

NATIONAL BREAST CANCER COALITION

FUND

*« a grassroots advocacy effort »*

## ***BREAST CANCER LEGISLATION IN THE 105<sup>TH</sup> CONGRESS***

### **In the Senate:**

- **S.67 – Breast Cancer Research Extension Act of 1997**--authorizes the appropriation of \$590 million for breast cancer research for the National Institutes of Health in FY'98 (introduced by Senator Snowe).
- **S.86—Consumer Involvement in Breast Cancer Research Act**—calls for the increased involvement of breast cancer advocates in the decision-making at the NCI (introduced by Senator Snowe).
- **S.89—Genetic Information Nondiscrimination in Health Insurance Act**—provides comprehensive federal protection against genetic discrimination. Prevents insurers from charging higher premiums based on genetic information, prohibits insurers from requiring or requesting a genetic test as a condition of coverage, requires informed written consent before an insurance company can disclose genetic information to a third party. It also extends these protections to Medigap policies (companion bill to H.R. 306-Rep. Slaughter).
- **S.143 – Breast Cancer Patient Protection Act of 1997**—requires that group and individual health insurance coverage and group health plans provide minimum hospital stays for mastectomies and lymph node dissections (introduced by Senator Daschle, this is a companion bill to the House DeLauro – Dingell – Roukema bill).
- **S. 249 – Women's Health and Cancer Rights Act of 1997**--ensures coverage of inpatient hospital care for mastectomies, lumpectomies and lymph node dissections (based on doctor's judgment), requires coverage for reconstructive procedures, and guarantees a second opinion for any cancer diagnosis (introduced by Senators D'Amato, Feinstein, Hollings and Snowe).
- **S.353- Health Insurance Bill of Rights Act-Quality Assurance and Patient Protection** sets basic standards for managed care organizations and other health insurance plans to protect consumers and improve the quality of care (introduced by Sen. Edward Kennedy).
- **Medicare Cancer Clinical Trial Coverage Act of 1997** - establishes a Medicare demonstration project that will pay for the patient care costs for individuals enrolled in qualified clinical trials (will be reintroduced by Senators Rockefeller and Mack).

### **In the House of Representatives:**

- **H.R. 135 – Breast Cancer Patient Protection Act of 1997**--guarantees a minimum stay of 48 hours for a woman having a mastectomy and 24 hours for lymph node removal for treatment of breast cancer (introduced by Representatives DeLauro, Dingell, and Roukema).

- **H.R. 616 – Women’s Health and Cancer Rights Act of 1997**--ensures coverage of inpatient hospital care for mastectomies, lumpectomies and lymph node dissections (based on doctor’s judgment), requires coverage for reconstructive procedures, and guarantees a second opinion for any cancer diagnosis (companion bill to Senator D’Amato’s ; introduced by Representatives Kelly, LoBiondo, and Molinari).
- **H.R. 164 – Reconstructive Breast Surgery Benefits Act of 1997**--guarantees that insurance companies cover the cost of reconstructive breast surgery that results from mastectomies for which coverage is already provided and additionally would secure insurance coverage for all stages of reconstructive breast surgery performed on a nondiseased breast to establish symmetry with the diseased one when reconstructive surgery on the diseased breast is performed (introduced by Congresswoman Eshoo).
- **H.R. 306 – Genetic Information Nondiscrimination in Health Insurance Act**— prevents health insurers from denying, canceling, refusing to renew, or changing the premiums, terms or conditions of coverage based on genetic information. It prohibits insurance companies from requesting or requiring a genetic test, and would require written informed consent before an insurer could disclose genetic information to a third party. H.R. 306 extends all these protections to Medigap policies (introduced by Congresswoman Slaughter).
- **H.R. 617-Mammogram Availability Act** - ensures that no insurance plan, public or private, be allowed to deny coverage to women for annual mammograms for women ages 40 and above ( introduced by Representatives Nadler, Lazio, Slaughter, Johnson (TX), Yates, Pallone, Engel, LaFalce, Martinez, Hinchey, Lofgren, Norton, Faleomavaega, and Christian-Green).

All of these bills are important to NBCC’s legislative agenda, and it is critical that we work to make sure they are passed during this Congress.

*NBCC is calling for the following breast cancer research appropriations for FY 1998:*

<b>National Institutes of Health</b>	<b>\$590 million</b>
<b>Department of Defense</b>	
<b>Breast Cancer Research Program</b>	<b>\$150 million</b>
<b>Other Agencies (EPA, VA, etc.)</b>	<b>\$20 million</b>

Beyond the strategy to endorse and push for passage of the above discussed legislation, NBCC

- continues to urge Members of Congress to endorse our **Breast Cancer Policy Platform**,
- seeks an amendment to the CDC program that sets aside funds for treatment of under- or uninsured women whose screenings require follow-up,
- is developing a health policy proposal that will call for federal legislation to address managed care, health care and breast cancer issues in a broader context.

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**United States Senate  
Democratic Policy Committee**

Washington, DC 20510-7050

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(AS SECRETARY OF CONFERENCE)

FOR IMMEDIATE RELEASE  
Tuesday, January 28, 1997

Contact: Ranit Schmelzer  
Molly Rowley  
(202) 224-2939

**DASCHLE BILL WOULD PROTECT WOMEN FROM  
"DRIVE-THROUGH" MASTECTOMIES**

A new bill introduced by Senate Democratic Leader Tom Daschle would end the practice of "drive-through" mastectomies.

The Breast Cancer Patient Protection Act guarantees that women can spend at least 48 hours in the hospital after a mastectomy. It is modeled on last year's unanimously supported bill to end "drive-through deliveries." Daschle introduced the bill on January 21, the first day legislation could be introduced in the Senate. Representatives Rosa DeLauro, John Dingell and Marge Roukema have introduced the identical bill in the House.

"Every three minutes another American woman is diagnosed with breast cancer. This year alone, more than 180,000 women will find out they have breast cancer. This disease strikes at the core of American families, taking our mothers, wives, sisters and daughters on an often terrifying tour of our health care system," Daschle said.

"For some women, that experience is made even more traumatic by policies that force them out of hospitals only hours after major breast cancer surgery. That's where our bill comes in. It will help ensure that women with breast cancer get the care and the treatment they need, and that decisions about that care rest with the woman and her doctor."

Congressional attention focused on this matter after a number of doctors and breast cancer survivors reported that they had been forced to perform or undergo mastectomies on an outpatient basis. This policy apparently resulted from a consulting firm's recommendation to its insurance clients that they cover only outpatient care for the procedure. But many doctors who perform breast surgery, including the American College of Surgeons, say that very few women can or should have such extensive surgery without hospitalization.

The Daschle bill requires insurers to pay for at least 48 hours of hospitalization for a mastectomy, and a minimum of 24 hours for lymph node removals. It leaves important health care decisions up to a woman and her doctor, not accountants. Under this legislation, a woman could chose to have a mastectomy on an outpatient basis, but could not be forced to do so.

The bill is supported by the National Breast Cancer Coalition, the National Alliance of Breast Cancer Organizations, the American College of Surgeons, the American Society of Plastic and Reconstructive Surgeons, the American Cancer Society, the Y-Me National Breast Cancer Organization, Families USA and the Women's Legal Defense Fund.

Another issue important to breast cancer patients -- coverage for breast reconstruction surgery -- will be addressed in separate bill to be introduced soon by Senators Edward Kennedy (D-MA) and Daschle.

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# The Breast Cancer Patient Protection Act of 1997

## Fact Sheet

### (S. 143)

#### *Summary*

The Breast Cancer Patient Protection Act would put critical health care decisions back in the hands of breast cancer patients and their providers.

It would require insurance companies to provide at least 48 hours of inpatient hospital care following a mastectomy and a minimum of 24 hours following lymph node dissection for the treatment of breast cancer. Patients and physicians -- not insurance companies -- could jointly decide whether it is appropriate for an individual patient to be discharged earlier.

The language is modeled after last year's unanimously passed and carefully crafted compromise that ended "drive through" deliveries.

By setting a floor for coverage of hospitalization following mastectomies and lymph node surgery, this bill establishes a clear and reliable standard upon which women and their doctors can depend.

#### *Statistical highlights: Breast Cancer*

- In 1997, more than 180,000 new cases of invasive breast cancer will be diagnosed, and approximately 44,000 women will die from the disease.
- A new breast cancer case is diagnosed every three minutes, and another woman dies from breast cancer every 12 minutes.
- Lymph node dissection and mastectomy are the most frequent forms of surgical treatment for breast cancer. Approximately 75 percent of breast cancer patients undergo either a lumpectomy with lymph node dissection or a mastectomy.
- Breast cancer is the leading cause of death for American women between the ages of 40 and 55.

#### *Supporters*

This bill is supported by the National Breast Cancer Coalition, the National Alliance of Breast Cancer Organizations, the American College of Surgeons, the American Society of Plastic and Reconstructive Surgeons, the Y-Me National Breast Cancer Organization, Families USA, the American Cancer Society, and the Women's Legal Defense Fund.

#### *Senate cosponsors*

S. 143 was introduced on January 21, 1997 by Senators Daschle-Hollings, Kennedy, Mikulski, Moseley-Braun, Boxer, Reid, Feinstein, Levin, Inouye, Murray, Bryan, Sarbanes, Ford, and Lautenberg. As of February 26, 1997 Senate cosponsors include Senators Reid, Harkin, Leahy and Glenn.

#### *House companion*

On January 7, Representatives DeLauro, Dingell and Roukema introduced with considerable bipartisan support the Breast Cancer Patient Protection Act of 1997 (H.R. 135).

# Congress of the United States

Washington, DC 20515

December 20, 1996

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

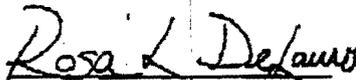
Dear Colleague:

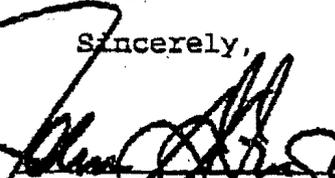
We are writing to urge you to become an original co-sponsor of legislation to guarantee that women who must undergo surgery for the treatment of breast cancer get the hospital stay they need and deserve. The DeLauro-Dingell-Roukema Breast Cancer Patient Protection Act of 1997 guarantees a minimum hospital 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

ONE HUNDRED FIVE CO-SPONSORS OF H.R. 135,  
THE DeLAURO-DINGELL-ROUKEMA  
BREAST CANCER PATIENT PROTECTION ACT OF 1997

Abercrombie  
Ackerman  
Allen  
Andrews  
Barrett (WI)  
Bentsen  
Bonior  
Boucher  
Brown (FL)  
Brown (OH)  
Carson  
Clayton  
Clement  
Conyers  
Costello  
DeFazio  
Delahunt  
Dellums  
Dingell  
Eshoo  
Engel  
Evans  
Faleomavaega  
Farr  
Fazio  
Filner  
Foglietta  
Fox  
Frank (MA)  
Frost  
Furse  
Gejdenson  
Gephardt  
Gonzalez  
Gordon

Green  
Gutierrez  
Hinchey  
Hinojosa  
Jackson-Lee  
Kaptur  
Kennedy (MA)  
Kennedy (RI)  
Kennelly  
Kildee  
LaFalce  
Lewis (GA)  
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McCarthy (NY)  
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McGovern  
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McNulty  
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Maloney (CT)  
Manton  
Markey  
Matsui  
Meehan  
Meek  
Miller  
Millender-McDonald  
Mink  
Moakley  
Moran  
Morella

Murtha  
Nadler  
Neal  
Norton  
Oberstar  
Olver  
Owens  
Pallone  
Pascrell  
Payne  
Pelosi  
Pickett  
Quinn  
Rahall  
Rangel  
Rivers  
Roukema  
Roybal-Allard  
Romero-Barcello  
Rush  
Sanders  
Schumer  
Scott  
Serrano  
Skaggs  
Slaughter  
Spratt  
Stokes  
Tauscher  
Thurman  
Tierney  
Townes  
Valazquez  
Waters  
Weygand  
Woolsey  
Yates

Summary of Mammogram Availability Act -- H.R. 617  
Congressman Jerrold Nadler -- 105th Congress

Breast cancer is the single leading cause of death for women ages 40-49 in the United States. Guaranteed access to mammograms is crucial to women's health and will save lives. On January 23, 1997 an expert panel convened by the National Institutes of Health unanimously called for insurance companies to cover mammograms for women ages 40-49. The report of the NIH panel states: "For women in their forties who choose to have mammography performed, costs of the mammograms should be reimbursed by third-party payors or covered by health maintenance organizations." The decision whether to have a mammogram is one best made by a woman in consultation with her health care provider on the basis of medical concerns -- not cost.

The Mammogram Availability Act will ensure that no insurance plan, public or private, be allowed to deny coverage to women for annual mammograms for women ages 40 and above.

Provisions:

Section 2: Group Health Plans and health insurers offering group health insurance coverage that provide coverage for diagnostic mammograms must provide coverage for screening mammography for women ages 40 and above under terms not less favorable than those for diagnostic mammography. The decision to have a mammogram resides with such women, following consultation with their health care practitioners.

Plans may not (1) deny to a woman such coverage on the basis that it is not medically necessary, or on the basis that the mammography is not pursuant to a referral, consent, or recommendation by any health care practitioner; (2) deny to a woman eligibility, or continued eligibility, enrollment or renewal of coverage under the terms of the plan in order to avoid the bill's requirements; (3) provide monetary payments or rebates to women to encourage such women to accept less than the minimum protections available in the act; (4) penalize or otherwise reduce or limit the reimbursement of an attending provider because the provider provided care consistent with the bill; or (5) provide incentives (monetary or otherwise) to a doctor to induce the practitioner to provide care inconsistent with the bill.

Nothing in the bill shall be construed to require a woman who is a participant or beneficiary to undergo annual mammography.

Insurers may charge deductibles, copayments, or other cost-sharing measures in relation to screening mammography, so long as such coinsurance is not greater than that for diagnostic mammography.

Women between the ages of 40 and 49 should, but are not required to, consult with appropriate health care practitioners before undergoing screening mammography. However, nothing in bill shall be construed as requiring the approval of such practitioner before undergoing an annual screening mammography.

Insurers may negotiate level and type of reimbursement with a provider in accordance with the above provisions.

This bill will set a floor, not a ceiling for coverage. Should a state have a law currently which provides for at least the same or a more comprehensive degree of coverage and associated penalties for non-compliance as stated above, this law shall not supersede it.

Section 3: The above provisions shall also apply to individual health coverage.

Section 4: Medicare shall provide coverage for annual mammograms for women ages 40 and above. Medicare may set deductibles or coinsurance with respect to screening mammography, provided such coinsurance is not greater than that for diagnostic mammography.

Section 5: Medicaid shall provide coverage for annual mammograms for women ages 40 and above. Medicaid may impose charges with respect to screening mammography, provided such coinsurance is not greater than that for diagnostic mammography.

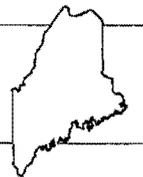
The provisions of this bill shall take effect in January 1998.

Current Co-Sponsors: Rick Lazio, Louise Slaughter, Eddie Bernice Johnson, Sidney Yates, Frank Pallone, Jr., Eliot Engel, Sheila Jackson-Lee, Nita Lowey, John LaFalce, Matthew Martinez, Maurice Hinchey, Zoe Lofgren, Eleanor Holmes Norton, Eni Faleomavaega, Donna Christian-Green, Julia Carson, Bernie Sanders, Patrick Kennedy, Gary Ackerman



## NEWS RELEASE

# OLYMPIA SNOWE



*U.S. Senator for Maine*

FOR IMMEDIATE RELEASE  
Wednesday, February 26, 1997

CONTACT: DAVE LACKEY  
or TOM PATRICELLI  
(202) 224-5344

### SNOWE CALLS FOR END TO GENETIC DISCRIMINATION

WASHINGTON, D.C. — Calling for an end to genetic discrimination in health insurance, Senator Olympia J. Snowe (R-Maine) today joined Congresswoman Louise M. Slaughter (D-N.Y.) and representatives of several major health organizations in calling for speedy passage of legislation to prevent the practice. Snowe and Slaughter are the Senate and House sponsors of the Genetic Information Non-Discrimination in Health Insurance Act, which will provide comprehensive federal protection against genetic discrimination.

"This important legislation builds on protections passed as part of the Kassebaum-Kennedy health care legislation last session by preventing insurers from discriminating on the basis of genetic information," said Snowe, who first introduced legislation on this issue with Slaughter in the 104th Congress. "The Snowe-Slaughter legislation will take the next important step by stopping insurers from charging higher premiums based on genetic information, prohibiting insurers from requiring or requesting a genetic test as a condition of coverage, requiring informed written consent before an insurance company can disclose genetic information to a third party, and extending these important protections to 'Medigap' coverage."

"Scientific advances have allowed us to isolate the genetic source of diseases like breast cancer. But the tremendous promise of genetic testing is significantly threatened when insurance companies use the results to deny or limit coverage to consumers," Snowe said, noting that a recent survey of individuals with known genetic conditions revealed that 22 percent had been denied health coverage because of genetic information.

"Yet, the *fear* of discrimination alone can lead to equally harmful consequences for consumers and for scientific research. For example, many women who might take extra precautions if they knew they had the breast cancer gene may not seek testing because they fear losing their health insurance," Snowe said. "Patients may be unwilling to disclose information about their genetic status to their physicians out of fear, hindering treatment or preventive efforts. And people may be unwilling to participate in potentially ground breaking research because they do not want to reveal information about their genetic status."

Snowe cited studies showing that women who inherit a mutated form of the breast cancer gene - BRCA1 or BRCA 2 - have an 85 percent risk of developing breast cancer in their lifetime, and a 50 percent chance of developing ovarian cancer. "Although there is no known treatment to ensure that women who carry the mutated gene do not develop breast cancer, genetic testing makes it possible for carriers of these mutated genes to take extra precautions in order to detect cancer at its earliest stages - precautions such as mammograms and self-examinations," Snowe said. "We need to make sure that these advances are not negated by discriminatory health insurance practices."

###

**COSPONSORS OF H.R. 306, THE GENETIC INFORMATION NONDISCRIMINATION  
IN HEALTH INSURANCE ACT**

(Total 74)

Rep. Neil Abercrombie  
Rep. Gary Ackerman  
Rep. Tom Barrett  
Rep. Rick Boucher  
Rep. Corrine Brown  
Rep. George Brown  
Rep. Julia Carson  
Rep. Donna Christian-Green  
Rep. Eva Clayton  
Rep. John Conyers  
Rep. Bill Coyne  
Rep. Pat Danner  
Rep. Danny Davis  
Rep. Peter DeFazio  
Rep. William Delahunt  
Rep. Rosa DeLauro  
Rep. Ron Dellums  
Rep. Anna Eshoo  
Rep. Lane Evans  
Rep. Eni Faleomavaega  
Rep. Chaka Fattah  
Rep. Tom Foglietta  
Rep. Martin Frost  
Rep. Sam Gejdenson  
Rep. Henry Gonzalez  
Rep. Gene Green  
Rep. Bill Hefner  
Rep. Earl Hilliard  
Rep. Maurice Hinchey  
Rep. Tim Holden  
Rep. Steve Horn  
Rep. Jesse Jackson, Jr.  
Rep. Sheila Jackson-Lee  
Rep. Joe Kennedy  
Rep. Dale Kildee  
Rep. John LaFalce  
Rep. John Lewis  
Rep. Zoe Lofgren  
Rep. Nita Lowey  
Rep. Carolyn Maloney  
Rep. Edward Markey  
Rep. Matthew Martinez  
Rep. Robert Matsui  
Rep. Jim McDermott  
Rep. James McGovern  
Rep. Cynthia McKinney  
Rep. Carrie Meek  
Rep. David Minge  
Rep. James Moran  
Rep. Connie Morella  
Rep. Jerrold Nadler  
Rep. Eleanor Holmes Norton  
Rep. James Oberstar  
Rep. John Oliver  
Rep. Donald Payne  
Rep. Nancy Pelosi  
Rep. Lynn Rivers  
Rep. Lucille Roybal-Allard  
Rep. Bobby Rush  
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Rep. Jose Serrano  
Rep. Christopher Smith  
Rep. Pete Stark  
Rep. Louis Stokes  
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Rep. Bennie Thompson  
Rep. Karen Thurman  
Rep. John Tierney  
Rep. Edolphus Towns  
Rep. Jim Traficant  
Rep. Maxine Waters  
Rep. Mel Watt  
Rep. Henry Waxman  
Rep. Sidney Yates

**SECTION-BY SECTION ANALYSIS OF H.R. 306,  
GENETIC INFORMATION NONDISCRIMINATION IN HEALTH INSURANCE ACT**

**Section 1. Short title.**

**Section 2. Amendments to ERISA.** Health insurance providers are prohibited from denying, canceling, refusing to renew, or changing the premiums, terms, or conditions of benefits on the basis of genetic information.

Insurers are prevented from requesting or requiring that an individual take or disclose the results of a genetic test.

An insurer must obtain prior written informed consent before disclosing genetic information to a third party.

Genetic information is defined in accordance with the recommendations of the Human Genome Project's Ethical, Legal, and Social Implications (ELSI) Working Group.

In addition to the existing remedies under ERISA, victims of genetic discrimination may also receive compensatory, consequential, and punitive damages at the discretion of the court.

**Section 3. Amendments to the Public Health Service Act.** Health insurance providers are prohibited from denying, canceling, refusing to renew, or changing the premiums, terms, or conditions of benefits on the basis of genetic information.

Insurers are prevented from requesting or requiring that an individual take or disclose the results of a genetic test.

An insurer must obtain prior written informed consent before disclosing genetic information to a third party.

Genetic information is defined in accordance with the recommendations of the Human Genome Project's Ethical, Legal, and Social Implications (ELSI) Working Group.

All the above prohibitions are applied to state-regulated health insurance plans in the individual market. In accordance with the section of the PHS Act where this provision would be placed, the Secretary is authorized to regulate such plans if the state fails to take appropriate action.

Victims of genetic discrimination under this section have access to the remedies under ERISA and may also receive compensatory, consequential, and punitive damages at the discretion of the court.

**Section 4. Amendments to the Social Security Act.** Medicare supplemental policy issuers are prohibited from denying, canceling, refusing to renew, or changing the premiums, terms, or conditions of benefits on the basis of genetic information.

Medigap insurers are prevented from requesting or requiring that an individual take or disclose the results of a genetic test.

Medigap insurers must obtain prior written informed consent before disclosing genetic information to a third party.

Genetic information is defined in accordance with the recommendations of the Human Genome Project's Ethical, Legal, and Social Implications (ELSI) Working Group.

Victims of genetic discrimination under this section have access to the remedies under ERISA and may also receive compensatory, consequential, and punitive damages at the discretion of the court.

**Section 5. Amendments to the Internal Revenue Code.** Any health insurer found to have engaged in genetic discrimination in violation of this section may be subject to tax penalties.

Penalties may be levied if the insurer is found to have denied, canceled, refused to renew, or changed the premiums, terms, or conditions of benefits on the basis of genetic information.

Insurers are prevented from requesting or requiring that an individual take or disclose the results of a genetic test.

An insurer must obtain prior written informed consent before disclosing genetic information to a third party.

Genetic information is defined in accordance with the recommendations of the Human Genome Project's Ethical, Legal, and Social Implications (ELSI) Working Group.

*from the office of*

*Senator Edward M. Kennedy  
of Massachusetts*

STATEMENT OF SENATOR EDWARD M. KENNEDY  
INTRODUCTION OF THE HEALTH INSURANCE BILL OF RIGHTS ACT -  
QUALITY ASSURANCE & PATIENT PROTECTION

For Immediate Release:  
February 25, 1997

Contact: Jim Manley  
(202) 224-2633

I am proud to join Congressman Dingell in announcing the introduction of the Health Insurance Bill of Rights Act - Quality Assurance and Patient Protection. It is a needed response to the surging growth of managed care and the rapid changes taking place in the health insurance market--changes that too often put insurance industry profits ahead of patients' health needs.

Managed care has mushroomed over the past decade. In 1987, only 13 percent of privately insured Americans were enrolled in HMOs. Today, that figure is 75 percent. At its best, managed care offers the opportunity to achieve both greater efficiency and higher quality in health care. In too many cases, however, the pressure for profits leads to lesser care--not better care. Too many managed care firms and other insurance companies have decided that the shortest route to higher profits and a competitive edge is by denying patients the care they need and deserve.

Some of the most flagrant abuses by insurance plans have been documented in recent months:

Just last year Congress enacted legislation to block drive-by deliveries and prevent new mothers and their babies from being evicted from hospitals in less than 48 hours.

Breast cancer patients are being forced to undergo mastectomies on an outpatient basis, when sound medical advice requires a reasonable hospital stay.

Children are being permanently injured or even losing their lives because their parents are forced to drive past the nearest emergency room to a more distant hospital because it has the contract with their health plan.

Doctors are being subjected to "gag rules" that keep them from giving their patients their best medical advice.

People with rare and dangerous diseases are being denied access to specialists to treat their conditions.

Patients can't get needed pharmaceutical drugs, because the particular drug they need is not on the list of drugs approved for coverage by their insurance plan; sometimes such lists are developed and administered by pharmaceutical companies bent on selling their own drugs and blocking competition.

-MORE-

## SENATOR KENNEDY ON THE HEALTH INSURANCE BILL OF RIGHTS 2-2-2

Patients are being misdiagnosed, sometimes with fatal results, because insurance plans cut corners on diagnostic tests.

Victims of cancer and other serious diseases are being denied participation in quality clinical trials offering the only hope of cure for otherwise incurable conditions.

Children afflicted with serious, chronic conditions are being denied access to the medical centers with the only available expertise to treat their conditions effectively.

These abuses are not typical of most insurance companies. But they are common enough that an overwhelming 80% of Americans now believe that their quality of care is often compromised by their insurance plan to save money. It is time to deal with these festering problems. Good business practices can improve health care, but health care must be more than just another business.

The legislation we are introducing today establishes basic standards for insurance plans in six specific areas:

- (1) Access to care, including specialty care, emergency care, and clinical trials
- (2) Standards for quality of care
- (3) Information that must be available to patients
- (4) Expedient and fair appeal procedures when physicians or patients disagree with plan decisions
- (5) Protection of the doctor-patient relationship, by banning gag rules and objectionable compensation arrangements
- (6) A requirement that plan guidelines may not override good medical practice

These steps will not eliminate every abuse that occurs in the insurance industry, but they will go a long way to addressing the major problems patients confront.

At the most basic level, the legislation establishes a right to needed care. A patient facing a health emergency should not be required to go to a distant emergency room, or to obtain prior authorization for care. Someone suffering from a serious condition requiring specialty care should not be denied that care because an insurance company thinks it is too expensive. Someone with a condition that cannot be addressed by conventional therapies should have a reasonable opportunity to participate in a quality clinical trial that offers the hope of effective treatment. Plans should set up clear, fair, and timely appeal procedures for cases in which the plan fails to fulfill its obligations.

Historically, patients have relied on their personal physician to be the best source of impartial advice on needed care. This legislation maintains that critical role by prohibiting plans from restricting doctor-patient communications or from establishing compensation plans that bribe or penalize doctors into representing the plan's interest at the expense of their patients' health.

### SENATOR KENNEDY ON THE HEALTH INSURANCE BILL OF RIGHTS 3-3-3

To maintain and improve quality of care, all managed care plans will be required to set up a separate unit dedicated to quality, and to collect data to verify that the plan, in fact, is providing care that meets objective quality standards.

Patients will be guaranteed full information about plan coverage, appeal rights, access to primary care doctors and other specialists, and other needed information. Plans will be required to collect and make available standardized data for consumers to compare plans.

These provisions add up to a Health Insurance Bill of Rights that will protect millions of Americans.

I look forward to working with a broad range of physician, patient, and industry groups as Congress considers this legislation. Action is essential and overdue to provide these needed protections. The bottom line in health care must be patient needs, not industry profits. Concerned citizens in all parts of the country are demanding action, and Congress owes them a response.

S. 353

## HEALTH INSURANCE BILL OF RIGHTS - QUALITY ASSURANCE AND PATIENT PROTECTION

Subpart 1: Access to care

Subpart 2: Quality Assurance

Subpart 3: Patient Information

Subpart 4: Grievance Procedures

Subpart 5: Protection of providers against interference with medical communications and improper incentive arrangements

Subpart 6: Promoting good medical practice and protecting the doctor-patient relationship

### Subpart 1: Access to Care

**Emergency care.** A plan may not deny coverage for emergency care assessment and stabilization if a prudent layperson would seek such care given the symptoms experienced. Prior authorization for such care is not required. After assessment and stabilization, further needed care is covered if medically necessary.

#### **Access to specialty care**

##### •Obstetrician/gynecologist care

If a plan requires patients to designate a primary care physician, women have the right to choose an obstetrician/gynecologist as their primary care provider. In any case, they have the right to direct access to an obstetrician/gynecologist for routine gynecological care and pregnancy services without prior authorization from their primary care provider.

##### •Other specialty care

Enrollees with life-threatening, chronic, degenerative or other serious conditions which require specialty care must be provided access to the appropriate specialists or centers of excellence capable of providing quality care for the condition. If a plan does not have a participating specialist for a condition covered under the plan, the plan must refer the patient to a non-participating specialist at no additional cost.

A plan must have a procedure to allow individuals with a serious illness and ongoing need for specialty care to receive care from a specialist who will coordinate all care for that individual.

A plan must have a procedure for standing referrals for individuals requiring on-going specialty care if a primary care provider, in consultation with the patient, the medical director of the plan and specialist (if any) determine that a standing referral is needed.

**Continuity of Care.** If a plan or provider terminates a contract for reasons other than failure to meet quality requirements, the plan must allow an enrollee continued treatment with the provider for a transitional period. Time frames vary depending upon type of care being provided (e.g. primary, institutional, pregnancy, terminal, etc.)

**Participation in clinical trials.** If an enrollee has a serious condition for which there is no effective standard treatment and is eligible for an approved clinical trial that offers the potential for substantial clinical benefit, the plan must pay for the routine patient costs of participation in the trial.

**Choice of Provider.** A plan must provide an updated list of all participating providers and their ability to accept additional patients. Enrollees must be permitted to obtain services from any provider within the plan identified in the plan documents as available to the enrollee.

**Prescription Drugs.** If a plan provides benefits for prescription drugs within a formulary, the plan must allow physicians to participate in the development of the plan formulary, disclose the nature of formulary restrictions, and provide for exceptions when medically necessary.

### **Subpart 2: Quality Assurance**

**Internal quality assurance program.** Every plan is required to establish and maintain a quality assurance and improvement program that uses data based on both performance and patient outcomes.

**Collection of standardized data.** Plans must report certain standard information to state agencies and the public. The information must be reported in accordance with uniform national standards to be specified by the Secretary. This information will include at least utilization data, demographic data, mortality rates, disenrollment statistics and satisfaction surveys, and quality indicators.

**Selection of providers.** The plan must have a written process for selection of providers including a listing of the professional requirements. The process must include verification of the provider's credentials. Plans may not use a high risk patient base or a provider's location in an area serving residents with poor health status as a basis for exclusion.

**Drug utilization program.** If the plan covers prescription medications, it must have a plan to encourage appropriate drug use and monitor and reduce illness arising from improper use.

**Standards for utilization review activities.** Utilization review refers to the plan's review of requests for care. It is defined as evaluation of clinical necessity and efficacy. Written clinical review criteria are required. Utilization review must be supervised by a licensed physician. Its activities must be executed by appropriately qualified staff. There can be no incentives to render adverse determinations. Deadlines for response to requests for authorization of care are established. Adverse determinations must be in writing and include the reasons for the determination. Such notices must also include instructions for making an appeal.

### **Subpart 3: Patient Information**

**Patient Information.** Plans must describe and make available to current and prospective enrollees procedures for providing emergency care and care outside normal business hours, for selecting and changing physicians, and for obtaining consultations. They must also list participating providers by category and make clear which members of that list are available to a prospective or current enrollee. The plan must provide information which describes coverage, financial responsibilities of enrollees, methods of obtaining referrals, utilization review processes, and grievance procedures and must include a description of how the plan addresses the needs of non-English speaking enrollees and others with special communication needs. It must describe how providers are paid.

**Protection of patient confidentiality.** A program to assure compliance with state and federal confidentiality requirements must be in place.

#### Subpart 4: Grievance Procedures

**Provisions relating to appeals of utilization review determination and similar determinations.** A plan must establish and maintain a system to handle and resolve complaints brought against the plan by enrollees and providers. The system should address all aspects of the plan's services, including complaints regarding quality of care, choice and accessibility of providers, and network adequacy. The legislation specifies several components of such a system, including provisions for staffing and staff accessibility, information about appeal procedures, and the time frame within which the plan must respond to complaints. The bill provides for a two stage appeal process, with requirements for a review panel of non-involved providers and consultants employed by the plan in the second phase. Written explanation of each stage of an appeal must be provided. Timely decisions are required. Examples of adverse determinations include denial for emergency care, access to specialists, choice of provider, continuity of care, or payment for routine costs in connection with an approved clinical trial. In the case of experimental therapy to save the life of a patient, an external independent review process with mandatory decision powers is available if the plan chooses not to provide coverage for the treatment. For appeals of other important issues, the plan must either (1) participate in an independent review process established by the state (or the Secretary of Labor for self-insured plans) to make advisory determinations; or (2) establish a third stage of appeal within the plan certified by the Secretary as fair, impartial, and involving independent reviewers to make advisory decisions.

**Health Insurance Ombudsman.** A Health Insurance Ombudsman will be established in each state to assist consumers in choosing health insurance, and to provide assistance to patients dissatisfied with their treatment. Assistance includes aiding enrollees in filing complaints and appeals, investigating poor quality or improper treatment, and bringing such instances to the attention of the applicable state authority or, in the case of self-insured insurance plans, to the attention of the Secretary of Labor. The legislation authorizes funds to be appropriated to the Secretary to provide grants to state authorities to establish the program.

#### Subpart 5: Protection of Providers against Interference with Medical Communications and Improper Incentives

**Prohibition of interference with certain medical communications.** The plan may not prohibit or restrict the provider from engaging in medical communications with the enrollee. Such communications may include discussion of the enrollee's health status, medical care, or treatment options; provisions of the plan's utilization review requirements; or any financial incentives that may affect the treatment of the enrollee.

**Ban on improper incentive arrangements.** There may be no incentives to limit medically necessary services. Provider risk is limited. The Secretary shall apply the same rules which apply to the Medicare program. The plan may not have a contract which requires transfer of liability for malpractice caused by the plan from the plan to the provider.

#### Subpart 6. Promoting Good Medical Practice and Protecting the Doctor-Patient Relationship

Plans are prohibited from denying coverage for medically necessary and appropriate care otherwise covered by the plan, as determined by the treating physician and consistent with generally accepted principles of good medical practice. This provision would prohibit plans from arbitrarily limiting care provided, for example, by requiring that mastectomies be provided on an outpatient basis.



# News from Congresswoman Sue Kelly

## ***The Women's Health & Cancer Rights Act of 1997 - Endorsees/Supporters***

To date, the following organizations have endorsed or are supporting the *Women's Health & Cancer Rights Act of 1997* - even before its formal introduction in either the House or the Senate:

The American Cancer Society  
The American Medical Association  
The Alliance with the Medical Society of the State of New York  
The American Association of Nurse Anesthetists  
The American Physical Therapy Association  
The Center for Patient Advocacy  
The Susan G. Komen Breast Cancer Foundation  
The Greater New York Hospital Association  
The Memorial Sloan-Kettering Cancer Center (NY)  
The National Association of Breast Cancer Organizations  
The National Breast Cancer Coalition  
The National Coalition for Cancer Research  
The New York State Chapter of the American Cancer Society  
The New York State Chapter of the American College of Obstetricians & Gynecologists  
The New York State Medical Society  
"1 in 9" - The Long Island (NY) Breast Cancer Action Coalition  
The Strang-Cornell Prevention Center (NY)

-o-

Here's what just a few of them had to say...

"We agree that medical decisions should be made by doctors, not by insurance companies. We also share your concern about the impact of managed care on the quality of care for persons with cancer. You are to be commended for your commitment to improving the care of women with breast cancer."

*The National Coalition for Cancer Research (January 14, 1997)*

"As you know, the diagnosis of cancer can be devastating -- not only must patients confront an array of medical decisions, they must deal with the financial and emotional burdens as well...(So) Like you, we strongly oppose the arbitrary limitation of available treatments for patients with cancer, including limits on hospital services that are put into some health plans...We thank you for taking the leadership on issues that are critical to cancer patients."

*The New York State Cancer Society (January 15, 1997)*



## News from Congresswoman Sue Kelly

### *The Women's Health & Cancer Rights Act of 1997 - Original Sponsors & Co-Sponsors*

To date, here is a complete listing of both the Senate and House original sponsors and co-sponsors of the *Women's Health & Cancer Rights Act of 1997*:

#### *U.S. Senate -*

##### *Original Sponsors:*

Sen. D'Amato (R-NY)  
Sen. Feinstein (D-CA)  
Sen. Hollings (D-SC)  
Sen. Snowe (R-ME)

##### *Original Co-Sponsors (11):*

Sen. Biden (D-DE)  
Sen. Domenici (R-NM)  
Sen. Faircloth (R-NC)  
Sen. Ford (D-KY)  
Sen. Gregg (R-NH)  
Sen. Hatch (R-UT)  
Sen. Inouye (D-HI)  
Sen. Moseley-Braun (D-IL)  
Sen. Moynihan (D-NY)  
Sen. Murkowski (R-AK)  
Sen. Smith (R-NH)

#### *U.S. House of Representatives -*

##### *Original Sponsors:*

Rep. Kelly (R, NY-19)  
Rep. LoBiondo (R, NJ-3)  
Rep. Molinari (R, NY-13)

##### *Original Co-Sponsors (51):*

Rep. Ackerman (D, NY-5)  
Rep. Andrews (D, NJ-1)  
Rep. Bilbray (R, CA-49)  
Rep. Brown (D, FL-3)  
Rep. Christian-Green (D, VI-At Large)  
Rep. Coadit (D, CA-18)  
Rep. Davis (R, VA-11)  
Rep. Deal (R, GA-9)  
Rep. Dunn (R, WA-8)  
Rep. English (R, PA-21)  
Rep. Filner (D, CA-50)  
Rep. Flake (R, NY-6)  
Rep. Forbes (R, NY-1)  
Rep. Foley (R, FL-16)  
Rep. Ford (D, TN-9)  
Rep. Fox (R, PA-15)  
Rep. Frost (D, TX-24)  
Rep. Ganske (R, IA-4)  
Rep. Gibbons (R, NY-2)  
Rep. Gilman (R, NY-20)  
Rep. Granger (R, TX-8)  
Rep. Green (D, TX-29)  
Rep. Gutierrez (D, IL-4)  
Rep. Horn (R, CA-38)  
Rep. Jackson-Lee (D, TX-18)  
Rep. King (R, NY-3)  
Rep. Kleczka (D, WI-4)  
Rep. LaFalce (D, NY-29)  
Rep. Lazio (R, NY-2)  
Rep. Lofgren (D, CA-16)  
Rep. Martinez (D, CA-31)  
Rep. McCarthy (D, NY-4)  
Rep. McNulty (D, NY-21)  
Rep. Morella (R, MD-8)  
Rep. Ney (R, OH-18)  
Rep. Oliver (D, MA-1)  
Rep. Pallone (D, NJ-6)  
Rep. Pappas (R, NJ-12)  
Rep. Price (D, NC-4)  
Del. Romero-Barcelo (D, PR-At Large)  
Rep. Roubema (R, NJ-5)  
Rep. Saxton (R, NJ-3)  
Rep. Sanders (I, VT-At Large)  
Rep. Shaw (R, FL-22)  
Rep. Slaughter (D, NY-28)  
Rep. Smith (R, NJ-4)  
Rep. Smith (D, WA-9)  
Rep. Stabenow (D, MI-08)  
Rep. Walsh (R, NY-25)  
Rep. Weiler (R, IL-11)  
Rep. Wolf (R, VA-10)

Women's Health and  
Cancer Rights Act of 1997  
D'Amato-Feinstein-Snowe Bill

MASTECTOMY, LUMPECTOMY PROVISION

- Senator D'Amato's legislation would address the problem of the so-called "drive-through mastectomies".
- "This is about patients' rights, and about ensuring the highest quality medical care for women and men in this country, the decision on length of stay must be left to the patient and the physician, not the insurance companies. We cannot leave the matter of one's health up to an arbitrary time frame,"
- The bill guarantees coverage of inpatient hospital care for mastectomies, lumpectomies, and lymph node dissection for the treatment of breast cancer for a period of time as is determined by the attending physician in consultation with the patient to be medically appropriate.
- The decision on length of stay is made by the patient and the physician, not the insurance company.

PROTECTION FOR DOCTORS

- The bill also guarantees that physicians will not be penalized for recommending proper medical care.
- The bill also prohibits HMOs from making payments to health care providers as an incentive to reduce or limit care to their patients.

RECONSTRUCTIVE SURGERY

- “It is mentally and physically imperative that women have the option to undergo reconstructive surgery after a mastectomy. To say this type of surgery is cosmetic is to deny the painful physical and emotional realities of a mastectomy. Under no circumstances should the insurance company be allowed to deny coverage for a woman in this position.”
- Reconstructive surgery coverage is provided for all stages of reconstruction including symmetrical reconstruction.
- Studies have documented that the fear of losing a breast is a leading reason why women do not participate in early breast cancer detection programs. With breast reconstruction available as a viable option more women would participate in detection programs and discover the cancer at an early stage.

#### SECOND OPINIONS PROVISION

- The bill would require health care providers to provide coverage for secondary consultations whenever any cancer has been diagnosed by the patient’s primary physician.
- The health plan would be required to cover second opinions even when the specialist finds that the patient does not have cancer.
- Additionally, if the attending physician recommends consultation by a specialist not in the HMO’s plan, the bill would allow the doctor to refer a patient to a specialist outside the plan, at no additional cost to the patient.

**List of Additional Co-Sponsors for the Reconstructive Breast Surgery Benefits Act of 1997****Update: February 26, 1997**

1. Rep. Patsy Mink (D-HI)
2. Rep. Louise Slaughter (D-NY)
3. Rep. Martin Frost (D-TX)
4. Rep. Rosa DeLauro (D-CT)
5. Rep. James P. McGovern (D-MA)
6. Rep. Edolphus Towns (D-NY)
7. Rep. Linsey Graham (R-SC)
8. Rep. Eleanor Holmes-Norton (D-DC)
9. Rep. George Miller (D-CA)
10. Rep. Jack Quinn (R-NY)
11. Rep. Ellen Tauscher (D-CA)
12. Rep. Julia Carson (D-IN)
13. Rep. Zoe Lofgren (D-CA)
14. Rep. John Lewis (D-GA)
15. Rep. Emi Faleomavaega (D-AS)
16. Rep. Carolyn Maloney (D-NY)
17. Rep. Bobby Rush (D-IL)
18. Rep. William D. Delahunt (D-MA)
19. Rep. Sam Gejdenson (D-CT)
20. Rep. Maurice D. Hinchey (D-NY)
21. Rep. James A. Traficant (D-OH)
22. Rep. David Bonior (D-MI)
23. Rep. Vic Fazio (D-CA)
24. Rep. Sidney Yates (D-IL)
25. Rep. Lane Evans (D-IL)
26. Rep. Nancy Pelosi (D-CA)
27. Rep. Henry Waxman (D-CA)
28. Rep. Sheila Jackson-Lee (D-TX)
29. Rep. James L. Oberstar (D-MN)
30. Rep. Loretta Sanchez (D-CA)
31. Rep. Steve Rothman (D-NJ)
32. Rep. Ronald Dellums (D-CA)

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**Rep. Anna Eshoo**

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February 4, 1997

COMMITTEE ON COMMERCE  
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TELECOMMUNICATIONS AND FINANCE  
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REGIONAL WHP  
CO-CHAIR  
MEDICAL TECHNOLOGY CAUCUS

Anna G. Eshoo  
14th District, California  
Congress of the United States  
House of Representatives  
Washington, DC 20515-0514

**Q: WHAT DO THESE TWELVE ORGANIZATIONS HAVE IN COMMON?**

*The American Cancer Society*  
*The National Breast Cancer Coalition*  
*The Breast Cancer Fund*  
*Breast Cancer Action of San Francisco*  
*The American Society of Plastic and Reconstructive Surgeons*  
*The American College of Surgeons*  
*The Breast Reconstruction Advocacy Project*  
*The Y-ME National Breast Cancer Organization*  
*The Community Breast Health Project*  
*The American Society of Plastic and Reconstructive Surgical Nurses*  
*The Association of Women Surgeons*  
*The Bay Area Breast Cancer Network*

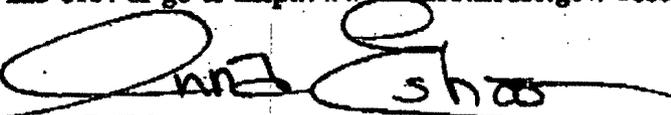
**A: THEY ALL ENDORSE THE RECONSTRUCTIVE BREAST SURGERY BENEFITS ACT OF 1997 (H.R. 164) TO GUARANTEE THAT INSURANCE COMPANIES PROVIDING COVERAGE FOR MASTECTOMIES ALSO COVER THE COST OF RECONSTRUCTIVE BREAST SURGERY.**

Dear Colleague:

Please join with me and eighteen of our House colleagues from both parties, and twelve of our nation's leading cancer patient advocacy groups in supporting this important legislation.

The broad support for the Reconstructive Breast Surgery Benefits Act reflects a growing recognition that reconstructive breast surgery is essential to the physical and mental recovery of breast cancer patients who undergo mastectomies. Insurance companies that dismiss reconstructive breast surgery as merely 'cosmetic' either do not know the realities of breast cancer or have a callous disregard for the needs of women who have survived this horribly disfiguring disease.

For the sake of the women in your district -- and their families -- I urge you to cosponsor this critical piece of legislation. A recent Washington Post article outlining the significance of H.R. 164 is on the back of this letter. If you are interested in more information, please contact my staff person, Kristin Holman at 225-8104 or go to <http://www.eshoo.house.gov/reconstructivefax.html> on the World Wide Web.

  
Anna G. Eshoo  
Member of Congress

## **Fact Sheet: the Reconstructive Breast Surgery Benefits Act Introduced by Rep. Anna G. Eshoo (D-CA)**

The Reconstructive Breast Surgery Benefits Act would amend the Public Health Service Act and Employee Retirement Income Security Act to do the following:

- require health insurance companies that provide coverage for mastectomies to cover reconstructive breast surgery that results from those mastectomies (including surgery to establish symmetry between breasts);
- prohibit insurance companies from denying coverage for breast reconstruction resulting from mastectomies on the basis that the coverage is for cosmetic surgery;
- prohibit insurance companies from denying a woman eligibility or continued eligibility for coverage solely to avoid providing payment for breast reconstruction;
- prohibit insurance companies from providing monetary payments or rebates to women to encourage such women to accept less than the minimum protections available under this Act;
- prohibit insurance companies from penalizing an attending care provider because such care provider gave care to an individual participant or beneficiary in accordance with this Act; and
- prohibit insurance companies from providing incentives to an attending care provider to induce such care provider to give care to an individual participant or beneficiary in a manner inconsistent with this Act.

The Reconstructive Breast Surgery Benefits Act would NOT:

- require a woman to undergo reconstructive breast surgery;
- apply to any insurance company that does not offer benefits for mastectomies;
- prevent an insurance company from imposing reasonable deductibles, coinsurance, or other cost-sharing in relation to reconstructive breast surgery benefits;
- prevent insurance companies from negotiating the level and type of reimbursement with a care provider for care given in accordance with this Act; and
- preempt state laws that require coverage for reconstructive breast surgery at least equal to the level of coverage provided in this Act.

## Medicare Cancer Clinical Trial Coverage Act of 1997

(previously S. 1963 in the 104th Congress)

Sponsored by Senators Rockefeller and Mack

Senate Cosponsors of S. 1963: Lott, Inouye, Hollings,

Hutchison, Leahy, Mikulski, Boxer, Moynihan,

D'Amato, Inhofe, Craig, Exon, and Cochran

### Current Law

Medicare's policy regarding coverage of clinical trials is unclear. Medicare carriers occasionally deny coverage of physician services or hospital charges on the grounds that they have been provided in the context of a clinical trial. Patients or physicians may be at risk for the cost of items or services that are normally covered by Medicare if they choose to enroll in a clinical trial, even though such trials are regarded as the standard of care for treatment of cancer.

### Proposed Change

The Secretary of HHS would be required to conduct a demonstration project, beginning no later than January 1, 1998, which would study the feasibility of covering patient costs for beneficiaries diagnosed with cancer and enrolled in certain approved clinical trials. Eligibility for coverage would be dependent on approval of the trial design by one of several high quality peer-review organizations, including the National Institutes of Health, the Food and Drug Administration, the Department of Defense, and the Department of Veterans Affairs. No later than January 1, 2002, the Secretary would be required to report to Congress concerning any incremental costs of such coverage and the advisability of covering other diagnoses under the same circumstances. The demonstration project would sunset on June 30, 2002.

### *Supported by:*

National Coalition for Cancer  
Survivorship

Candlelighters Childhood  
Cancer Foundation

Cancer Care, Inc.

National Alliance of Breast Cancer  
Organizations (NABCO)

US TOO International

Y-ME National Breast

Cancer Organization

American Cancer Society

American Society of Clinical Oncology

American Society of Pediatric  
Hematology/Oncology

Association of American Cancer  
Institutes

Association of Community Cancer  
Centers

Cancer Research Foundation  
of America

North American Brain Tumor Coalition

Leukemia Society of America

National Breast Cancer Coalition

National Childhood Cancer Foundation

National Coalition for Cancer Research

Oncology Nursing Society

Prostate Cancer Support-group Network

Society of Surgical Oncology

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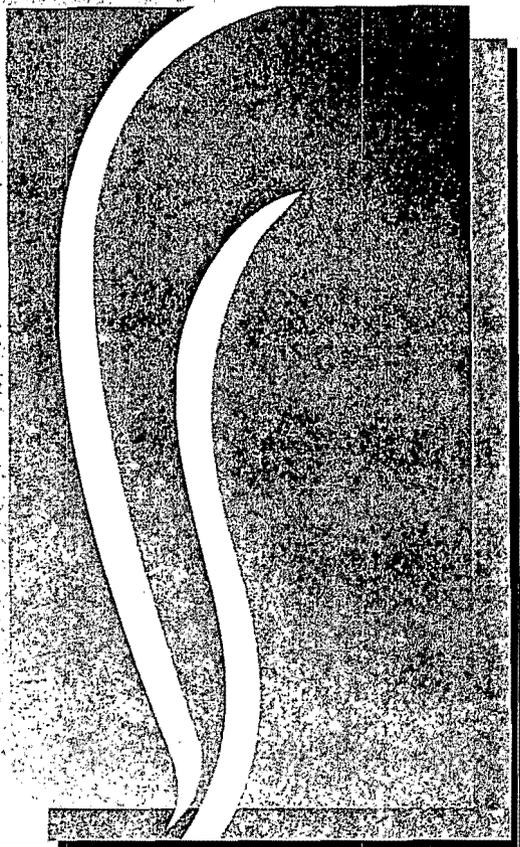
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# BREAST CANCER

# FACTS & FIGURES

# 1996



*Revised December 1995*

# FACTS

## About Funding Year-by-Year

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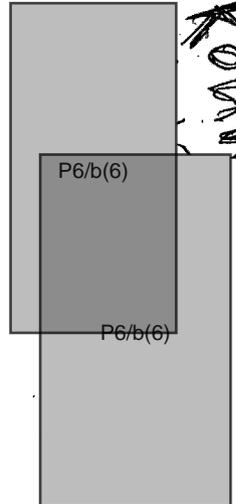
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Breast cancer

The following represent funds appropriated by Congress in each fiscal year for breast cancer research within the Department of Defense. (Totals appear in bold type; if applicable, subtotals are in italics.)

FY 1992	<b>\$25 million</b> <i>For research on screening and diagnosis for military women and dependents</i>
FY 1993	<b>\$210 million</b> <i>For the Breast Cancer Research Program</i>
FY 1994	<b>\$30 million</b> <i>\$25 million for the Breast Cancer Research Program \$5 million for a breast cancer Center of Excellence at the National Navy Medical Center</i>
FY 1995	<b>\$150 million</b> <i>\$115 million for the Breast Cancer Research Program \$20 million for mammography efforts \$15 million for dedicated breast cancer centers</i>
FY 1996	<b>\$75 million</b> <i>For the Breast Cancer Research Program</i>
FY 1997	<b>\$112.5 million</b> <i>\$100 million for the Breast Cancer Research Program \$6 million for computer-based decision support systems \$3 million for computer-aided diagnostic research \$3.5 million for an advanced cancer cell detection center</i>

Naval  
Kofas



# FACTS

## About the Department of Defense Breast Cancer Research Program (BCRP)

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### Overview

The *Department of Defense Breast Cancer Research Program* is an unprecedented partnership between the military, scientists, physicians, and the community, bringing together disparate spheres of interest to create a highly focused scientific endeavor. The program differs significantly from traditional biomedical research while maintaining the highest standards of scrutiny in peer review. Unlike any other major research program, the BCRP is distinguished in part by the involvement of survivors of the disease in key decisions. The BCRP offers grants in three major areas: multidisciplinary research; training and recruitment, including through fellowships, special sabbaticals and career development; and enhancement of the research infrastructure, such as funding tissue banks. The BCRP is intended to invigorate research in breast cancer by quickly responding to promising avenues of inquiry, fostering new directions in research, addressing neglected or under-studied issues, ushering new scientists into the field of breast cancer, and providing breast cancer survivors a seat at the table -- all with the goal of eradicating the disease.

### Genesis of the Breast Cancer Research Program

It was through the vocal and persistent grassroots efforts of breast cancer survivors, led by the National Breast Cancer Coalition, that Congress agreed to earmark more federal funds to research breast cancer, one of the most significant public health problems in this country. From an initial \$25 million appropriation in fiscal year 1992 to research the screening and diagnosis of breast cancer among military women and dependents, the BCRP has expanded to become second only to the National Cancer Institute in the funding of breast cancer research. To date, Congress has appropriated a total of approximately \$600 million for the program.

### Key Components of the Breast Cancer Research Program: Advocacy and Innovation

One of the most important and innovative aspects of the BCRP is that selected breast cancer survivors are actively engaged as voting members on the panel which decides the direction of the program itself, and scientific panels which review grant proposals. Their first-hand experience with the disease adds a sense of urgency and passion, ensuring that the research focuses on what matters most to women with breast cancer. At the same time, their interaction with scientists gives these breast cancer survivors a richer understanding and appreciation of the realities and challenges researchers face in the laboratory. Involving breast cancer survivors has furthermore enhanced the program's efforts to address the needs of rural, low-income and minority populations to help make breast cancer education, diagnosis and treatment more widely available to all women.

To stimulate and give life to the most creative and cutting-edge scientific ideas, the *Breast Cancer Research Program* initiated the Innovative Developmental and Exploratory Awards (IDEA) category of grants. These IDEA projects are the seeds of scientific inquiry that will eventually feed and strengthen traditionally funded research. They encourage the pursuit of novel, untested and high-risk ideas as well as the participation of young, promising scientists or researchers who might not otherwise study breast cancer. This category of grants has grown dramatically within the program, and IDEA projects currently represent more than half of the new grants in the BCRP, complementing rather than competing with research programs at other institutions including the National Institutes of Health.

### Research Portfolio at a Glance

The *Breast Cancer Research Program's* funding portfolio includes over 1,000 grants to scientists from all disciplines related to breast cancer, including the fields of molecular biology, genetics, radiology, and behavioral science. The scientists, from 828 institutions in the U.S. and abroad, are investigating new methods to prevent, detect, diagnose, and treat breast cancer, and facilitate recovery and improve the quality of lives of women diagnosed with breast cancer. While the program is still in its early years, the scientists involved have already published more than 380 manuscripts about their work and participated in more than 300 national and international meetings to share the knowledge they have gained. Researchers currently hold nine patents or licenses for advances resulting from the *Department of Defense Breast Cancer Research Program*.

National Aeronautics and  
Space Administration

Fax Number: 202/358-4345  
Office Number: 202/358-1898

Headquarters

Office of Public Affairs  
Associate Administrator

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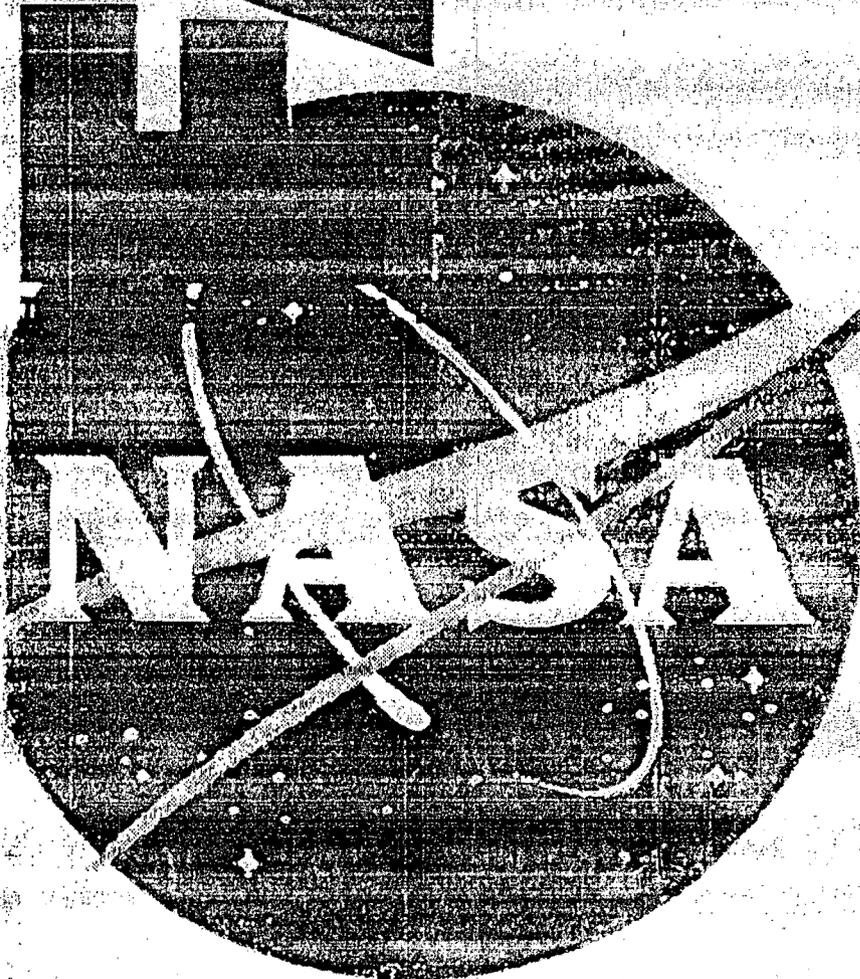
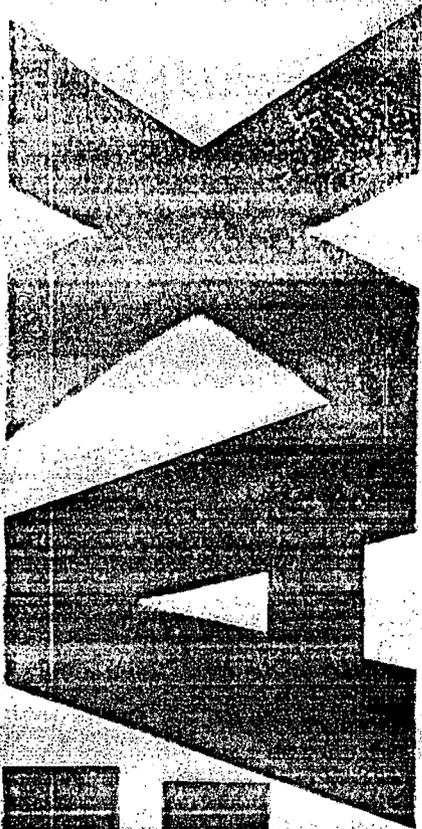
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## SPACE TECHNOLOGY USED TO DETECT AND TREAT BREAST CANCER

NASA research and technology is revolutionizing American lifestyles in many ways, including improving ways to diagnose and treat breast cancer. NASA, teaming with industry, academia, and government, is applying aerospace research and technology to battle the leading cause of death among American women ages 35 to 50.

### IN YOUR DOCTOR'S OFFICE TODAY

#### Digital Breast Imaging Technology

From NASA's investigations into the mysteries of the universe comes technology to better detect breast cancer. Silicon chips used in the Hubble Space Telescope were adapted so doctors can easily detect tiny spots in breast tissue and analyze the tissue using a needle rather than subject a patient to painful surgery. This procedure also eliminates scarring or disfigurement, requires half the time of traditional techniques, reduces exposure to x-rays, and reduces cost from \$3,500 to \$850.

### TOMORROW'S TECHNOLOGY

#### Next-Generation Digital Imaging Mammography

Space-based instruments studying the atmosphere will soon be in the medical examination room. NASA is developing a mammogram to produce an image of the entire breast and provide a better image — two times better than currently available — to identify tumors. Current technology does not allow doctors to view the entire breast. This approach also is significant because it will accommodate different tissue density, which is particularly important for younger women who have more dense tissue.

#### Telemammography

NASA expertise in transmitting high-resolution digitized photographs has led to improvements in global satellite networks. Soon, women in rural areas will have a link to medical experts across the country using these networks. This new technology will be more cost-effective and faster than traditional transmission of data through telephone lines, which can take hours to transmit one image. High-resolution mammography also will help doctors detect breast cancer tumors earlier.

#### Tissue Growth in the NASA Bioreactor

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

#### Advanced Ultrasound Technology

Mars Pathfinder technology developed to enhance pictures is being modified to make three-dimensional models of breast tissue. Combining ultrasound with advanced computing, the imaging device discerns cancerous from healthy tissue by comparing changes in shape and analyzing the ultrasound signal. This enables doctors to differentiate the tissue more accurately without using painful invasive procedures.

#### Smart Robot Brain Surgeon Probe Adapted for Cancer Detection

Technology being developed for surgery on astronauts in space is being adapted to help physicians operate on delicate parts of the human body and minimize harm to healthy tissue. The robot maps the physical characteristics of the brain, allowing the surgeon to make precise movements and reduce potential damage to nearby healthy tissue. Researchers plan to teach the robot to feel and see tumors in other parts of the body, such as the breast. One component includes a small probe that may allow real-time measurement and analysis of a breast cancer tumor to determine its severity and appropriate treatment.

### NASA'S SPACE TECHNOLOGY PROMISES A HEALTHIER TOMORROW FOR WOMEN

Women's Outreach Initiative • Office of Public Affairs • National Aeronautics and Space Administration • October 1997

NASA  
FACTS

**Teresa Hudkins, 10/22/1997 5:30 PM -0400, PR**

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**Telermammography**

Photos: ACTS Satellite

93-HC-527 color; 93-H-575 b&w

Video: Cleveland Clinic with 1 Interview 10/97

Interviews:

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**Teresa Hudkins, 10/22/1997 5:30 PM .0400, PR**

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Teresa Hudkins, 10/22/1997 5:30 PM -0400, PR

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### **Telemammography**

The most effective method for improving breast cancer survival is early detection. For women living in remote areas, access to mammography experts may be hundreds of miles away. Currently, the traditional transmission of data through telephone lines is slow and costly; it can take hours to transmit one image.

NASA technology will help provide quality medical diagnosis and information services to remote areas in a faster, more cost-effective manner.

Telemammography, the electronic transmission of digitized mammograms, can connect patients in rural locations with medical experts across the country.

NASA Lewis Research Center in Cleveland, Ohio, working with breast cancer research hospitals, including the Cleveland Clinic and the University of Virginia, is performing critical research to allow new satellite networks to support telemammography.

### **Tissue Growth in the NASA Bioreactor**

NASA's Johnson Space Center in Houston, Texas, is leading a project using the microgravity of space to assemble and grow human tissue for research and transplantation.

The bioreactor is a special tissue culture chamber designed by NASA to grow cells in three-dimension. One of the first experiments in this unique environment will allow cancer tissue to be assembled and grown from individual cells. The three-dimensional tissues are crucial to understanding cancer and how the human immune system responds. The bioreactor permits scientists to grow cells similar to tissues found in the human body. By testing three-dimensional tissues for sensitivity to chemotherapy and hormonal therapy, researchers gain valuable knowledge important to the treatment of breast and ovarian cancer.

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### **EDITOR'S NOTE:**

Photo and video resources and interview opportunities with contacts nationwide are provided below:

#### **Stereotactic Biopsy using HST technology**

- Photos: Stereotactic Biopsy Machine
  - 94-HC-168 color; 94-H-180 b&w
- Charged Coupling Device
  - 94-HC-169 color; 94-H-183 b&w
- Hubble Photos of Star Fields Using STIS
  - 97-HC-314 color; 97-H-314 b/w
- Hubble Space Telescope in space
  - 94-HC-10 color; 94-H-13 b&w
- Eagle Nebula Image using HST
  - 95-HC-631 color; 95-H-631 b&w

- Video resources: "War Against Breast Cancer" October 1995  
"Stereostatic" Testimonials, Aug. 1996 TRT 3:30

- Interviews: Space Telescope Science Institute:  
Mr. Ray Villard  
Director of Public Affairs

**Teresa Hudkins, 10/22/1997 5:30 PM -0400, PR**

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From research into the mysteries of the universe comes a technology to better detect breast cancer. Silicon chips in Hubble Space Telescope that convert a distant star's light directly into digital images has been adapted so doctors can easily detect tiny spots in breast tissue. Locating the exact spot allows doctors to analyze the tissue using a needle rather than by traditional surgery. This procedure is less painful and less traumatic for the patient and eliminates scarring or disfigurement. The new procedure requires half the time of traditional techniques and reduces costs from \$3500 to \$850.

The new technology images breast tissue more clearly and efficiently than conventional x-rays. Both the Hubble Telescope and mammograms require similar technology: high resolution to see fine details, wide dynamic range to capture in a single image structures spanning many levels of brightness, and low light sensitivity to shorten exposure and reduce x-ray dosage. The new highly sensitive Hubble-based technology is improving breast cancer detection. Scientists working with Hubble at NASA's Goddard Space Flight Center, Greenbelt, Maryland, continue to refine and develop this technology.

## **TOMORROW'S TECHNOLOGY**

### **Next Generation Digital Imaging Mammography**

Space-based instruments used to study the atmosphere may soon have a place in the medical examination room. This new approach is significant because it can accommodate different tissue density. This is particularly important for younger women, who have more dense tissue than older women. This new technology application is possible because atmospheric studies and mammography both require compact, reliable, low-power sensors and digital computers.

NASA is working with the National Institutes of Health on a prototype that would create an image of the entire breast with superior resolution.

The computer scans each part of every mammogram image and reports any suspicious areas. The electronic images can then be transmitted to other experts if more opinions are needed. Using the best mammogram technique currently available, tumors as small as 0.2 mm, about the thickness of a piece of thread, have been detected. The goal of digital mammography is to identify clearly tumors as small as 0.1 mm. The Langley approach will be faster, safer, easier to use and save countless lives.

### **Advanced Ultrasound Technology**

Technology developed to improve the quality of pictures from Mars Pathfinder is being modified to make three-dimensional models of breast tissue. The NASA effort, led by scientists at NASA's Ames Research Center's Computational Sciences Division, Mountain View, Calif., combines ultrasound with advanced computing, automated learning, and high-resolution imaging techniques developed for space missions. Using the three-dimensional model physicians will be able to differentiate between cancerous and healthy tissue without painful invasive procedures. The experimental system also will discern differences in tissue by comparing changes in shape and by analyzing the ultrasound signal. The system will potentially improve cancer treatment by focusing ultrasound signals on cancerous tissue without destroying healthy tissue.

### **Smart Robot Probe for Cancer Detection**

NASA technology being developed to perform surgery on astronauts in space is being adapted to help physicians operate on delicate parts of the human body, including the brain and the breast. Led by the NeuroEngineering Group at NASA's Ames Research Center, scientists have developed a robot that can map physical characteristics of the brain, allowing the surgeon to make precise movements during surgery. The technology is being modified further to have the robot feel tumors in other parts of the body to determine severity and appropriate treatment.

The density of cancerous tissue is different from healthy tissue. While a surgeon can, through experience, learn to feel the difference, the experimental robot can use a smaller, less invasive probe, and it can make more delicate and precise movements than a human, thus reducing damage to healthy tissue and arteries.

**Teresa Hudkins, 10/22/1997 5:30 PM -0400, PR**

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Date: Wed, 22 Oct 1997 17:30:07 -0400 (EDT)  
X-Sender: thudkins@mall.hq.nasa.gov  
Mime-Version: 1.0  
To: Roderic Olvera Young <ryoung@hq.nasa.gov>  
From: Teresa Hudkins <thudkins@hq.nasa.gov>  
Subject: PR

The newroom will have final tomorrow a.m.

October 23, 1997

Terrl Hudkins  
Headquarters, Washington, D.C.  
Phone (202/358-1977)

Feature: 97-02

### **Space Technology Used to Detect and Treat Breast Cancer**

NASA today announced how its research and technology is revolutionizing American lifestyles in many ways, including the diagnosis and treatment of breast cancer. Teaming with industry, academia and government, NASA joins the front lines in the battle against the disease and begins its October campaign for Breast Cancer Awareness Month.

"As a husband, father of two daughters, and a grandfather, few subjects are as important to me as women's health," said NASA Administrator Daniel S. Goldin. "That is why I am so proud of how NASA technologies, originally developed for our space and aeronautics programs, improve health care for women, men and children around the world."

Breast cancer is the leading cause of death of women ages 35 to 50 in the United States. More than half a million women undergo breast biopsies in the U.S. each year.

"The statistics of breast cancer are startling. Thanks to NASA technology, doctors are using a more sensitive and efficient diagnostic tool and a less painful, less traumatic procedure," said Administrator Goldin. "Looking to the future, NASA will continue to search for more ways to use technology for breast cancer diagnosis and treatment."

In addition to exploring space and developing aeronautics, NASA is charged with applying its technology to improve the quality of life.

"Our visionary researchers and entrepreneurs have made giant leaps in applying technology to medical uses. Who would have dreamed that we could map breast tissue by using the same technology for mapping distant stars?" he concluded.

Several NASA biomedical experiments have resulted in successful new technology programs between NASA, the National Institutes of Health, the National Cancer Institute and the U.S. Department of Health and Human Services Office on Women's Health.

**IN YOUR DOCTOR'S OFFICE TODAY**

**Digital Breast Imaging Technology**

Printed for Roderic Olvera Young <ryoung@hq.nasa.gov>

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October 1, 1997

**NATIONAL BREAST CANCER AWARENESS MONTH, 1997**

Message Creation Date was at 1-OCT-1997 15:02:00

THE WHITE HOUSE

Office of the Press Secretary

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For Immediate Release

October 1, 1997

NATIONAL BREAST CANCER AWARENESS MONTH, 1997

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BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

Every year we dedicate the month of October to focus on breast cancer and to reaffirm our national commitment to eradicate it. But for thousands of American women and their families and friends, breast cancer is a devastating reality that casts a shadow over their lives every day. In this decade alone, nearly half a million women will die of breast cancer, and more than 1.5 million new cases of the disease will be diagnosed.

Our greatest weapon in the crusade against breast cancer is knowledge; knowledge of its causes and knowledge about prevention and treatment. My Administration has established a National Action Plan on Breast Cancer to unite organizations across the country in a collaborative effort to find out more about the disease and how best to respond to it.

The Department of Health and Human Services is taking the lead in this national effort, through education and research at the National Cancer Institute and the Agency for Health Care Policy and Research; through nationwide screening and detection programs at the Centers for Disease Control and Prevention; through certification of mammography facilities by the Food and Drug Administration; through prevention services and treatment by health benefit programs such as Medicare and Medicaid; and through increased access to clinical treatment trials for cancer patients who are beneficiaries in Department of Defense and Department of Veterans Affairs programs. The Department of Defense has also initiated a breast cancer research program to reduce the incidence of breast cancer, increase survival rates, and improve the quality of life for women diagnosed with the disease.

We can be proud of the progress we have made. One of the most promising recent research achievements is our increased understanding of the role of genetics in the cancer process. We have learned that cancer is a disease of altered genes and altered gene function, and research into the relationship between breast cancer and genes is helping us to better understand the basis of the disease. However, we must ensure that progress in genetic information is used only to advance and to improve the Nation's health -- not as a basis for discrimination. That is why this year I have urged the Congress to pass a law that prevents health insurance plans from discriminating against individuals on the basis of genetic information.

more

(OVER)

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High-quality mammography has also proved to be a powerfully effective tool in the effort to detect breast cancer in its earliest, most treatable stage. The National Cancer Institute, the American Cancer Society, and many other professional organizations agree that women in their forties benefit from mammography screening, and earlier this year I was pleased to sign legislation that will help Medicare beneficiaries with cost-sharing for annual screening mammograms. The First Lady has also launched an annual campaign to encourage older women to use the Medicare mammography screening benefits.

We have real cause for celebration during National Breast Cancer Awareness Month this year: recent data show that the breast cancer rate for American women is declining. Heartened by this knowledge, let us reaffirm our commitment to the crusade against breast cancer. Let us ensure that all women know about the dangers of breast cancer, are informed about the lifesaving potential of early detection, receive recommended screening services, and have access to health care services and information. Let us continue to move research forward to improve treatments and find a cure for this disease.

Working

together, we can look forward to the day when our mothers, wives, daughters, sisters, and friends can live long, healthy lives, free from the specter of breast cancer.

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 1997 as National Breast Cancer Awareness Month. I call upon government officials, businesses, communities, health care professionals, educators, volunteers, and all the people of the United States to reflect on the progress we have made in advancing our knowledge about breast cancer and to publicly reaffirm our national commitment to controlling and curing this disease.

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

WILLIAM J. CLINTON

# # #

THE WHITE HOUSE  
WASHINGTON

November 17, 1997

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FG-001  
THE PRESIDENT HAS SEEN  
11-18-97

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN *Phil*  
SEAN MALONEY

SUBJECT: Recent Information Items

We are forwarding the following recent information items:

- (A) **Prostate Cancer Update from Chris Jennings** -- Chris has sent you a detailed memo responding to the issues raised with you recently and provides an overview of possible actions under review by the Administration. *Please see memo for details.*
- (B) **Berger Memo on Gulf War Veterans' Comp./Health Care Oversight Panel** -- responds to your question, "Is there a recommendation to create an oversight panel to review the handling of Gulf War veterans' compensation or health care?"; Sandy says the Presidential Advisory Committee (PAC) on Gulf War Veterans' Illnesses was not tasked to address benefits/compensation issues and he is not aware of any recommendation in any of the relevant GAO reports to create such a panel; notes that in its Special Report, the PAC did again recommend that VA incorporate Gulf War veterans into its health care case management process; NSC has tasked VA, along with other agencies, to respond to the PAC recommendations by December 19.
- (C) **Secy Glickman Lake Tahoe Follow Up**-- reports on Oct. 29 signing ceremony in Zephyr Cove, NV, following up on July's Lake Tahoe Summit; Gov. Miller, Washoe Tribe leaders and others made very supportive remarks (*i.e.*, you delivered on your commitments); Glickman signed a Federal Interagency Partnership Agreement, committing agencies to work together on the Lake, and an Intergovernmental Memorandum of Agreement, committing the States, Washoe Tribe, and Tahoe Regional Planning Agency to adhere to the Regional Planning Compact and to adopt and implement an environmental improvement program; Glickman also announced a package of deliverables from various agencies; media coverage was good; clips attached.
- (D) **Jacob Weisberg piece from Slate, "Big Tent Democrats"** -- Forwarded by Rahm. Weisberg writes that, "If Democrats are doing less infighting, it isn't because they've reached some sort of ideological consensus." Weisberg argues that the election of 1994 galvanized Democrats, but "as the Newt peril fades, Democratic differences are becoming clearer." [piece was written before fast-track was pulled].

THE WHITE HOUSE  
WASHINGTON

THE PRESIDENT HAS SEEN  
11-20-97

November 7, 1997

MEMORANDUM FOR THE PRESIDENT

*Jennings*

*copied  
Jennings  
COS*

FROM: Chris Jennings  
SUBJECT: Prostate Cancer  
cc: Bruce Reed

Responding to your interest in developments on the prostate cancer front, this memo summarizes our response to the issues that were raised with you recently and also provides an update on actions the Administration can take to help advance the fight against prostate cancer.

**BACKGROUND**

This year over 210,000 men are expected to be diagnosed with prostate cancer and over 42,000 men are projected to die from this disease (virtually the same number of women who die from breast cancer). Only lung cancer claims more cancer deaths for men.

Prostate cancer does not manifest itself in most men until they have reached traditional retirement age and, when it does, there are great disparities among minorities relative to incidence. In fact, fully 80 percent of those diagnosed with this disease are over age 65. African American men have an incidence rate over 35 percent higher than white men. Interestingly, Asian-Americans have an incidence rate that is less than half of white Americans. (Clinical trials are underway at NIH to determine the causes of these differences.)

**CONCERNS RAISED BY PROSTATE CANCER ADVOCATES**

The concerns that were recently raised to you and echoed by prostate cancer patient advocates, such as the American Cancer Society's Man to Man, USTOO, CaPCure (Michael Milken's foundation for prostate cancer), and Beth Kobliner Shaw are as follows: (1) Federal funding for prostate cancer research is inadequate, particularly relative to breast cancer and AIDS, (2) administrative shortcomings have unacceptably delayed the allocation of Defense Department prostate cancer research funds to scientists, and (3) there has been insufficient high level Administration attention paid to this devastating disease (some have suggested a White House-sponsored conference). The following responds to the concerns that have been raised.

**Issue: Prostate Cancer Research is Inadequately Funded.** *Response: Probably true, but depends on how you look at the numbers. The overall dollars for funding are low in comparison to some highly-publicized diseases such as breast cancer and AIDS. However, relative to other diseases, prostate cancer has increased significantly since you took office. Moreover, this issue is more complicated than simple dollar comparisons.* Overall spending on breast cancer still is more than four times that of prostate cancer research (\$625 million versus over \$140 million). According to NIH, this is due in part to limited opportunities for scientifically-sound prostate cancer-specific research. They also argue that there is a great deal of overlap in cancer research, so that the most promising leads in prostate cancer research may in fact result from dollars spent in research for another cancer. It seems clear though that the large amount of public attention to breast cancer has had a major impact on funding.

Notwithstanding the disparity of investments, significant increases in prostate cancer funding have occurred under your Administration and, as will be discussed below, more dollars are likely to be recommended in the very near future. Prostate cancer research has increased about 60 percent since 1993. Such an increase is substantial when compared with other major diseases, such as diabetes (11 percent increase) and heart disease (21 percent increase). Despite these numbers, it does appear that a good case can be made that research funding this type of cancer is inadequate.

**Issue: DoD Needs to Allocate Their Prostate Cancer Funding More Quickly.**

*Response: Partially true, but understandable since DoD has never had such funding before.* In an attempt to address the limitations in research spending imposed by the budget caps, the Appropriations Committees began in the early 1990s to allocate breast cancer research dollars in the Defense budget. Building on the Congress' build-up of breast cancer research at the DoD, Congress appropriated about \$45 million for prostate cancer in FY'97 and again this year. (Since the DoD believes biomedical research is not their mission, OMB has never suggested using DoD dollars for research in any budget proposal; however, this is something we might want to discuss in this year's budget.)

Although there has been excessive delay in getting these dollars out, DoD did just complete a multi-month consultative process with prostate cancer experts, patients, and advocates to find the best ways to fund top-of-the-line research. They have received over 600 grant proposals and plan to fund as many peer reviewed grants as possible by no later than next April.

**Issue: Prostate Cancer Needs a Higher Level Administration Focus.** *Response: We agree, and, in fact, the National Cancer Institute has already convened a high-level panel that will provide recommendations next Spring about new research opportunities and the need for more funding.* This process was pulled together in order to assess how to best move forward on some promising recent break-throughs in prostate cancer made in the last year, including:

(1) the discovery of a new hormone therapy which given after radiation therapy can prolong survival of patients with locally advanced prostate cancer; (2) the general location of the first heredity prostate cancer gene; and (3) the identification of hundreds of genes expressed in prostate cancer as the first cancer studied in the recently-launched Cancer Genome Anatomy Project (CGAP) at NIH.

## NEW ACTIONS UNDER REVIEW ON PROSTATE CANCER

**Increases in Prostate Cancer Research Funding.** The panel discussed above is scheduled to be completed by March and Dr. Rick Klausner, the NCI Director, fully expects that it will result in greater attention to and more funding of this disease. We are reviewing options to give this work even a higher profile. Preliminary discussions with NCI have led us to conclude that it may be possible for you to announce their Spring recommendations for more funding of prostate cancer research.

**Legislation for Medicare Coverage of Cancer Clinical Trials.** One of the highest priorities by the cancer research advocacy community is enacting a bill that would allow Medicare, for the first time, to cover cancer clinical trials. Having Medicare cover clinical trials would be particularly helpful to those with prostate cancer because: (1) most of the prostate victims are Medicare beneficiaries; (2) the lack of participation of elderly men in trials has undermined clinical research for the treatment, prevention, and screening for this disease; (3) given the promising new findings, NCI expects there will be an increase in clinical trials for prostate cancer, creating a need for even more participants.

We are working with HCFA, NIH, and OMB to develop a policy proposal, to cost it out, and to develop Medicare offsets. As of this writing, it appears that the policy we are considering could cost between \$1.5 billion and \$3 billion over 5 years. Even by Medicare standards, this option is a significant investment, particularly for a targeted new benefit. Having said this, it would have the dual benefit of increasing the number of cancer clinical trials and, in so doing, likely help encourage private sector plans to increase their coverage of these trials. This policy would be widely heralded by the scientific community, cancer patient advocates, and Senators' Mack and Rockefeller. If you decided you want us to pursue this initiative, we would of course have to determine how best to pay for it, whether to include it in your FY'99 budget and when best to announce it.

Currently, HCFA has the authority to pay for trials on procedures they believe have the potential to no longer be experimental. (This is different than payment for experimental trials, mentioned above, on drugs and devices not yet given FDA approval for certain kinds of treatments.) You recently saw a *USA Today* article referencing possible coverage for a trial on cryotherapy, a treatment that some think has the potential to reduce prostate cancer where the cancer has not yet spread. We have since learned that both HCFA and NIH are skeptical that the procedure merits coverage and may not authorize it. Having said this, it is encouraging that HCFA and NIH are working together to target such procedures for coverage.

**Revenue from the National Tobacco Legislation for a Major Increase in Research Funding and/or Raise Funds from Other Revenue Sources.** Another option currently being developed in the policy process is to call on the Congress to dedicate much of the new revenue from any tobacco legislation to a Trust Fund designed to vastly increase investments in biomedical research, including new increases in prostate cancer research. Senator Kennedy has just introduced his tobacco legislation bill, which includes provisions to use his assumed and unrealistically high tobacco revenue to be used, in part, to double the NIH budget. Senator Mack and Senator Harkin are also calling for a doubling of the budget. In addition, Donna Shalala's budget submission includes a new insurance premium tax to be used to eventually double the NIH budget. (If you are interested, I can send you a pro/con memo on this proposal.)

Certainly any such actions could be incorporated into a number of events that would visibly associate the Administration with an unprecedented new commitment to cancer research in general, and prostate cancer in particular. We will keep you informed of developments.