding that "understanding of these relationships is still incomplete."

The continued increase in breast cancer mortality rates in older women extends a long-standing, increasing trend in breast cancer risk for women born from 1900 to 1920, Tarone said. Researchers believe the increasing mortality rates in this group reflect changes in various risk factors such as delayed childbearing early in the century.

Less well-understood is the declining mortality among women under age 40, who generally are not screened. The trend in this group appears to reflect a recent change in risk factors above and beyond the improvements due to medical intervention.

HHS support for breast cancer research, prevention and treatment has increased from \$271 million in 1993 to \$476 million in 1996. Special programs include:

- the National Cancer Institute's comprehensive effort to identify the genetic and biological basis of breast cancer, characterize patterns of risk in the population, and apply the knowledge gained through basic research to more effective prevention and treatment strategies;
- the Centers for Disease Control's National Breast and Cervical Cancer Early Detection program, which offers free or low-cost mammography to uninsured or low-income women;

(more)

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- the Food and Drug Administration's quality standards for mammography services; and
- the clinical practice guidelines on mammography issued by the Agency for Health Care Policy and Research.

In addition, HHS' Health Care Financing Administration helps pay for mammography for beneficiaries of the Medicare program. In recent years, some 37 percent of women beneficiaries have been making use of Medicare's mammography coverage. An ongoing HHS campaign, targeted especially at women over 65, aims at increasing the use of the benefit to at least 60 percent by the year 2000.

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The Cancer Information Service (CIS), a program of the National Cancer Institute, provides a nationwide telephone service for cancer patients and their families, the public, and health care professionals. CIS Information specialists have extensive training in providing up-to-date and understandable information about cancer and cancer research. They can answer questions in English and Spanish and can send free printed material. In addition, CIS offices serve specific geographic areas and have information about cancer-related services and resources in their region. The toll-free number of the CIS is 1-800-4-CANCER (1-800-422-6237).

This document is available through the National Cancer Institute's CancerFax and CancerNet services, and in the News Section of the NCI's PDQ database. To get the document from CancerFax, dial (301) 402-5874 from the handset on your fax machine and follow the recorded instructions to receive the contents list. Individuals who have access to the Internet may access the document on CancerNet, through an electronic mail service or via the NIH gopher. To get the CancerNet contents list from the e-mail service, send an e-mail message that says "help" in the body of the message to cancernet@icicc.nci.nih.gov. To get the documents from CancerNet via the NIH gopher, point your gopher client to gopher.nih.gov and look for CancerNet under "Health and Clinical Information." To get the document from NCI's PDQ database, access PDQ News on the National Library of Medicine's MEDLARS system or consult a medical librarian for assistance. Additional information on this and other research topics may be found on the home page of the NCI's International Cancer Information Center's World Wide Web server located at <http://www.icic.nci.nih.gov>.

The attached MMWR article of October 4, 1996 describes statistics about breast cancer. The third page of the article includes:

- a chart showing dramatic improvements in death rates from 1989 through 1992 even while the number of cases of diagnosed breast cancer increased; and,
- an "editorial note" which briefly summarizes the data and its implications.

Highlights

- The article says that breast cancer incidence (i.e., the number of new cases) increased from 1973 to 1992 "most likely [because of]...increased use of breast cancer screening methods...which enable earlier diagnosis of the disease."
- The article says that "the decrease in breast cancer deaths during 1989 to 1992 may reflect...earlier diagnosis and improved treatment." The sooner breast cancer is diagnosed, the better the odds of survival.
- Black women are more likely to die of breast cancer than white women -- from 1988 to 1992 death rates for black women were 1.2 times the death rates for white women. CDC staff that this difference is probably related to differences in access to screening and treatment.

Funding in FY 1997

Congress has appropriated \$140 million for CDC breast and cervical cancer screening programs in FY 1997, \$15 million more than the President requested.



October 4, 1996 / Vol. 45 / No. 39

MNWR

MORBIDITY AND MORTALITY WEEKLY REPORT

- 833 National Breast Cancer Awareness Month — October 1996
- 833 Breast Cancer Incidence and Mortality — United States, 1992
- 837 Suffocations in Grain Bins — Minnesota, 1992–1995
- 841 Dengue Fever at the U.S.–Mexico Border, 1995–1996

National Breast Cancer Awareness Month — October 1996

October is National Breast Cancer Awareness Month. Each year, CDC; other government agencies; and major nonprofit, national cancer organizations cosponsor this month, which is dedicated to increasing awareness about the importance of early detection of breast cancer. Through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), CDC supports early detection of breast and cervical cancers through cooperative agreements with health departments in all 50 states, the District of Columbia, five territories, and 13 American Indian/Alaskan Native organizations.

Additional information about Breast Cancer Awareness Month and the NBCCEDP is available from CDC's Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, (770) 488-4751, and from the World Wide Web (<http://www.cdc.gov/nccdcphp/dccp/dccpchome.htm>).

Breast Cancer Incidence and Mortality — United States, 1992

Breast cancer is the most commonly diagnosed nondermatologic cancer and the second leading cause of cancer-related deaths among women in the United States (1–3). In 1996, a total of 184,300 new cases of and 44,300 deaths from invasive breast cancer are projected among women (3). To assess trends in incidence and death rates for breast cancer among U.S. women, CDC analyzed national incidence data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program (2) and death-certificate data from CDC's National Center for Health Statistics (NCHS) (4). This report presents incidence and death rates for breast cancer for 1992 (the most recent year for which SEER data were available) and summarizes trends in these rates for 1973–1992. Overall, these findings indicate that incidence rates for invasive breast cancer increased among women during 1973–1987 and stabilized during 1988–1992, while mortality rates remained stable during 1973–1988 and decreased during 1989–1992.

The incidence rate of breast cancer in the United States is estimated by using aggregate data reported by the SEER program, which includes a nonrandom sample

Breast Cancer — Continued

of approximately 14% of the U.S. population (2,5). Based on 1990 data from the Bureau of the Census, the demographic characteristics of persons included in SEER is representative of the total U.S. population for whites and blacks; in addition, persons included in SEER reflect the percentage of persons among the total U.S. population living below the poverty level* and the percentage of adults who graduated from high school (5). However, a higher proportion of persons included in SEER resided in urban areas (5). This analysis includes all cases of invasive breast cancer (*International Classification of Diseases, for Oncology*, codes C50.0–C50.9) registered in SEER. Annual incidence rates were computed for 1973–1992, and race- and age-specific average annual incidence rates were computed for the combined years of 1988–1992.

Decedents for which the underlying cause of death was breast cancer (*International Classification of Diseases, Adapted, Ninth Revision*, codes 174.0–174.9) were identified from public-use mortality data tapes (4). Annual death rates were computed for 1973–1992, and race-specific average annual death rates by age and by state were computed for the combined years of 1988–1992.

Denominators for annual incidence and death rate calculations were derived from U.S. census population estimates. Rates were directly standardized to the age distribution of the 1970 U.S. population using 5-year age groupings. Data are presented only for whites and blacks because numbers for other racial/ethnic groups were too small for meaningful analysis.

Breast Cancer Incidence

In 1992, the overall age-adjusted incidence rate for breast cancer was 110.6 per 100,000 women. The rate for white women (113.1) was higher than that for black women (101.0).

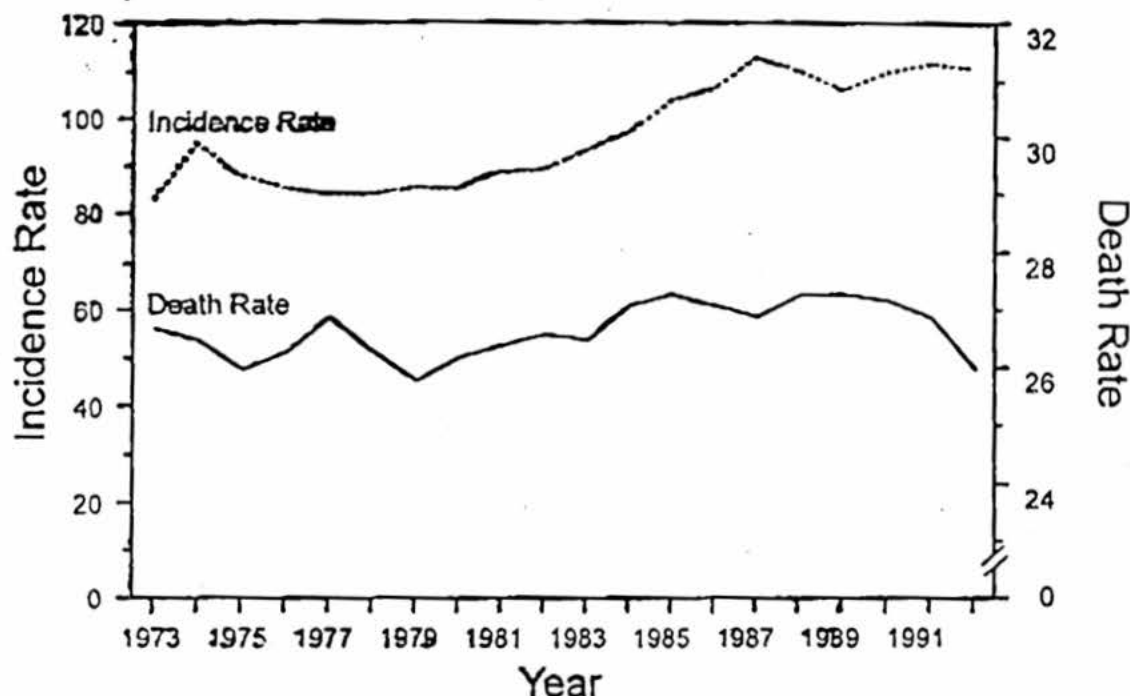
During 1973–1992, the overall incidence rate increased from 82.5 to 110.6; rates increased steadily during 1973–1987, and stabilized during 1988–1992 (Figure 1). During 1988–1992, incidence rates increased directly with age until age 75–79 years for whites and age 80–84 years for blacks (2); the rates for whites and blacks were similar for women aged <45 years, but for women aged ≥45 years, the rate was higher for whites than for blacks. During 1973–1992, race-specific rates varied: for white women, the age-adjusted rate increased 34% (from 84.3 to 113.1) and, for black women, increased 47% (from 68.7 to 101.0) (2).

Breast Cancer Mortality

In 1992, a total of 43,063 U.S. women died from breast cancer. The death rate was 26.2 per 100,000 women.

During 1973–1992, the overall death rate varied; rates were stable during 1973–1988, before decreasing during 1989–1992 (Figure 1). During 1988–1992, the overall ratio of black-to-white death rates was 1.2 (Table 1). Rates increased directly with age (2). For women aged <70 years, the rate was higher for blacks than for whites; for women aged ≥70 years, the rate was higher for whites than for blacks. During this period, race-specific rates varied. During 1989–1992, the rate for white women decreased 6% (from 27.5 to 26.0) and, for black women, increased 3% (from 30.4 to 31.2).

*Poverty statistics are based on a definition originated by the Social Security Administration in 1964 that was subsequently modified by federal interagency committees in 1969 and 1980 and prescribed by the Office of Management and Budget as the standard to be used by federal agencies for statistical purposes.

*Breast Cancer—Continued***FIGURE 1. Age-adjusted incidence and death rates* for invasive breast cancer† — United States, 1973–1992**

*Per 100,000 women. Standardized to the age distribution of the 1970 U.S. population.

†Cases of invasive breast cancer (*International Classification of Diseases, for Oncology*, codes C50.0–C50.9) were registered in SEER. Decedents for which the underlying cause of death was breast cancer (*International Classification of Disease, Adapted, Ninth Revision*, codes 174.0–174.9) were identified from public-use mortality data tapes (4).

Source: National Cancer Institute's, Surveillance, Epidemiology, and End Results program.

(2). During 1988–1992, the state-specific age-adjusted death rate ranged from 18.2 in Hawaii to 35.3 in the District of Columbia (Table 1).

Reported by: Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC.

Editorial Note: The findings in this report indicate that incidence rates for breast cancer increased 34% during 1973–1992. The increase and later stabilization of incidence rates during the 1980s is most likely related to increased use of breast cancer screening methods (6)—particularly mammography and clinical breast examination, which enable earlier diagnosis of the disease (3).

The decrease in breast cancer death rates during 1989–1992 may reflect a combination of factors, including earlier diagnosis and improved treatment. For example, screening mammography and clinical breast examination are effective methods for reducing breast cancer mortality among women aged ≥50 years (7). Survival from breast cancer increases when the disease is diagnosed at earlier stages, and from 1974–1976 to 1986–1991, the survival rate for invasive breast cancer increased substantially (2).

Differences in the race-specific and state-specific incidence and death rates for breast cancer during 1973–1992 may reflect differences in factors such as socioeconomic status, access to and delivery of medical care, and the prevalence of specific

Breast Cancer — Continued

TABLE 1. Number of deaths from breast cancer* and age-adjusted death rate†, by state and race‡ — United States, 1988–1992

State	No. deaths			Rate			Black-to-white ratio
	White	Black	Total	White	Black	Total	
Alabama	2,440	871	3,318	23.5†	31.5	25.2	1.3
Alaska	158	**	190	26.3	**	23.8	**
Arizona	2,609	**	2,707	24.6	**	24.0†	**
Arkansas	1,668	298	1,972	22.9†	30.3	23.8†	1.3
California	18,702	1,579	21,121	28.9	32.1	28.0†	1.2
Colorado	2,169	**	2,280	24.9	**	24.7	**
Connecticut	2,897	181	3,089	26.7	30.0	26.9	1.1
Delaware	593	**	692	32.0	**	32.6	**
District of Columbia	197	509	712	29.3	38.0	35.3†	1.3
Florida	11,859	1,158	13,044	26.2†	29.0	26.6†	1.2
Georgia	3,419	1,116	4,547	24.3†	27.4	24.9†	1.1
Hawaii	177	**	548	25.4	**	18.2†	**
Idaho	712	**	717	25.0	**	24.7	**
Illinois	9,467	1,353	10,853	29.3†	32.8	29.5†	1.1
Indiana	4,513	365	4,888	26.7	33.9	27.2	1.3
Iowa	2,726	**	2,758	26.5	**	26.4	**
Kansas	2,078	**	2,191	25.7	**	25.8	**
Kentucky	2,823	231	3,062	25.4	33.0	25.8	1.3
Louisiana	2,324	1,046	3,386	25.0	33.2	27.2	1.3
Maine	1,110	**	1,116	26.7	**	26.7	**
Maryland	3,188	859	4,073	28.0	32.0	28.6	1.1
Massachusetts	6,110	201	6,335	30.1	31.2	30.0†	1.0
Michigan	6,959	1,071	8,070	27.5	33.7	28.1	1.2
Minnesota	3,686	**	3,744	27.1	**	26.9	**
Mississippi	1,290	631	1,922	22.7	27.8	24.2†	1.2
Missouri	4,271	449	4,734	26.1	32.0	26.6	1.2
Montana	626	**	646	24.8	**	24.8	**
Nebraska	1,431	**	1,463	26.9	**	26.8	**
Nevada	803	**	861	26.7	**	28.3	**
New Hampshire	1,021	**	1,025	30.8	**	30.7	**
New Jersey	7,474	894	8,423	31.6†	34.7	31.6†	1.1
New Mexico	963	**	1,000	24.6	**	23.6	**
New York	16,211	2,292	18,643	31.1†	29.6	30.5†	1.0
North Carolina	4,307	1,160	5,518	25.3	30.5	26.3	1.2
North Dakota	564	**	575	27.3	**	27.2	**
Ohio	9,404	987	10,409	28.3	32.2	28.6	1.1
Oklahoma	2,259	136	2,468	24.9	24.7	24.0†	1.0
Oregon	2,339	**	2,389	25.7	**	25.4	**
Pennsylvania	12,081	1,089	13,200	29.2†	34.8	29.6†	1.2
Rhode Island	1,103	**	1,141	31.6	**	31.6	**
South Carolina	1,995	745	2,744	25.5	29.0	26.3	1.1
South Dakota	606	**	624	26.5	**	26.3	**
Tennessee	3,358	688	4,056	24.1†	34.2	25.4	1.4
Texas	9,638	1,412	11,100	23.5†	30.3	24.0†	1.3
Utah	883	**	897	23.3	**	23.2	**
Vermont	494	**	494	28.0	**	27.9	**
Virginia	4,035	983	5,057	27.2	33.4	27.9	1.2
Washington	3,713	**	3,851	27.1	**	26.5	**
West Virginia	1,564	**	1,631	24.7	**	24.9	**
Wisconsin	4,312	130	4,455	27.3	33.1	27.3	1.2
Wyoming	320	**	324	25.9	**	25.6	**
Total	189,639	23,114	215,039	27.0	31.3	27.1	1.2

*Decedents for which the underlying cause of death was breast cancer (International Classification of Diseases, Adapted, Ninth Revision, codes 174.0–174.9) were identified from public-use mortality data tapes (4).

†Per 100,000 women. Adjusted to the age distribution of the 1970 U.S. population.

‡Numbers for racial/ethnic groups other than black and white were too small for meaningful analysis. However, all totals include numbers for other races.

§The difference between the state-specific rate and the corresponding U.S. rate is statistically significant (p<0.0002, Bonferroni-adjusted).

**These data were excluded because the annual average number of persons in the denominator was <75,000.

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Breast Cancer — Continued

risks for disease (1,5,8). For example, women in minority populations are less likely than white women to be screened for breast cancer (9). Although socioeconomic and risk-factor data were not analyzed in this report, the findings underscore the need for further characterization of the burden of cancer for U.S. women in racial/ethnic, geographic, and other subgroups.

Early detection and appropriate treatment are essential to reducing the burden of breast cancer in the United States. CDC's National Breast and Cervical Cancer Early Detection Program provides early detection screening and referral services for cancers of the breast and cervix among older women who have low incomes or are uninsured, underinsured, or in a racial/ethnic minority. Additional efforts by this program and health-care professionals are needed to ensure that every U.S. woman at risk for breast cancer receives breast cancer screening, prompt follow-up, and assurance that tests are conducted in accordance with current federal quality standards.

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Suffocations in Grain Bins — Minnesota, 1992-1995

Suffocation in flowing grain is the most common cause of death associated with grain storage structures in the United States (1,2): during 1985-1989, suffocation accounted for 49 grain- and silage-handling-associated fatalities (3). During 1992-1995, nine persons in Minnesota died in separate incidents from asphyxiation after becoming engulfed in flowing grain within a grain storage structure (Figure 1). The Minnesota Fatality Assessment and Control Evaluation program (FACE), a program sponsored by CDC's National Institute for Occupational Safety and Health (NIOSH)*,

* Minnesota is one of 14 states (Alaska, California, Colorado, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, and Wisconsin) that

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Divider Title: Rose Garden Event



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

October 24, 1996

NOTE FOR THE DIRECTOR

FROM: Nancy-Ann Min *NAM*
RE: Genetic Breast Cancer Funding Announcement--Call to Dr. Harold Varmus (NIH)
(301) 496-2433

Purpose of Call: To request that Dr. Varmus allocate an additional \$7 million from his FY 1997 budget for genetic research devoted to breast cancer, which--together with the approximately \$3 million in additional FY 1997 funding NIH is devoting to this item, and the \$20 million DOD is willing to devote to a joint effort--would represent a 50% increase in this initiative from FY 1996. This additional funding and joint DOD/NIH effort will be announced on Sunday, October 27, in a Rose Garden event.

Background: Kevin Thurm, Deputy Secretary at HHS, spoke with Dr. Varmus this morning. He was somewhat defensive about the way he has chosen to allocate the new funding. He did say that if NIH were to receive up to an additional \$30 million to spend on genetic breast cancer research, they could find research grants of sufficient quality to justify awarding the funds.

For a number of years, DOD has received appropriations to be used for breast cancer research, although it has never requested this funding in its budget. In FY 1995, DOD received \$150 million for this purpose; in FY 1996, it received \$75 million, and in the most recent budget, FY 1997, DOD received \$112 million. This afternoon, Gordon Adams spoke with the Assistant Secretary for Health Affairs, Steve Joseph, who was enthusiastic about genetic breast cancer research and interested in committing \$20 million to a joint effort with NIH, assuming that NIH can come up with the other \$10 million. They do not want to transfer the funds to NIH, however; rather, they believe that this initiative should be modelled on another joint NIH-DOD research project at the National Cancer Institute.

For a more detailed discussion of DOD's proposal, see the attached e-mail from Gordon. Gordon believes that Dr. Joseph can make this commitment on behalf of DOD without your having to make a call to Secretary Perry.

Your call to Dr. Varmus should request that he come up with another \$7 million, which he can easily do--either (1) out of his discretionary fund, to which Congress appropriated \$16 million for

FY 1997, or (2) by transferring funds from other institutes, which the appropriations language gives him authority to do.

Suggested Outline of Call

- In FY 1996, NIH spent \$61,931 on genetic breast cancer research. A major discovery of two genes that appear to be related to breast cancer--BRCA-1 and BRCA-2--was announced by NIH scientists this spring.
- The President wants to highlight what we are doing to build upon the discovery of these two genes by devoting increased funding to additional research aimed at discovering other genetic links to breast cancer, as well as research to develop techniques to screen women for these genes and devise therapies for these particular forms of breast cancer.
- Although NIH received an \$830 million increase in FY 1997--\$420 million more than the President's FY 1997 request, which itself was \$410 more than FY 1996 enacted--I understand from OMB staff that you have allocated only about \$3 million in new funding to genetic breast cancer research. This seems odd in view of (1) the strong priority the President has placed on combatting breast cancer, and (2) the recent breakthroughs in genetic breast cancer research.

[Note: The increase allocated for all breast cancer research at NIH is disproportionately lower than the increase that NIH as a whole received (NIH received a 7% increase, while the amount allocated to breast cancer research only represents a 4% increase)].

- I have convinced DOD to "donate" \$20 million of the funds Congress appropriated to the Army for breast cancer research to a joint effort with NIH directed at genetic breast cancer research. If you will come up with an additional \$7 million (on top of the \$3 million in new FY 1997 funds already allocated), that will give us the \$30 million total we need for the President's announcement.

[Note: In the FY 1997 budget, Dr. Varmus received around \$16 million in discretionary funds that he can use for research projects he deems worthy. He also has the ability to transfer up to 1% of NIH's total budget (\$12.7 billion) among the institutes, although this may require Congressional notification depending on how he goes about it].

cc: Jack Lew
Gordon Adams
Rebecca Culberson

Cancer Survivors Attending the President's Announcement

Jane Reese-Coulbourne of Alexandria, VA

Jane Reese-Coulbourne, 42, is a breast cancer survivor for six years. She discovered a lump in her right breast during self-examination. Her cancer was in an advance stage and considered inoperable. She joined the FLAC clinical trial at the National Cancer Institute where she has received all of her treatments. She went through eight rounds of chemotherapy, eight weeks of radiation and four and a half years of tamoxifen treatments. A chemical engineer, Ms. Reese-Coulbourne is now a full-time breast cancer advocate, serving as executive vice president of the National Breast Cancer Coalition, representing over 350 member organizations involved with breast cancer. She has testified before Congress on such issues as the Department of Defense breast research program and health care reform. She is a member of the steering committee of the National Action Plan on Breast Cancer.

Dorothy Bankhead of Fort Washington, MD

Dorothy Bankhead, 72, retired U.S. Navy civilian worker and realtor, is a breast cancer survivor for 19 years. A lump was detected in her left breast during a regular checkup. Following the checkup, a biopsy was performed and her tumor was diagnosed as cancer. Her surgery was performed at the National Institutes of Health. She has been recovering very well through the years and is now a part-time student at the University of Maryland. She is the mother of one son and grandmother of four.

Patrick Garbe of Fairfield Connecticut

Patrick Garbe, 37, is a cancer survivor of 16 years. He is a legal assistant with the law firm of Shearman & Sterling. He was diagnosed in 1980 with a rare soft tissue tumor (paraganglioma-a tumor on the nerve system) which was removed successfully. Over the next few years, Mr. Garbe found tumors in different areas of his body - the pelvis, cervical vertebra, and throat. All were slow growing tumors. Since 1993, he has been in remission and in good health. Mr. Garbe is an advocate for increasing funding for all cancers.

Olda Mondragon of Baltimore, MD

Olda Mondragon, 54, the mother of one daughter, is a breast cancer survivor of three years. She was treated at Johns Hopkins Hospital in Baltimore after a mammography detected a lump in her left breast. She had a mastectomy and has been recovering very well. Ms. Mondragon said that the cancer changed her life and now she is dedicated to teaching others about cancer. As a member of The Center of the Hispanic Community in Baltimore, Ms. Mondragon teaches others about the importance of early detection and mammograms.

Erin Schraibman of Rockville, MD

Erin Schraibman, 9, is a seven-year cancer survivor. She was diagnosed with acute lymphatic leukemia (known as childhood leukemia) at 2 and a half years old and has been in remission more than six and a half years. Erin is doing well and is very athletic. She is a fourth-grader at Ritchie Park Elementary School.

Clinton Administration Cancer-Related Initiatives

Since taking office, the Clinton Administration has devoted increased resources to the prevention, detection, and treatment of cancer. The following are examples of new initiatives launched by the Administration to reduce cancer rates and increase cancer survival in this country:

- **Developed a National Action Plan on Breast Cancer.** The Clinton Administration has established a National Action Plan on Breast Cancer (NAPBC), which supports innovative research and outreach projects on breast cancer, with a special emphasis on the development of public-private partnerships. On October 27, 1996, President Clinton announced the new NAPBC web site, coordinated by the Department of Health and Human Services, in partnership with the private sector. The web site provides answers to frequently asked questions about breast cancer, information on breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences and meetings, publications, and other resources.
- **Created the Office of Cancer Survivorship.** Recognizing the need for research into the physical, psychological, and economic well-being of the growing number of cancer survivors, on October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.
- **Increased spending on cancer by \$400 million.** In FY 1997, the National Cancer Institute was funded at \$2.38 billion, a \$400 million increase over FY 1993. Since the Clinton Administration has taken office, funding for breast cancer research, prevention and treatment has increased by more than 95 percent in HHS alone, from about \$276 million in FY 1993 to an estimated \$541 million in FY 1997.
- **Accelerated approval of and expanded access to cancer drugs.** The Food and Drug Administration (FDA) has taken several steps to speed approval of cancer drugs and provide patients access to promising therapies not yet approved. For example, the FDA is using tumor shrinkage as a "surrogate marker" for effectiveness, cutting years off drug development time and months off of FDA review. This year the FDA approved *topotecan*, the first member of a promising new class of anti-tumor drugs that provides new hope to ovarian cancer patients and others. The FDA has given patients more of a voice in the drug review process by placing patient representatives on all cancer drug advisory committees. FDA is also working with other countries and manufacturers to make promising drugs approved in other countries available to patients in the United States.
- **Launched the Medicare mammography campaign.** The Clinton Administration has made it a priority to educate older women about the importance of detecting breast cancer early and to inform them about Medicare coverage of mammography services. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings.

• **Worked to ensure quality mammography facilities.** In March 1996, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA). The rules will ensure that the roughly 10,000 mammography facilities nationwide accredited by the FDA meet high quality standards for equipment and personnel.

• **Proposed expanding Medicare coverage for mammograms.** In his balanced budget proposal, President Clinton proposes to expand Medicare coverage to include: annual mammograms for beneficiaries age 50 and over with no copayment or deductible requirement; and procedures for early detection of colorectal screening.

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

• **Adapted imaging technologies from the defense, space and intelligence communities to detect cancer and other diseases earlier and with greater accuracy.** The Department of Health and Human Services has been working with the Departments of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer.

• **Signed the Kassebaum-Kennedy legislation into law, ending pre-existing condition exclusions.** As a result of this legislation, no American will live in fear of losing their coverage just because they have a pre-existing condition. This legislation is particularly helpful for the millions of cancer victims who will no longer face the dilemma of hesitating to go to a new and better job for fear of losing their health insurance.

• **Protected children from tobacco.** President Clinton announced in August 1996, measures to eliminate easy access to tobacco products by children and to restrict advertising that makes tobacco appealing to kids. More Americans die every year from smoking related diseases than from AIDS, car accidents, murders, and suicides combined. Each day, almost 3,000 children start smoking and nearly 1,000 of them die earlier as a result. Tobacco use is responsible for over 30 percent of American cancer deaths and over 90 percent of lung cancer (NIH report: President's Cancer Panel, Report of the Chairman, Sept. 1996).



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

October 15, 1996

NOTE FOR DON BAER

FROM: Nancy-Ann Min

RE: Ideas for Possible Breast Cancer Event

I wanted to give you a preliminary response to your request for ideas that we could pursue for a possible event highlighting the Administration's commitment to breast cancer research, screening, etc. There are a couple of directions we could go: (1) emphasizing breakthroughs in research about breast cancer's genetic links at NIH; and/or (2) emphasizing the increased funding that has been provided for screening mammography through CDC and its importance to the trend of reduced breast cancer mortality. I've sketched out each of these alternatives briefly below:

Research--I've spoken with Dr. Francis Collins, director of the Human Genome Project at NIH, and with Dr. Al Rabson, deputy director of the National Cancer Institute there. Unfortunately, there have not been any new breast cancer genes discovered since the announcement last summer of BRCA-1 and BRCA-2. (There was a discovery in the past month of a specific mutation that appears to suggest a genetic link between breast cancer and people who are of Ashkenazi Jewish descent, but the news has already appeared fairly widely and it is difficult to envision how we could appropriately stage an event or announcement around it).

Although it does not relate solely to breast cancer, there is some exciting research about to be published (embargoed until Thursday, October 24) that hits all of our themes: technology, bridge to the future, possible cures for life-threatening diseases, we're doing things with our genetic research that only 2-3 years ago, scientists were laughing at (Dr. Collins said this was true with respect even to the discovery of a genetic link with breast cancer, which no one believed a few years ago). The Human Genome Project is about to announce that it has completed a "genetic map" that shows the location of 16,334 genes that are most likely to be involved in causing diseases. Dr. Collins said that this "genetic map" has been long awaited in the scientific community, and is of major significance in helping researchers find the next breast cancer gene or prostate cancer gene. When I asked him to give me some idea of how significant this discovery is, he said that while in the past, the discovery of a gene's location has taken up to 15 years, with the new "genetic map", the amount of time a researcher could expect to spend would be reduced to 2-3 years, and perhaps as little as 1 year for some diseases.

Dr. Collins says that the other significant aspect of this announcement is that NIH plans to put the "genetic map" on the Internet. He has a demo that he could show us; from his description, it sounds like a great visual.

If you're interested in this, I will follow up with Dr. Collins to get a better description of the importance of the "genetic map" and what it can do for the average American. From what I have heard so far, it sounds like we could use it to highlight what we've already done and that we're on the verge of some very big things: e.g., NIH has received the largest dollar increase over 4 years in its history; it has used these funds for critical biomedical research that has great potential to save lives; the research is paying off, as we saw last year with the historic discovery of two of the genes that cause breast cancer; now we are building a bridge to the future with a "genetic map" that will be accessible to all researchers on the Internet, and will allow them to identify genetic links that can help find cures for breast cancer and other diseases). You get the picture.

Screening/Reducing Breast Cancer Deaths--Here the emphasis would be on the increased funding that has been provided to CDC for comprehensive breast and cervical cancer screening since we took office in 1994. I'm still filling in some facts and figures, but the basic story would go something like this: This Administration is spending some \$140 million for CDC breast and cervical cancer screening programs in FY 1997 (more than an 80% increase since FY 1993). When we took office, the CDC Breast and Cervical Cancer Early Detection Program (which offers free or low-cost mammography to low-income or uninsured women) was not available nationwide. (I'm getting the information on Tuesday AM about which states got the funding and which states didn't). As of FY 1996, we implemented this screening program in all 50 states. Breast cancer screening rates are the highest in history. And this is important because screening and early detection saves women's lives. To make this case, you could link our spending on screening to the National Cancer Institute's (NCI's) announcement in May 1996 that the breast cancer death rate continued to decline through 1993, which the NCI attributed predominantly to increases in screening. NCI found that the breast cancer mortality rate declined by 5% over 1989-1993, which represents the largest short-term decline in 40 years. (And for the first time, the data indicated that the trend is starting to move in a positive direction for African American women as well as white women).

Unfortunately, the most recent data NCI can give me about breast cancer mortality rates is for 1993. Therefore, if you decide to use this, we will need to emphasize the points about the increased funding for nationwide screening and simply state that the NCI results confirm the importance of this commitment to screening. You could also link this initiative with the First Lady's campaign to ensure that Medicare-eligible women take advantage of the mammography benefit, and the proposal in the President's balanced budget plan to remove the co-pays for mammograms for Medicare beneficiaries.

I'm campaigning in Tennessee from Tuesday afternoon through the weekend. If you want to pursue either of these ideas, or have something new that you'd like me to follow up on, please

let me know as early as possible Tuesday. Of course, if you have time, you could call Dr. Francis Collins at NIH yourself. His numbers are (301) 496-0844 (National Center for Human Genome Research); or (301) 468-5672 (home).

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Divider Title: Breast Cancer Funding

Richard J. Turman

10/11/98 07:09:37 PM

Record Type: Record

To: Nancy A. Min/OMB/EOP, Sarah A. Bianchi/OMB/EOP
cc: Barry T. Clendenin/OMB/EOP
Subject: Breast Cancer -- NIH Information

The short story is that one could talk about three things:

- 1) CDC and NIH funding going up;
- 2) breast cancer mortality going down through 1993, and projected by the Cancer Society to drop in the future, and screening catching more women with cancers earlier on (and therefore with better survival rates); and
- 3) 3 genes found to date, which account for most of the portion of breast cancer that is known to be caused by hereditary factors (which is about 10% -- though on such a large base, this is a lot of women).

It is not clear if this is 'enough' for what some may have in mind; much may depend on how immediate #3 can be made for people. Details follow:

I spoke with Al Rabson of the Cancer Institute (Deputy Director, and Ruth Kirschstein's husband). He laid out similar mortality statistics as CDC had given us earlier (and we included in the package on Wednesday. I'll ship it over to you now.

I spoke at length with Frances Collins. He is a renowned expert in breast cancer research, and now the head of the Human Genome center. He said that when the President visited the campus within the last year, he had an opportunity to discuss some of the genetic basis of breast cancer issues with him.

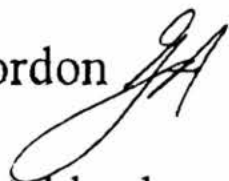
Collins believed that a case can be made that we are making great progress in breast cancer research, and that more will be coming soon.

His argument was to say that until 6 years ago, the idea that there was a hereditary basis for some cancer was laughed at by many, and that within these 6 short years we have gone from laughing about it to having found 3 genes (BRCA-1, BRCA-2, and ATM) and having genetic tests available to some women for the first two genes found (BRCA-1 and BRCA-2).

While the only place those genetic tests are available are through 20 research protocols at NIH grantees around the US, that is still a great step forward. Further, the lab that developed the test for the drugs (Myriad, of Utah) apparently plans to make the test available to physicians who want to test their patients within the next few months.

Collins said that right now, we don't know exactly how many of the women who test positive for the genetic predisposition for breast cancer will get it, but expects to know within the next three months. Right now, the best he could say is that with a positive BRCA-1 test, one might have an 85% chance of developing breast cancer. The concern with that statistic is that the sample they are taking it from is known to be a biased sample. NIH has done epidemiological work and is now crunching the numbers on a study of 5,000 women that they believe will give a better (and he figures lower) number of the chances of a woman developing breast cancer when they have a positive genetic test.

To: Nancy-Ann

From: Gordon 

Here is a table showing PHS discretionary spending on breast cancer in FY 1993 and FY 1997. (You had asked for the FY 1997 analog to the budget numbers on page 4 of the NCI press release that we sent you last week, and again on Monday.) Note that CDC funding is listed as \$81 million in FY 1997; while Congress appropriated \$140 million for breast and cervical cancer screening in FY 1997, CDC estimates that \$81 million of this will be spent on breast cancer alone.

CDC tells us that in FY 1993 18 states received comprehensive breast and cervical cancer grants; some other States also received smaller, "capacity building" grants which did not fund all aspects of the prevention program. Now all States receive grants for comprehensive programs.

October 15, 1996

PHS Breast Cancer Funding

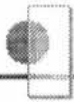
(budget authority in millions)

	FY 1993	FY 1997
NIH	229	420 *
CDC	43	81
FDA	3	26 **
IHS	1	3 ***
AHCPR		1 **
Total	276	531

* HHS estimate. The Budget requested \$410 million.

** OMB Estimate. Figures from Budget , which closely matches the appropriation.

*** OMB estimate based on House and Senate committee reports.



Chin-Chin Ip

10/02/96 06:31:41 PM

Record Type: Record

To: Sarah A. Bianchi/OMB/EOP
cc: Richard J. Turman/OMB/EOP
Subject: numbers you requested

Spending on breast cancer research in FY 93:

NIH - \$229 million
DOD - \$207 million

Let me know if you anything else. Thanks.

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Divider Title: Genetic

BREAST CANCER GENES

Discovery of BRCA1 and BRCA 2 Genes for Breast Cancer

- o Promising news came late in 1994 when a team of investigators at the University of Utah, Myriad Genetics and the NIH identified a breast cancer susceptibility gene (BRCA1) that may account for 5-10 percent of the breast cancers diagnosed each year.
- o The discovery of a second, entirely different breast cancer susceptibility gene, (BRCA2), has helped us understand even more about the genetics of breast cancer.
- o In addition, researchers have recently discovered a particular variant of the BRCA 1 susceptibility gene in Jewish women of Eastern European descent. While only 5-10 percent of all breast cancers are the result of an inherited anomaly, these findings hold promise for the development of new prevention and treatment strategies.
- o In families where women inherit the altered gene, they have up to a 90 percent lifetime risk of developing breast cancer. Researchers estimate that more than half of these women will be diagnosed with breast cancer by age 50, and more than 85 percent will have a diagnosis of breast cancer by age 70.

WHAT THE DEPARTMENT IS DOING

- o Following the discoveries of BRCA1 and BRCA 2, the NIH began a number of studies that will further identify the BRCA1 and BRCA2 genes in the population. Currently, of the \$420 million the NIH spends on breast cancer research, approximately \$10 million will be spent on research related to BRCA1 and BRCA2.
- o This NIH sponsored research will help us better determine the role of BRCA1 and BRCA2 in breast cancer. These studies will allow us to move rapidly toward our goal of identifying high-risk women and helping them to prevent breast cancer before it strikes.

Page 2

- o As indicated above, we already have findings that suggest the BRCA1 may be more common in the Ashkenazi Jewish population than in the general population.
- o In one such study, NIH scientists are working closely with Jewish community leaders to conduct a follow-up study of a sample of 3,000 to 5,000 people from the Ashkenazi Jewish population in the Washington, D.C. area. Jewish community leaders are assisting to develop educational materials, contact members of the Jewish community and inform participants and the Jewish community about the findings.
- o Individual results will not be revealed to participants in this phase of the study. However, genetic testing and counseling will be available once more is known about the effects of this particular gene. (At the present time, several gene tests are being offered in research studies only as a way to help track patient's progress during cancer treatment. However, no genetic tests are currently available for determining risk of breast cancer in the general population.)
- o In another study, the National Cancer Institute and the National Center for Human Genome Research are examining whether an "alteration" in BRCA1 is associated with breast cancer risk in African America families having multiple individuals with breast cancer.
- o Once these and other studies are complete, discussions must take place within the Department, other government agencies and the scientific community about how results of these studies can be used to reduce the incidents of breast cancer in the United States and beyond.

Breast
Cancer

October 29, 1996

~~File~~
Notebook



Health Division



Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Please route to:

Nancy-Ann Min

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Subject: FYI--New York Times article on
BRCA1

With informational copies for:
BC, RT, HPS Chron

From: Vikki Wachino

\Ph: 202/395-4926
Fax: 202/395-3910
Room: #7026

FYI, here is a copy of a Tuesday *New York Times* article on the difficulties researchers are having understanding how the BRCA1 gene works. I thought it would be of interest, given the recent focus on breast cancer genetics.

Discovery of Breast Cancer Gene Produces Clues but No Answers

By GINA KOLATA

JUST two years ago, a team of scientists won a fevered race to find an elusive gene that causes breast cancer in women who inherit it. And researchers hoped, with bated breath, that it might be the answer to breast cancer.

But science is rarely so neat and simple, and the gene, known as BRCA1, for breast cancer 1, has turned out to be an enigma.

To have any chance of correcting the damage done by the mutated gene, scientists need to find out what the ordinary version of the gene is meant to do in the cell. So far they know that the gene directs cells to make a protein that is apparently needed to prevent a sort of wild proliferation. Women who inherit a changed, or mutated, form of the gene have as much as a 90 percent chance of developing breast cancer and as much as a 60 percent chance of developing ovarian cancer. Beyond that rudimentary understanding, however, ignorance reigns.

At a recent meeting of breast cancer researchers, sponsored by the University of Texas Southwestern Medical Center in Dallas and the Susan G. Komen Foundation, all the excitement and uncertainty of the chase were apparent as scientists exchanged notes, hoping to catch a new scent that would lead them out of the impasse.

Despite all the powerful tools of molecular biology, it was clear that hunches and analogies also had leading roles in the attacks being planned on the BRCA1 gene.

But it was also clear that some

Researchers are galvanized but bewildered.

order was emerging above the confusion of BRCA1 research. Some groups are finding a skein of interacting proteins inside human cells that includes the BRCA1 protein, which is the protein made from the BRCA1 gene. If any of those proteins is disrupted, a cell can turn cancerous, the researchers propose. Another group believes the natural role of BRCA1, in its normal, unmutated form, is to act as a brake on the cell's growth. These scientists have such confidence in this idea that they have given the normal form of BRCA1 to patients to put brakes on proliferating tumor cells.

And it was clear that many of these scientists are keenly aware that the high tech, glitzy molecular biology studies that sometimes seem to be an end in themselves are ultimately aimed at relieving real human suffering.

"In my book at least, breast cancer research is not a job, it's a mission," said Dr. Edison Liu, the director of the division of clinical science at the National Cancer Institute.

Living cells have complicated genetic programs designed to insure that they divide when needed but destroy themselves for the body's good if they are genetically damaged. It is when the genes in this control program themselves become damaged that aberrant cells get the chance to enter cancerous growth.

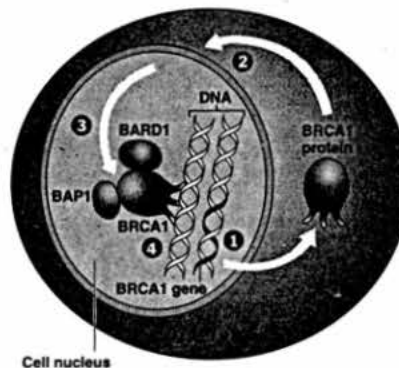
Many so-called cancer genes have turned out to be mutated or defective versions of the genes in the cell's growth control program. But even with this strong clue, it is hard to figure out what a newly discovered gene like BRCA1 is meant to do. In fact, initial hypotheses have proved to be wrong.

So how do scientists figure out what a mystery gene, like BRCA1, does? Dr. Frank J. Rauscher 3d, the exuberant son and namesake of a well-known cancer researcher and former head of the American Cancer Society, said the usual approach was to reason by analogy.

First, said Dr. Rauscher, who is a

A Framework for a Mystery

In thinking about how the BRCA1 gene might act to produce cancer, scientists theorize that the BRCA1 protein it encodes (1) might enter the nucleus (2) to form a complex (3) with one or both of two other proteins, BARD1 and BAP1. In its normal form, such a complex might act as a switch for the DNA mechanisms for cell division (4), preventing the abnormal proliferation of cells.



The New York Times, Illustration by Judy Emery

molecular biologist at the Wistar Institute in Philadelphia, virtually every scientist studying BRCA1 sought out possible similarities with genes of known function. Unfortunately, BRCA1 seemed totally novel.

"By and large, it was a big black box," Dr. Rauscher said. And so, he continued, "most studies are descriptive." Scientists' next move is to find out where in the cell the BRCA1 protein is active. If it is in the nucleus, for example, where the genetic material nestles, the protein's role might be to switch other genes on or off. Researchers are also scrutinizing the structure of the BRCA1 protein, looking for regions that might be designed to bind to DNA or known protein molecules.

Dr. Rauscher said he had found a protein that he called BAP1, for breast cancer 1 associated protein, that latched onto the BRCA1 protein and that was found in the nucleus of the cell, where genes are flicking on and off. And, he said, it now appears that the gene that makes the BAP1 protein was frequently mutated in breast cancer cells and also in cells of patients with lung cancer, raising the odds that the interaction of the BAP1 and BRCA1 proteins might be important.

But, Dr. Rauscher confessed, "that still does not tell us much about what BRCA1 does." So far, he said, "what

A crucial question is what the gene is supposed to do.

we are left with is more descriptions of an unknown biochemical pathway."

Dr. Richard Baer, a tall and dignified microbiology professor at the University of Texas Southwestern School of Medicine, said he had found a different protein that attached itself to BRCA1, a protein he called BARD1, for breast cancer associated ring domain protein. This protein, Dr. Baer explained, emerged as a result of two years of patiently screening 11 million fragments of DNA for pieces that might make proteins that would stick to BRCA1. From the 11 million fragments, Dr. Baer found 16 possibilities that looked promising. And among those he found BARD1.

Dr. Baer said he was now looking to see if BARD1 was mutated in breast cancer cells, which might indicate that it was crucial to the normal functioning of cells. So far, he confessed, he has no idea what BARD1 does. And, he added, it is perfectly plausible that BAP1,

BARD1 and BRCA1 all attach to each other to make a melded protein that controls cell growth.

The search for proteins that attach to BRCA1 "is rational at first," Dr. Baer said. After all, several well-known molecules that cells use to copy genes are actually conglomerates of two or more proteins. And, Dr. Baer said, everyone hopes to find proteins that attach themselves to BRCA1 and whose functions are known. The problem is, he said, that the proteins that have been found — BARD1 and BAP1 — are as baffling as BRCA1 itself.

Dr. Roy Jensen, a cell biologist at Vanderbilt University Medical Center in Nashville, took a different tack. He asked whether he could cure tumors in animal experiments by restoring a normal BRCA1 gene to cells.

The studies involved mice that lacked normal immune systems and so did not reject human tissue as foreign cells. Dr. Jensen implanted cells from human breast cancers into animals' abdomens. The tumors grew large and lumpy, grotesque masses that bulged from the soft underbellies of the mice. But when Dr. Jensen treated the mice with the BRCA1 gene, the tumors began to shrink and a few melted away.

It was surprising, Dr. Jensen said, because in laboratory experiments, when researchers added normal BRCA1 genes to cancer cells, the cell stopped growing but did not die. Yet in the mice, "in every case, the tumor was at least shrunk," Dr. Jensen said, adding, "We're trying to figure out why."

Encouraged by this result, Dr. Jensen's colleagues, Dr. Jeffrey Holt and Dr. David Tait, conducted a small study of 10 women with advanced ovarian cancer and with mutated BRCA1 genes. They supplied the women with normal BRCA1 genes, injecting the women in their abdomens with viruses containing the genes. The viruses, which can slip through cell walls, were necessary to carry the BRCA1 genes inside the tumor cells.

The investigators are still analyzing their data and it is far too soon to say whether the gene therapy will be effective. More than 90 percent of treatments that look promising in laboratory and animal studies fail to pan out when they are tested in humans.

But, Dr. Jensen added, no matter what happens with the current studies, the discovery of the BRCA1 gene has galvanized breast cancer research.

"The most difficult question in breast cancer is deciding what to work on," Dr. Jensen said. But now, he said, with the BRCA1 gene in hand, "it becomes less of a fishing expedition and more a matter of getting from point A to point B."

New York Times
10/29/96
Page C3



OFFICE ON WOMEN'S HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

OFFICE OF PUBLIC HEALTH AND SCIENCE

OFFICE ON WOMEN'S HEALTH

Humphrey Building

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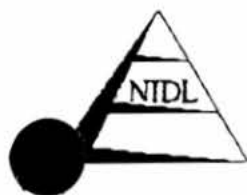
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Susan O'Malley
Sund.



Detecting Changes in Serial Mammograms for Early Detection of Breast Cancer

A dual use application of two-dimensional image alignment technology

National Information Display Laboratory • Princeton, New Jersey
U.S. Public Health Service's Office on Women's Health • Washington, DC

Comparison of mammograms enables a physician to detect change that signals the early start of cancer. The physician currently views two mammograms side by side, mentally matching key features to align and compare the mammograms. Change

detection is a challenging task because soft tissue takes on different shapes at different imaging sessions, resulting in misaligned mammograms. At the early start of cancer, important change may be quite subtle and difficult to detect.



Original Mammogram



Mammogram 1 Year Later



Difference Before Alignment
(suspicious region is cluttered by false differences due to misalignment)



Difference After Alignment
(suspicious region is easily identified)

Computer-assisted change detection in mammograms is a dual use application of change detection applied to aerial imagery. At the National Information Display Laboratory (NIDL) we are developing techniques to align aerial imagery for detection of change. For surveillance, it can be imprecise, costly and inefficient to have a human compare each image and search for change; the same holds true for mammogram evaluation. Computer-assisted change detection can provide an invaluable tool by improving the physician's ability to detect change.

The first step in our approach to computer-assisted change detection is the precise alignment of mammograms by optimally matching corresponding image features. Accurate alignment is obtained employing all useful information in the mammogram. Once aligned, two mammograms are digitally subtracted and the physician can examine the resulting difference image. The figure shows two mammograms (top two images) and the corresponding difference images before alignment (third image) and after alignment (fourth image). After alignment, regions that have changed appear bright in

the difference image while regions that have not changed appear dark. In the difference images, the suspicious regions have been marked with a gray circle. Notice that the difference image before alignment is difficult to interpret because true change is obscured by differences due to misalignment. The difference image after alignment shows only those differences due to change and the suspicious region is readily identified.

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Detecting Lesions in Magnetic Resonance Breast Scans

A dual use application of three-dimensional volume alignment technology

National Information Display Laboratory • Princeton, New Jersey

U.S. Public Health Service's Office on Women's Health • Washington, DC

Physicians are exploring the use of MR imaging to detect and diagnose breast cancers using contrast agents that enhance the visibility of cancer on MR scans. Cancerous areas appear as bright regions in the "post" MR scans acquired after administration of the contrast agent. Tumors are detected by comparing the "post" MR with a "pre" MR scan to look for differences. This process can be facilitated and the accuracy increased if the two scans are subtracted to highlight any change. However, patient movement of the breasts causes the "post" and "pre" MR scans to be misaligned. False bright areas

which appear in the difference image may cause the physician to improperly label areas affected by the motion as cancerous. Therefore, for precise detection and localization of the tumor by the physician, it is necessary to align the "pre" and "post" MR data sets.

Alignment of the "pre" and "post" MR scans is a challenging task for computer based techniques because of the non-rigid flexible nature of the breasts.



Slice of "Pre" MR



Slice of "Post" MR



Change before alignment



Change after alignment

Figure represents alignment of Pre and Post MR data sets

In the Department of Defense, we have developed image processing techniques for automatic alignment of multi-sensor two dimensional images. These techniques have been employed to detect change over time in target scenes from images taken from different viewpoints. For example, the detection of a new missile site might be made possible by registering two reconnaissance images acquired before and after the installation.

We are extending these two dimensional techniques to estimate the non-rigid three dimensional deformation of the "pre" MR breast scan to align with the "post" MR breast scan. In the Figure above, the top row shows a slice from a "pre" and "post" MR study. The bottom row shows the difference slices before and after alignment. Before alignment, the difference image (bottom left image) falsely indicates the presence of a change in the upper left corner of the breast. This area is (correctly) not highlighted in the difference image obtained after alignment (bottom right), and hence will not be labeled as a cancerous area by the physician.

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Pattern Recognition Tools to Assist Early Detection of Breast Cancer

A dual use application for learning image context in mammography

National Information Display Laboratory • Princeton, New Jersey
U.S. Public Health Service's Office on Women's Health • Washington, DC

Mammography is an important technique for detecting cancerous tumors when the tumors are small and therefore more easily treated. The main problem for the physician, as well as for any automated detection system, is that cues for cancerous tissue are often very subtle and cannot always be spotted due to imaging noise or surrounding tissue and anatomy.

Detecting small targets in reconnaissance imagery is an extremely challenging problem in the Department of Defense because military targets may only occupy a very small region in a large image. At the National Information Display Laboratory (NIDL) we

are developing a novel system for overcoming the problems of target size by utilizing target context. The location of most targets is not random, rather their position is linked to its surrounding area. For example, transportation requirements tend to place buildings near roads (see Figure 1). Since roads appear in large areas, they are more readily detectable and can be utilized to guide the search for the associated small scale targets, in this case buildings.



Figure 1

Targets and associated context information for both a reconnaissance image and a mammogram.



Figure 2

The automatic target detection system we are developing exploits this type of context

information, making the detection scheme more accurate and efficient for detection of targets of interest. We utilize a neural network, a computational processor inspired by biology, to learn context automatically through training on a large set of examples.

Our detection system can potentially be used for mammogram screening by taking advantage of contextual relationships seen in breast cancer tissue. For example, microcalcification position is often dependent upon mammalian duct and vasculature location (see Figure 2), and integration of this context aids in detection of cancerous tumors. A further advantage of the neural network approach is that after the system has learned the task, the network can be analyzed to discover the specific nature of the underlying context that it recognized as being important. The system therefore can contribute in several ways to current state-of-the-art mammography, acting as both an automatic screening system and a tool physicians can use to uncover subtleties in the breast image which may not be easily detectable via traditional methods.

Private Sector Partners: Dr. R. Nishikawa, University of Chicago;
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Fact Sheet

U.S. Public Health Service's Office on Women's Health

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



Director: Susan J. Blumenthal, M.D., M.P.A., Deputy Assistant Secretary for Women's Health

BREAST CANCER

Understanding how breast cancer develops and how to prevent, detect, and treat this illness in women across different age groups and socioeconomic and cultural backgrounds is a top priority for the U.S. Department of Health and Human Services.

BACKGROUND

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer death in American women. The lifetime risk for developing breast cancer is now 1 in 8 women, a significant increase from the 1 in 20 risk just two decades ago. The rate of breast cancer has increased steadily over the last 50 years, rising 25.3 percent between 1973 and 1992. In 1996, an estimated 184,300 women will develop breast cancer and 44,560 will die of the disease.

While the disease affects women of all races, it is more prevalent in non-Hispanic white women than in African-American, Hispanic, or Native-American women. (see figure 1) The exception is Native-Hawaiian women, whose breast cancer rate is almost as high as it is in white women.

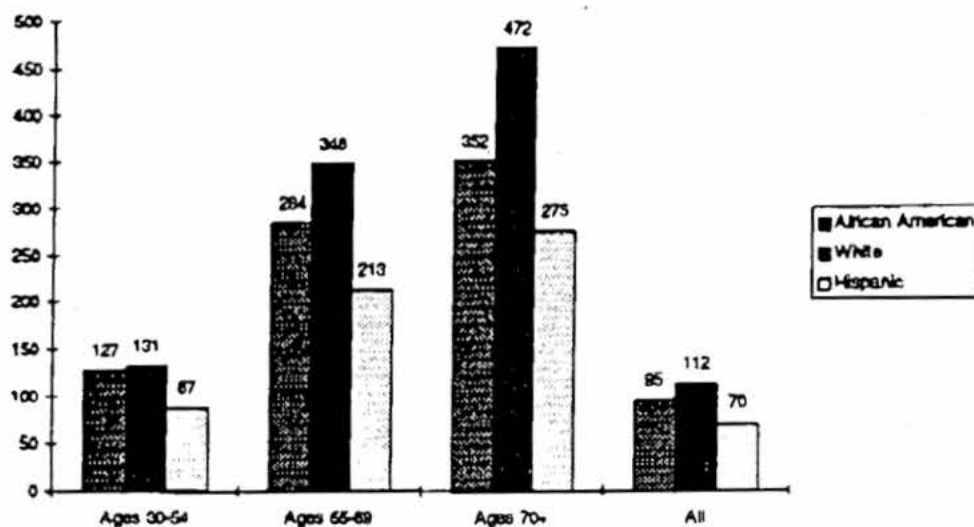
Despite the increasing incidence of breast cancer since 1940, the overall death rate (mortality rate) in American women has been declining in the 1990s. Among white women, the mortality rate has dropped approximately 6 percent between 1989 and 1993. For African-American women, increases in mortality persist, especially among older women, but the overall increase has slowed significantly. From 1989 to 1993, the mortality rate rose about 1 percent in African-American women. By comparison, from 1980 to 1989, mortality increased 3 percent in white women and 16 percent in African-American women.

Experts believe the recent overall decline in breast cancer death rates is partly the result of mammography screening, which rapidly increased in the United States during the 1980s, and resulted in a shift toward detection of breast cancer at earlier stages, when treatment can be most effective and survival rates are higher.

African-American and Hispanic women have poorer 5-year survival rates from breast cancer than do non-Hispanic white women. (see figure 2) Part of the reason for poorer survival in minority



Figure 1: Breast Cancer Incidence Rates among Hispanic, White, and African American Women, 1988-1992



Data Source: National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program, 1995 (Whites and African Americans); NCI Initiatives for Special Populations, 1973-1994 (Hispanics).

populations is more advanced stage of disease at time of diagnosis. It is anticipated, therefore, that improved access to mammography screening for early detection could have an important impact on decreasing mortality rates and increasing survival rates from breast cancer for all women, particularly minority populations.

ETIOLOGY OF BREAST CANCER

Understanding the etiology, or causes, of breast cancer is an important part of the national cancer research agenda. In the last 25 years, scientists have made great strides in understanding the internal workings of the normal human cell—how it operates, how it communicates internally and with other cells, and what happens when something goes wrong and it becomes a cancer cell. Breast cancer growth occurs when breast cells become abnormal and divide without control or order. Central issues in cancer research include increasing knowledge about the factors that (1) cause the DNA damage that initiates cancer, (2) act as contributors or promoters of the cancer process, and (3) act to protect the body from cancer. The specific events that trigger the transformation of a normal cell into a

cancerous one are not fully understood, but the process seems to involve a complex interplay of genetics and environmental factors. Factors including hormones, lifestyle, chemicals, radiation, and genetic makeup may contribute to the development and/or progression of breast cancer. Persons with or exposed to these factors have a higher risk of developing the disease.

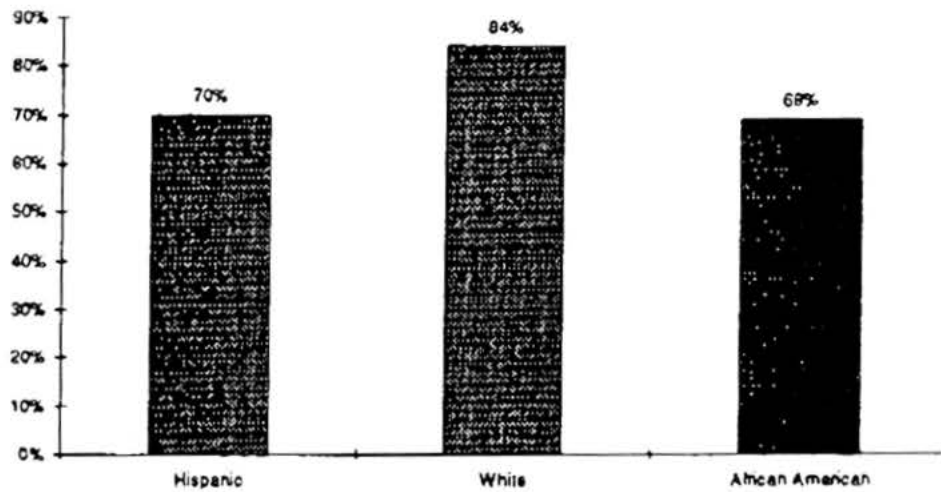
RISK FACTORS

One of the most important risk factors for breast cancer is increasing age. Women older than age 50 account for almost 80 percent of all breast cancer cases.

Other risk factors include:

- Family history of the disease
- Early onset of menstruation and/or late menopause
- Never having had a child, or a first full-term pregnancy after age 30
- History of cancer or atypical changes on a breast biopsy

Figure 2: Breast Cancer 5-Year Relative Survival Rates among Hispanic, White, and African American Women



Data Source: National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program, 1995 (Whites and African Americans); NCI Initiatives for Special Populations, 1973-1994 (Hispanics).

- Exposure to high levels of radiation, particularly during puberty
- Alcohol consumption

An increased risk for breast cancer also has been identified among women of higher socioeconomic status, married women, women living in urban versus rural areas, and women living in northern States.

Researchers estimate that about 5 to 10 percent of breast cancer cases may be hereditary, occurring in women whose family members have a substantially greater risk of developing premenopausal breast cancer. Recently, two breast cancer susceptibility genes, BRCA-1 and BRCA-2, have been discovered. Inheritance of abnormality in these genes accounts for about 25 percent of breast cancers in women younger than age 30. These discoveries may lead to the development of more effective treatment strategies and, one day, to the discovery of genetic interventions to prevent the disease from occurring.

Other potential risk factors for breast cancer currently under investigation include environmental toxins, hormonal therapies, and a high-fat diet. Scientists have studied immigrant populations

moving from countries with a low incidence of cancer (e.g., Japan) to high-incidence areas (e.g., the United States). They found that rates of breast cancer in these populations increased within a generation, strongly suggesting that environmental and lifestyle factors play a role in the development of breast cancer.

As many as 60 percent of breast cancers occur in women with no known risk factors except increasing age. Therefore, all women are considered to be at risk for developing breast cancer at some point in their lifetime.

DETECTION AND DIAGNOSIS OF BREAST CANCER

Early detection of breast cancer is key to effective treatment and improved survival from the disease. Experts estimate that when a breast tumor is found in the earliest stage, the 5-year survival rate is as great as 95 percent. Currently, breast cancer can be detected (1) through x-ray mammography, (2) through a breast examination by a trained health professional, or (3) by the woman herself. Conventional x-ray mammography is one of several imaging methods discussed below.

CONVENTIONAL MAMMOGRAPHY

X-ray mammography currently is the most effective method of screening for breast cancer in the general population. It is a technique that uses x-rays to create an image of the internal structure of the breast on film. In recent years, advances have refined the procedure to produce better images at very low radiation doses. Today's mammograms provide better images with greater safety than ever before. Additionally, the Food and Drug Administration's implementation of the Mammography Quality Standards Act of 1992 requires that all mammography facilities meet strict requirements for equipment, personnel, and reporting of the findings. This certification program ensures that women receive the safest mammography and most reliable mammograms available in their communities.

Mammography can detect cancers several years before a woman experiences physical symptoms of the disease and before the tumor can be felt as a lump. In 1951, only 51 percent of all detected localized tumors were small (i.e., less than 2 cm); by 1988, with the increase in mammography screening, 62 percent of the detected tumors were this small. Small tumors have less chance of metastasizing—breaking off from the primary tumor and traveling through the blood or lymph systems to spread to other places in the body. Therefore, early detection of the tumor while it is still small is vital to survival.

Mammography has decreased the breast cancer mortality rate in women by 25 to 30 percent. Women should consult with their health care providers to determine the frequency of mammography screening that is best for them.

Mammography is also used for diagnosis to differentiate cancer from benign tumors. Diagnostic mammography is also a valuable tool for investigating symptoms such as lumps, breast pain or swelling, or nipple discharge, and it can guide fine-needle biopsy for tumors that are too small to be felt. Such image-guided biopsies can yield more accurate diagnosis and replace many

surgical biopsies, reduce costs, and eliminate scarring.

Despite these successes, x-ray mammography has limitations: Three out of four lesions that it detects are benign, resulting in unnecessary medical procedures including biopsies. Mammography misses about 15 percent of cancers, especially in the 40 percent of women in the general population who have dense breast tissue, which can mask the presence of a tumor.

ULTRASOUND

High-resolution breast ultrasound is often used in conjunction with diagnostic mammography and clinical examination to help determine which breast masses are benign fluid-filled cysts and which are potentially malignant solid tumors. Because about 50 percent of well-defined masses are benign cysts, ultrasound imaging can help avoid unnecessary surgical biopsies for ruling out cancer.

Ultrasound is also used to evaluate abnormalities found on mammograms and to image palpable masses in women who are younger than age 30, pregnant, or lactating. Ultrasound is not currently used to screen for breast cancer because it often misses microcalcifications (small calcium deposits), which are important for diagnosing cancer.

Technical advances in ultrasound under study include the use of contrast agents to highlight areas of tumor angiogenesis, a hallmark of malignant tumors, which involves the development of new blood vessels in and around the tumor to support the tumor's growth.

NEW DIAGNOSTIC TECHNOLOGIES

Several new imaging technologies and molecular diagnostic techniques being studied have the potential for improving the early detection and diagnosis of breast cancer. Some have been adapted from technologies used in the defense, space, and intelligence communities and the

computer graphics industry, such as technologies used to track spy satellites and guide missiles. Some of these technologies, discussed below, are not appropriate to screen for breast cancer today, but could prove effective as diagnostic aids if they replace less accurate tests, eliminate biopsies, or provide improved biologic information about the detected abnormalities, and improve treatment planning.

Digital Mammography

Using this technique, a dedicated electronic detector system captures mammographic images and displays this digitized information on computers. Processing of digital images can substantially improve the visualization of the presence and extent of breast cancer, particularly in women whose breast tissue is very dense. Digital mammography is expected to improve the early detection, staging, and tissue diagnosis of breast cancer. Furthermore, this information can be stored and transmitted through digital information networks to other medical centers nationwide. This technique, known as tele-mammography, gives women in more isolated and/or underserved communities access to medical experts for interpretation of their mammograms.

Computer-Aided Diagnosis (CAD)

CAD involves the use of sophisticated computer programming to assist radiologists in analyzing medical images. A specially programmed computer scans a mammogram for questionable areas, enhances and isolates those areas from the rest of the image, and uses parameters such as size and shape to predict whether the suspicious area is cancerous. Research studies suggest that CAD can identify approximately half of the breast cancer lesions that are not being detected by routine means. However, the computer may tend to question too many areas that eventually prove to be normal.

Magnetic Resonance Imaging (MRI) and Positron-Emission Tomography (PET)

MRI, which creates images from signals generated by the excitation of nuclear particles in a magnetic field, can find small breast cancers not detectable by clinical breast examination or mammography. MRI can also help distinguish between benign and malignant tumors. MRI examination is free of ionizing radiation and can detect angiogenesis—the development of new blood vessels in the primary tumor to support the tumor's growth. Currently, breast MRI is performed with conventional whole-body MRI units that have been specially adapted for breast imaging.

PET is a nuclear medicine imaging technique that produces "molecular images" of biochemical and physiological processes in the body. For example, one kind of PET scan uses a radioactive form of sugar to produce images of glucose utilization in tumors. "Molecular imaging" with PET and other nuclear medicine techniques may detect disease not visible with other imaging methods. It also can help detect metastases to other sites in the body.

BREAST CANCER TREATMENT

Important advances in basic and clinical research are contributing to the development of a spectrum of treatments for breast cancer patients. Standard treatments include surgery, radiation therapy, chemotherapy, and hormonal interventions. Improved molecular diagnostic techniques, which give more definitive staging information about a breast tumor, permit clinicians to tailor the treatment options to an individual patient's needs. Another positive trend is that women are becoming more involved in their treatment decisions. Their choices may include some of the following treatments:

- Modified or simple mastectomy, which removes only the breast tissue, or

lumpectomy, which removes only the tumor. (Radical mastectomy, which removes the muscle underlying the breast in addition to breast tissue, was the standard treatment in the past.)

- Lumpectomy and radiation instead of mastectomy, for treatment of early stage breast cancer. Studies have found the long-term survival rates of patients treated with lumpectomy plus radiation to be equivalent to those achieved with simple mastectomy or mastectomy plus radiotherapy in patients with early stage breast disease.
- Adjuvant therapy—chemotherapy or hormonal therapy given in addition to surgery or radiation therapy—has been established as a treatment that improves both disease-free and overall survival of many breast cancer patients. A recent analysis of many research studies found that adjuvant therapies can decrease the likelihood of death in women with no regional lymph node metastasis. Tamoxifen, a drug studied since 1975 as an adjuvant treatment after surgery, has been found to give women who have had breast cancer a 38 percent better chance of remaining disease-free for 5 years as compared with those who did not receive the medication.
- A wider choice of chemotherapy regimens, even for advanced or recurrent cancer. Research has shown that combinations of drugs may be more effective than individual drugs used alone. New drugs include taxol, which is used to treat breast cancer that has recurred or progressed despite treatment; a new family of chemotherapeutic agents called anthracyclines; and "multi-drug resistant" drugs that counter the problem of cancer cells that become unresponsive to a variety of chemotherapeutic agents.
- High-dose chemotherapy in combination with bone marrow transplantation for women with advanced cancer. Other techniques to permit high-dose chemotherapy include the administration of growth factors to increase the production of blood cells and experimental gene therapy to protect the bone marrow or enhance its function.
- Monoclonal antibodies, such as her-2/neu-oncogene, that target special antigens on the surface of the breast cancer cell to boost the immune system to fight cancer growth. Monoclonal antibodies may offer a way to treat microscopic amounts of breast cancer cells and to prevent the disease from recurring after surgery or radiation.
- The use of a protein inhibitor, TIMP-2, may help stop the action of a cancer cell enzyme that breaks down tissues and enables cancer cells to metastasize.
- Psychological support. One study found that women with metastatic breast cancer who participated in support groups lived 18 months longer than women who were not in such groups.

PREVENTION OF BREAST CANCER

Research is under way to find more effective and specific ways to prevent breast cancer. Of particular interest are the identification of lifestyle and environmental factors linked to breast cancer and the development of strategies to eliminate these hazards to women's health. Other prevention approaches include the development of drugs and vaccines.

Preliminary evidence indicates that increased physical fitness with moderate levels of aerobic exercise may reduce the risk of breast cancer. One report found that young women who exercised an average of 3.8 hours per week had

lower breast cancer rates than did those who exercised less or not at all.

While dietary studies have not been conclusive, it is generally considered prudent to increase daily fiber intake and to decrease fat consumption to reduce the risk of developing most malignancies, including breast cancer. Other factors linked to a higher risk of breast cancer, such as alcohol consumption, obesity, chemical hazards, and radiation, can be avoided.

Since 1992, the National Cancer Institute (NCI) has conducted a trial to determine whether tamoxifen, a cancer drug, can be used to prevent cancer in women considered to be at high risk: women older than age 60 or women age 35-59 who have multiple risk factors for the disease.

The search to develop vaccines to prevent breast cancer is under way and include studies targeting antibodies on breast cancer cells. Other approaches being investigated include gene therapy techniques.

DHHS BREAST CANCER INITIATIVES

Consistent with its mission to protect and advance the Nation's health, the U.S. Department of Health and Human Services (DHHS) undertakes a broad array of activities to advance our understanding of breast cancer and to promote the health and well-being of women and empower them to make informed choices about their health. Federal funding for breast cancer has increased dramatically from \$90 million in 1990 to over \$600 million today. DHHS funding for breast cancer nearly doubled between 1993 and 1996: from \$271 million to \$476 million.

PHS OFFICE ON WOMEN'S HEALTH

In 1991, DHHS established the U.S. Public Health Service's Office on Women's Health (PHS OWH) to coordinate and stimulate programs and activities across the agencies and offices of the U.S. Public Health Service. The PHS OWH

serves as the focal point for women's health activities and programs in the Department and collaborates with other government organizations and consumer and health care professional groups to advance women's health. Major PHS OWH initiatives on breast cancer include the following:

National Action Plan on Breast Cancer

In response to the National Breast Cancer Coalition's 2.6-million-signature petition, the DHHS convened a conference in 1993 that resulted in the establishment of the National Action Plan on Breast Cancer (NAPBC). The NAPBC is an innovative public/private partnership (involving agencies of government, advocacy groups, and scientific and health care professional organizations) that is catalyzing actions in research, service delivery, and education to eradicate breast cancer as a threat from the lives of women. The PHS OWH is charged with coordinating the implementation of the NAPBC.

Working Groups have been established to address each of the six NAPBC priorities, including to: (1) develop innovative strategies for information dissemination; (2) establish a national biological resource bank; (3) ensure consumer involvement; (4) expand research on breast cancer etiology; (5) enhance clinical trials accessibility; and (6) address the needs of individuals carrying breast cancer susceptibility genes and the need for education among consumers, health care professionals, and at-risk patient groups.

In addition to supporting \$9.2 million in small grants and grants supplements for innovative research and outreach programs in each priority area, the Working Groups are implementing a broad range of activities. For example, these groups are developing an NAPBC Worldwide Web Home Page; implementing a media campaign to promote awareness of breast cancer clinical trials; developing recommendations regarding legal and ethical issues surrounding the identification of breast cancer susceptibility genes;

developing an educational curriculum for health care providers and an educational video for the public concerning breast cancer susceptibility genes; and establishing a national resource bank for biological tissues for research.

Federal Coordination of Breast Cancer Programs

The PHS OWH has convened a Federal Inter-agency Coordinating Committee on Breast Cancer composed of representatives from each of the DHHS agencies and other Federal agencies. This Committee shares information about breast cancer programs within the Federal government, fosters collaborations, and is developing an inventory of all government breast cancer activities that will be accessible via the Internet.

Initiative to Develop New Breast Cancer Imaging Techniques

In July 1994, the PHS OWH, in collaboration with NCI, began an initiative to examine technologies currently under exploration for improving breast imaging. The Federal Multi-Agency Consortium on Imaging Technologies to Improve Women's Health is exploring the application of imaging technologies from other fields to improve the early detection and diagnosis of illnesses and conditions affecting women. Collaborations are being facilitated among government officials, academic researchers, radiologists, and imaging and computer scientists from the Department of Defense (DoD), Central Intelligence Agency (CIA), and National Aeronautics and Space Agency (NASA) to enhance the ability to detect breast cancer at its earliest stages and to explore opportunities in telemedicine. The PHS OWH is also supporting clinical trials of technologies being transferred from the intelligence and defense communities to improve the early detection of the disease. Additionally, the Office is collaborating with the DoD and NCI to develop a Mobile Digital Telemammography Breast Care Center that will transmit a

patient's digital mammogram by satellite to a breast screening center, where a radiologist would instantly interpret the images and relay any need for additional evaluation back to the mobile unit. This project should benefit all women but especially underserved populations and women living in rural areas.

Older Women Mammography Initiative

The PHS OWH is working with the White House and the Health Care Financing Administration (HCFA) to encourage women older than 65 years of age to use their screening mammography benefits provided by Medicare. During 1994, about 50 percent of the newly diagnosed breast cancer cases and about 56 percent of the deaths attributed to breast cancer were in women in this age group. Yet, more than 60 percent of older women do not take advantage of Medicare-covered mammography screening.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR)

The AHCPR has developed and disseminated clinical practice guidelines on quality determinants of mammography for consumers and health care providers. In addition, AHCPR supports several research projects related to breast cancer, including studies that examine barriers to cancer screening among low-income minority women; patient notification and followup to abnormal screening mammograms; validation of women's self-reports of mammogram experience; methods to improve use of screening mammography by primary care physicians; and the relationship of tamoxifen therapy to subsequent occurrence of breast cancer in the other breast.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The CDC, in collaboration with other Federal agencies and professional, voluntary, and consumer

organizations, administers the National Breast and Cervical Cancer Early Detection Program, which aids State health departments in developing comprehensive prevention programs for breast and cervical cancer. The program, authorized in 1990, now encompasses all fifty States, three territories, the District of Columbia, and nine Native American tribal organizations. The program makes low-cost mammography and Pap tests available to medically underserved women, such as low-income women, older women, and minority women. Other projects include educational programs for women and health care providers and efforts to improve quality assurance measures for mammography.

CDC launched the National Program of Cancer Registries (NPCR) in 1992. With fiscal year 1995 funds of \$17.6 million, 42 states and the District of Columbia are currently receiving CDC support for enhancing existing cancer registries or developing new ones. These registries are part of surveillance efforts that provide the data on cancer incidence and mortality needed to make policy decisions and allocate resources.

FOOD AND DRUG ADMINISTRATION (FDA)

The FDA implements the Mammography Quality Standards Act of 1992 (mentioned earlier), which requires the establishment of a Federal certification program for mammography facilities; regulations and standards for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. FDA reviews and approves devices, such as the new technologies used to detect and diagnose breast cancer, and is examining ways to facilitate the transfer of new technologies to the clinical setting.

The FDA also has speeded up the review and approval of new drugs to increase the treatment options for breast cancer patients.

NATIONAL INSTITUTES OF HEALTH (NIH)

The National Cancer Institute (NCI) of NIH supports a comprehensive research program on breast cancer through studies of prevention, early detection, basic breast cancer biology and immunology, diagnosis, treatment, and quality of life. Priority areas of research include the contribution of genetics, environment, and hormones to the development of breast cancer, the implementation of primary prevention and treatment clinical trials; the accessibility and delivery of appropriate medical care to medically underserved women; the development of promising new treatment strategies, including gene therapy, vaccines, and new chemotherapeutics; the identification of breast cancer susceptibility genes; and the support of interdisciplinary programs on breast cancer, including the Specialized Programs of Research Excellence (SPORE) and the National Cancer Program Trans-NIH Collaborative Effort, to translate basic research discoveries to clinical practices.

In September 1994, scientists from the National Institute for Environmental Health Sciences (NIEHS) collaborated with NCI-funded scientists to announce that they had isolated BRCA-1 and BRCA-2, genes implicated in inherited susceptibility to breast cancer. NIEHS is also conducting studies on environmental contaminants in our homes, workplaces, and the atmosphere, such as DDT, DDE, PCBs, and plant hormones, which may mimic the biological activity of estrogen in promoting breast cancer. Other environmental factors under study are low-frequency electric and magnetic fields and other sources of radiation and the contribution of diet to the development of breast cancer.

The Women's Health Initiative, a trans-NIH multi-year research program, focuses on three of the most common causes of death, disability, and impaired quality of life in postmenopausal women: cardiovascular disease, cancer, and osteoporosis. The randomized controlled clinical

trial component of the Women's Health Initiative includes evaluation of the effect of low-fat dietary patterns on prevention of breast cancer and the effect of hormone replacement therapy on increasing the risk of breast cancer.

The NCI's Cancer Information Service (CIS) marked its 20th anniversary in 1996. The CIS responds to about 600,000 phone calls to its toll-free telephone number (1-800-4-CANCER) each year, providing the public with information on cancer prevention, detection, and treatment.

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

HCFA's Medicare Program supports mammography through reimbursement for screening and diagnostic mammograms and has developed an educational campaign for older women to promote the use of this screening benefit. In addition, HCFA is collaborating with NCI on the development of a database that links Medicare data with tumor registry data in an effort to evaluate the costs of cancer care and access to cancer prevention and treatment services.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

HRSA promotes the delivery of primary and preventive health services to underserved populations. The agency administers the Maternal and Child Health Services Block Grant to the States, through which screening for breast cancer is included as part of the delivery of health services to women.

INDIAN HEALTH SERVICE (IHS)

The IHS actively collaborates with the CDC's National Breast and Cervical Cancer Early Detection Program to bring mobile mammography services to American-Indian and Alaska-

Native women at remote reservation sites. The IHS established the IHS Alaska Native Cancer Surveillance Project, a comprehensive cancer registry for all Alaska-Native/American-Indian residents. IHS also collaborates with NCI and CDC on a study of organochlorine exposure and breast cancer among Alaska-Native women. Organochlorines, chemicals widely distributed in the environment, have been suggested as risk factors for breast cancer because of their estrogen-like effects.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

SAMHSA focuses on the impact of cancer on mental health. Through the programs of its three centers, SAMHSA is providing mental health services to women with breast cancer, exploring the role of social support in preventing and treating this disease and providing information about the possible role of alcohol consumption as a risk factor. SAMHSA has also begun an effort to evaluate treatment effectiveness through a combination of clinical and subjective information that may be helpful to women and their health care providers in assessing primary treatment outcome in terms of quality of life.

SUMMARY

The U.S. Public Health Service's Office on Women's Health, working with other agencies and offices of the DHHS, is dedicated to reversing the toll that breast cancer takes on the lives of American women through the prevention, early detection, and effective treatment of breast cancer. Activities and programs ongoing in the DHHS and other Federal agencies in partnership with initiatives in the private sector will ensure that significant progress is made in the fight against breast cancer.

For Further Information:**U.S. Public Health Service's Office on
Women's Health**

Department of Health and Human Services
200 Independence Avenue, S.W., Room 730B
Washington, DC 20201
Phone: (202) 690-7650
Fax: (202) 690-7172

National Cancer Institute
The Cancer Information Service
Building 31, Room 10A-16
31 Center Drive
Bethesda, MD 20892
1-800-4-CANCER

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Divider Title: Breast Awareness

THE WHITE HOUSE

WASHINGTON

National Breast Cancer Awareness Month, 1996

By the President of the United States of America

A Proclamation

Each year we set aside the month of October as a time to assess the toll that breast cancer takes on our society and the progress we have made in our battle to overcome it. For those of us who have lost loved ones to this disease—mothers, wives, daughters, sisters, and friends—the battle holds special urgency.

Breast cancer remains the second leading cause of all deaths among women ages 40 to 55. In 1996, a woman will die from breast cancer every 12 minutes, and 184,300 women in the United States will be diagnosed with the disease. Every one of these diagnoses changes not only that woman's life, but the lives of all who love and care for her.

We have embarked on an all-out assault to combat this threat. The Federal Government has nearly doubled funding for breast cancer research, detection, and treatment since 1993, from \$271 million to \$476 million in the Department of Health and Human Services alone. And in response to requests from 2.6 million of our Nation's citizens, we launched the National Action Plan on Breast Cancer, an innovative public-private partnership to develop a national strategy for prevention, education and care.

We can be proud of the progress we are making in the fight against breast cancer. During the most recent 5-year period for which data are available (1989-1993), age-adjusted mortality rates for white women fell almost 6 percent. Although mortality rates among African American women are still increasing, the rate of increase has slowed to 1 percent, compared to 16 percent during the 1980's.

One of our most successful weapons in the fight against breast cancer is early detection. The new Mammography Quality Standards Act now ensures that every woman who obtains a mammogram to detect breast cancer in its earliest, curable, stages can be certain that facilities meet the highest quality standards for equipment and personnel. We are implementing the National Breast and Cervical Cancer Early Detection Program to make free or low-cost mammography available to medically under-served women. The First Lady launched an education campaign to inform and encourage older women to use Medicare's mammography screening benefit. And to improve early detection, we are transferring imaging technologies from the space, defense, and intelligence communities.

I urge women throughout our nation to have appropriate mammograms, to perform routine self-examination, and to take advantage of the latest in preventive medical care. Armed with this commonsense approach and the promising advances in research and treatment, we can look forward with confidence to the day when breast cancer is finally eradicated.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1996 as National Breast Cancer Awareness Month. I call upon government officials, businesses, communities, volunteers, educators, and all the people of the United States to celebrate the successes we have had in advancing our knowledge of breast cancer, and to reaffirm our commitment to continue to work together to fight this disease.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of October, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton