

PRESIDENT WILLIAM J. CLINTON
ANNOUNCEMENT OF NEW CANCER
INITIATIVES

THE ROSE GARDEN

OCTOBER 27, 1996

I want to thank all of you for joining me on a Sunday afternoon to discuss our efforts to fight cancer. I also want to thank Sec. Shalala and Dr. Susan Blumenthal, my Deputy Assistant Secretary for Women's Health, for their tireless service on behalf of women throughout America. Dr. Richard Klausner, the Director of the National Cancer Institute, and Dr. Steven Joseph, Assistant Sec. of Defense for Health, have both been instrumental in the efforts we are here to talk about today. I especially want to thank Jane Reese-Coulbourne for her courage and her dedication to find a cure for breast cancer.



Finally, I want to thank all of the survivors and advocates here today who are fighting the battle against cancer every day, for all of us.

I believe that America is only as strong as our families are healthy. And nothing is more devastating to a family than when someone is diagnosed with a life-threatening disease like cancer. I know this from my personal experience: my step-father died of cancer, and I lost my mother, Virginia, to breast cancer just under three years ago. Vice President Gore's sister died of cancer.

And this year alone, nearly 1.4 million American men, women and children will be diagnosed with cancer. I don't think there is a family in America that has not been touched by this disease.

This is the 25th anniversary of the National Cancer Act, and in those 25 years we have come a long way in our fight against cancer. This month is also Breast Cancer Awareness Month, a time to remember the terrible toll breast cancer has taken, to assess our progress and to redouble our efforts to find a cure. That is why I wanted us to come together today: to talk about the new steps we are taking to fight all cancer . . . and breast cancer in particular.

Since I took office, this Administration has mounted a comprehensive campaign to prevent and treat cancer. We are working to get tobacco out of our children's lives forever. We have accelerated FDA approval of cancer drugs and made it easier for patients to obtain promising therapies before they are formally approved. The Department of Health and Human Services, the Department of Defense, NASA and the CIA have joined forces to develop cutting edge imaging technology for the early detection of cancer. Most important of all, we have increased spending on cancer research, treatment and prevention by \$400 million.

In the battle against breast cancer, we have increased funding for research and prevention by nearly 80% since 1993. We launched a public awareness campaign to encourage older women to use Medicare to have mammograms. And my balanced budget goes even further -- it will guarantee free annual mammograms to Medicare beneficiaries, removing financial barriers that prevent some women from obtaining this vitally important test.

We are making progress. The survival rate for cancer has gone up -- 7 out of 10 children with cancer survive it -- that's up from 1 out of 10 twenty-five years ago.

The death rate for breast cancer has gone down every year in the last seven -- it has dropped by nearly 8% since 1990. Just last week, the NIH announced a milestone in the Human Genome Project, which is identifying the location and function of nearly every human gene. We have now mapped out 20% of all human genes -- and anyone can use that map on the Internet. Soon, we will know the genes that contribute to cancer and our genetic predisposition to inherit it -- and possibly prevent it before it strikes.

But as far as we have come, we still have far to go. We must continue to build on our progress and strengthen our efforts against cancer.

Today, I am announcing three new steps that will bring us closer to a cure and improve the lives of those who do survive.

First, we know that genetic research may be the key to understanding -- and curing -- breast cancer. In the last two years, scientists have discovered two genes that indicate susceptibility to breast cancer. This remarkable discovery is giving hope to women everywhere. Last month I signed a budget that reflects our values and devotes substantial resources to cancer research.

Today, I am announcing that we are directing \$30 million out of that new budget to support and expand breast cancer genetic research at hospitals, universities and labs across the country. This step -- which represents a major increase in breast cancer genetic research -- will ensure the development of this promising new research and bring us that much closer to a cure.

Second, we must use all the technology at our disposal to give women the information they need about breast cancer, and we must unite the forces of the public and private sectors to achieve this goal.

That is why I am pleased to announce the launch of the new National Action Plan on Breast Cancer Website on the Internet. This easily accessible website -- the address is right here -- will answer the questions women have about early detection, clinical trials, and much more.

Finally, there is no greater proof of the progress we have made than the more than 10 million Americans who have survived cancer. Many have special psychological, physical and health care counseling needs that we are only beginning to understand -- some face recurrence of their illness; some can't get health insurance.

I am proud to have passed landmark legislation to guarantee that cancer survivors will no longer live in fear of losing their health care coverage because they have a pre-existing condition. And today I am announcing that this Friday, November 1st, the National Cancer Institute will open its new Office of Cancer Survivorship. This office will support much needed research that will help cancer survivors deal with the problems they face even after their cancer is cured.

With these steps we are taking today, we are putting science at the service of our families, and saying that we will do whatever it takes in our fight to find a cure for cancer, and to improve the lives of those who do survive.

Just a few moments ago in the Oval Office, I signed a piece of the Ribbon of Hope. This yellow ribbon, which is already over 750 feet long in its entirety, has been signed by more than 10,000 cancer survivors around the world.

My wife Hillary was the first person to sign the Ribbon, and I was honored to place my own signature alongside those of so many courageous people.

This ribbon is a symbol of the hope that sustains people in their struggle with cancer . . . but it is also a symbol of the progress we have made, and the progress still to come in our fight against cancer.

And now, I would like to present the piece of the Ribbon of Hope that I signed to Erin Schraibman [shrayb-man].

Thank you and God bless you all.

PRESIDENT CLINTON ANNOUNCES NEW CANCER INITIATIVES

Sunday, October 27, 1996

In honor of National Breast Cancer Awareness month and the 25th anniversary of the National Cancer Act, President Clinton today will announce three important new initiatives that will build on his Administration's efforts to fight breast cancer and to address the needs of cancer survivors.

The new initiatives being announced by the President are: (1) a \$30 million increase in funding for new research into the genetic basis of breast cancer, through a collaborative initiative between the Departments of Defense and Health and Human Services; (2) the opening of a breast cancer web page site, a recommendation of the National Action Plan on Breast Cancer, a public-private partnership created under the Clinton Administration; and (3) the new Office of Cancer Survivorship in the National Cancer Institute, which will research issues relating to the physical, psychological, and economic well-being of the growing number of cancer survivors in this country.

Prior to his announcement in the Rose Garden, President Clinton will meet in the Oval Office with five cancer survivors and their families and sign a ribbon, the symbol of the nation's fight against breast cancer. They will be joined by Susan Blumenthal, Deputy Assistant Secretary in charge of the Office of Women's Health at the Department of Health and Human Services; Steven Joseph, Assistant Secretary for Defense for Health Affairs, Rick Klausner, Director of the National Cancer Institute, Ellen Stovall, Executive Director of the National Coalition for Cancer Survivorship; and Elizabeth Clark, Director of the National Coalition for Cancer Survivorship.

Biographies of the survivors are attached. The speaking program in the Rose Garden is as follows: Remarks by Susan Blumenthal, Deputy Assistant Secretary in charge of the Office of Women's Health at the Department of Health and Human Services; Remarks by Jane Reese-Coulbourne of Alexandria, Virginia, a cancer survivor; and Remarks by the President.

Over the past 25 years, the United States has made great strides in reducing cancer rates and increasing cancer survival. For example, 25 years ago, only one in 10 children survived childhood cancer and leukemia. Today, seven out of 10 children who get cancer are cured. Still, nearly 1.4 million people will be diagnosed with cancer this year, and over forty percent of Americans will have the disease over their lifetime. And, while the President will note today that death rates from breast cancer have fallen seven years in a row, studies estimate that the disease will be diagnosed in about 1.5 million American women and claim nearly half a million lives in this decade.

\$30 MILLION IN FUNDING FOR BREAST CANCER GENETIC RESEARCH

President Clinton will announce a \$30 million increase in funding for new research into the genetic basis of breast cancer, through a collaborative effort between the Departments of Defense and Health and Human Services. This represents a 50 percent increase in funding devoted to genetic breast cancer research over FY 1996. Of the \$30 million, \$20 million is being directed from within DOD's FY97 general breast cancer research funding to focus specifically on breast cancer genetic research; \$10

million is being directed from within NIH's biomedical research funds, also to focus on breast cancer genetic research.

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. Since the Administration has taken office, funding for these activities has increased more than 95 percent, from \$276 million in FY 1993 to an estimated \$541 million in FY 1997 at the Department of Health and Human Services alone. This investment has yielded promising results, including the recent identification of two genes, BRCA1 and BRCA2, which researchers say may account for five to 10 percent of the breast cancers diagnosed each year. Researchers estimate that more than half of the women who inherit these genes will be diagnosed with breast cancer by age 50, and more than 85 percent will have a diagnosis of breast cancer by age 70. This new research initiative, a collaboration between the Department of Defense and the National Institutes of Health, will focus on a broad range of investigations related to the role of genes in the development of breast cancer. The Administration's objective is to move rapidly toward the goal of identifying high-risk women and preventing breast cancer before it strikes.

NATIONAL ACTION PLAN ON BREAST CANCER GOES ON-LINE

President Clinton today announced that the National Action Plan on Breast Cancer (NAPBC) will take its resources on-line. The launch of the web site coincides with the three year anniversary of the creation of the National Action Plan on Breast Cancer, which catalyzes and supports innovative research and outreach projects on breast cancer, with a special emphasis on the development of public-private partnerships. The web site, coordinated by the Department of Health and Human Services in partnership with the private sector, provides answers to frequently asked questions about breast cancer and serves as a gateway to information on breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences and meetings, publications, and other resources. The web site location: <http://www.napbc.org>

NEW EFFORTS PART OF A COMPREHENSIVE STRATEGY TO FIGHT BREAST CANCER

These new efforts are part of the Administration's comprehensive strategy to fight breast cancer in this country. For example, on October 1, 1996 the Administration announced the expansion of the National Breast and Cervical Cancer Early Detection program to all 50 states, with \$102 million in federal funding for the upcoming year. The program, run by the Centers for Disease Control and Prevention, provides screening services for low income and medically underserved women. In March 1996, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA), to ensure that mammography facilities meet high quality standards for equipment and personnel. First Lady Hillary Rodham Clinton also launched a campaign urging older women to get mammograms and promoting Medicare's coverage of mammography. In addition, the Department of Health and Human Services, the Central Intelligence Agency, and the Department of Defense have created a unique partnership to transfer defense and imaging technologies to improve early detection of breast cancer.

LAUNCHING OF THE OFFICE OF CANCER SURVIVORSHIP

President Clinton also today unveiled the new Office of Cancer Survivorship at the National

Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

Today, more than 10 million Americans are cancer survivors. Seven million of these individuals are long-term survivors who were diagnosed with cancer more than five years ago. About 135,000 of these survivors are under the age of 15, and one in every 1,000 Americans between the ages of 20 and 40 is a survivor of childhood cancer. The number of breast cancer survivors is also growing, largely due to improved mammography screening and more effective treatment. The death rate from breast cancer has gone down seven years in a row. According to provisional statistics released earlier this month by the National Center for Health Statistics, there was a 7.7 percent reduction in age-adjusted breast cancer mortality from 1989 to 1995.

A fact sheet on the Clinton Administration's cancer-related initiatives is attached.

-30-30-30-

TO: N. A. Min

From: Mary Dixon
The Press Officethis - Is this language like
OK
Mary
6-7307

EXECUTIVE OFFICE OF THE PRESIDENT

25-Oct-1996 05:53pm

TO: Mary A. Dixon
FROM: Kathy McKiernan
Office of the Press Secretary
SUBJECT: to check

President Clinton will announce \$30 million in ~~new~~ ^{create in new} funding for ~~new~~ research into the ~~hereditary~~ causes of breast cancer, through a collaborative effort between the Departments of Defense and Health and Human Services. This represents a 50 percent increase in funding devoted to genetic breast cancer research in the past ~~year~~. Of the \$30 million, \$20 million is being ~~redirected~~ from within DOD's FY97 general breast cancer research funding, to focus specifically on breast cancer genetic research; \$10 million is being ~~redirected~~ from ~~this~~ general research budget, also to focus on breast cancer genetic research.

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1996.

PRESIDENT CLINTON ANNOUNCES NEW CANCER INITIATIVES

Over the past 25 years, the nation has made great strides in reducing cancer rates and increasing cancer survival. For example, 25 years ago, only one in 10 children survived childhood cancer and leukemia. Today, seven out of 10 children who get cancer are cured. Still, nearly 1.4 million people will be diagnosed with cancer this year, and over forty percent of Americans will have the disease over their lifetime. And, while the President noted today that death rates from breast cancer have fallen seven years in a row, studies estimate that the disease will be diagnosed in about 1.5 million American women and claim nearly half a million lives in this decade.

Today, in honor of National Breast Cancer Awareness month and the 25th anniversary of the National Cancer Act, President Clinton announced three new initiatives to fight breast cancer and to address the needs of cancer survivors. The President announced \$30 million in new funding for research into the hereditary causes of breast cancer, through a collaborative initiative between the Department of Defense and the National Institutes of Health. The President also announced that the National Action Plan on Breast Cancer, a public-private partnership created under the Clinton Administration, is taking its informational resources on-line. Finally, President Clinton unveiled the new Office of Cancer Survivorship in the National Cancer Institute, which will research issues relating to the physical, psychological, and economic well-being of the growing number of cancer survivors in this country.

NEW RESOURCES FOR BREAST CANCER GENETIC RESEARCH

Today, President Clinton also announced \$30 million in new funding for research into the hereditary causes of breast cancer, through a collaborative effort between the Department of Defense and the Department of Health and Human Services. This represents a 50 percent increase in funding devoted to genetic breast cancer research in the past year.

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. Since the Administration has taken office, funding for these activities has increased almost 95 percent, from \$276 million in FY 1993 to an estimated \$541 million in FY 1997 at the Department of Health and Human Services alone. This investment has yielded promising results, including the recent identification of two genes, BRCA1 and BRCA2, which researchers say may account for five to 10 percent of the breast cancers diagnosed each year. Researchers estimate that more than half of the women who inherit these genes will be diagnosed with breast cancer by age 50, and more than 85 percent will have a diagnosis of breast cancer by age 70. This new research initiative, a collaboration of the Department of Defense and the National Institutes of Health, will focus on a broad range of investigations related to the role of genes in the development of breast cancer. The Administration's objective is to move rapidly toward the goal of identifying high-risk women and preventing breast cancer before it strikes.

NATIONAL ACTION PLAN ON BREAST CANCER GOES ON-LINE

The President announced today that the National Action Plan on Breast Cancer (NAPBC) will take its resources on-line. The launch of the web site coincides with the three year anniversary of the creation of the National Action Plan on Breast Cancer, which supports innovative research and outreach projects on breast cancer, with a special emphasis on the development of public-private partnerships. The web site, coordinated by the Department of Health and Human Services, in partnership with the private sector, provides answers to frequently asked questions about breast cancer, as well as information on breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences and meetings, publications, and other resources.

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Harold Varnus

234-5568

Draft 10/26/96 7:00pm

**PRESIDENT WILLIAM J. CLINTON
ANNOUNCEMENT OF NEW CANCER INITIATIVES
THE ROSE GARDEN
OCTOBER 27, 1996**

I want to thank all of you for joining me on a Sunday afternoon to discuss three important new steps we are taking in the war against cancer. I also want to thank Sec. Shalala and Dr. Susan Blumenthal, my Deputy Assistant Secretary for Women's Health, for their tireless service on behalf of women throughout America. I especially want to thank Jane Reese-Coulbourne for her courage and her dedication to find a cure for breast cancer. Finally, I want to thank all of the advocates here today who are fighting the battle against cancer every day, for all of us.

I believe that America is only as strong as our families are healthy. And nothing is more devastating to a family than when someone is diagnosed with a life-threatening disease like cancer. I know this from my personal experience: my step-father died of cancer, and I lost my mother, Virginia, to breast cancer just under three years ago. Vice President Gore's sister died of cancer. And this year alone, nearly 1.4 million American men, women and children will be diagnosed with cancer. I don't think there is a family in America that has not been touched by this disease.

Since I took office, this Administration has mounted a comprehensive campaign to prevent and treat cancer. We have been relentless in our efforts to get tobacco out of our children's lives forever. We have increased spending on cancer research, treatment and prevention by \$400 million. We have accelerated FDA approval of cancer drugs and made it easier for patients to obtain promising therapies before they are formally approved. And NASA, the CIA and the Department of Defense have joined forces to use cutting edge imaging technology for early detection of cancer to help save lives.

In the battle against breast cancer, we have increased funding for research and prevention by nearly 80% since 1993. We launched a public awareness campaign to encourage older women to use Medicare to have mammograms. And my balanced budget goes even further -- it will guarantee free annual mammograms to Medicare beneficiaries, removing financial barriers that prevent some women from obtaining this vitally important test.

These efforts of scientists, doctors, women and men across the country are producing results. The survival rate for cancer has gone up -- 7 out of 10 children with cancer survive it -- that's up from 1 out of 10 twenty-five years ago. The death rate for breast cancer has gone down every year in the last seven -- it has dropped by nearly 8% since 1990. Just last week, the NIH announced a milestone in the Human Genome Project, which is identifying the location and function of nearly every human gene. We have now mapped out 20% of all human genes -- and anyone can access that map on the Internet. Soon, we will know the

genes that contribute to cancer and our genetic predisposition to inherit it -- and possibly prevent it before it strikes.

This is the 25th anniversary of the National Cancer Act, and in those 25 years we have come a long way. But as far as we have come, we still have far to go. This month is also Breast Cancer Awareness Month, a time to remember the terrible toll breast cancer has taken, to assess our progress and to redouble our efforts to find a cure.

More and more, we understand that early detection and timely access to information and resources can make all the difference in a woman's battle against breast cancer. That is why I am pleased to announce the National Action Plan on Breast Cancer Website on the Internet. This easily accessible website -- the address is right here -- will answer women and their families' questions about breast cancer, early detection, new treatments, clinical trials, advocacy groups, and much more.

Over the last two years, scientists have made significant breakthroughs in their understanding of the genetic causes of breast cancer. The remarkable discovery of two genes that indicate susceptibility to breast cancer is giving new hope to women everywhere. Last month I signed a budget that reflects our priorities and devotes substantial resources to cancer research. Today, I am announcing that we will expand our genetic breast cancer research program by \$30 million out of that new budget. These funds will go to researchers at hospitals, universities and labs across the country. And with this single step -- which will represent a [major] [50%] increase in breast cancer genetic research -- we will be that much closer to finding a cure for breast cancer.

Just a few moments ago in the Oval Office, I signed the Ribbon of Hope. This yellow ribbon, which is already over 750 feet long, has been signed by more than 10,000 cancer survivors around the world. It symbolizes the spirit of hope that has sustained so many people in their struggles against cancer. My wife Hillary was the first person to sign the Ribbon, and I was honored to place my own signature alongside those of so many courageous people.

More than 10 million Americans are cancer survivors. Many have special psychological, physical and health care counseling needs that we are only beginning to understand -- some face employment discrimination; some can't get health insurance. I am proud to have passed landmark legislation to guarantee that cancer survivors will no longer live in fear of losing their health care coverage because they have a pre-existing condition. And today, we take another step to help cancer survivors -- the creation of the Office Cancer Survivorship. This office will support much needed research that will help cancer survivors deal with the problems they face even after their cancer is cured.

We can win the fight against breast cancer . . . and all cancers. With the measures I am announcing today -- a new breast cancer website, \$30 million in breast cancer genetic research and a new Office of Cancer Survivorship -- we take three important steps to save lives and bring us closer to a cure.

And now, I would like to present the section of the Cancer Survivors Ribbon that I signed a few moments ago to Erin Schraibman [shrayb-man].

Thank you and God bless you all.



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

October 24, 1996

NOTE FOR THE DIRECTOR

FROM: Nancy-Ann Min *NAM*

RE: Genetic Breast Cancer Funding Announcement--Call to Dr. Harold Varmus (NIH)
(301) 496-2433

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

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

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

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

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

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

Suggested Outline of Call

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

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

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

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

cc: Jack Lew
Gordon Adams
Rebecca Culberson

Gordon Adams

10/24/96 02:23:45 PM

Record Type: Record

To: Franklin D. Raines/OMB/EOP, Jacob J. Lew/OMB/EOP, Nancy A. Min/OMB/EOP

cc: Rebecca R. Culberson/OMB/EOP, Jill M. Blickstein/OMB/EOP, Sandra L. Via/OMB/EOP

Subject: Joseph/Rausch conversation - Breast Cancer

Dr. Joseph and Terry Rausch (also Health Affairs) both feel the following:

1. The substance of the research program is on target, important and a winner.
2. They get their funding because a Congressional coalition, led by Pat Schroeder, but supported by Inouye, Harkin, Leahy, Murtha and Markey, among others, feels NIH is too theoretical and too slow in spending its funds. They want it done in the Army.
3. Therefore, they reject a "transfer" and think it will have negative blowback from the Hill.
4. They also feel \$27.4 m. is too much and would distort the DoD/Army program in this direction.
5. But, they would be willing to commit \$20 m. to such an effort, with a \$10 m. match from NIH (back to the previous number Varmus was supposed to be able to get), create a joint program (like one they do now with National Cancer Institute), create a joint oversight group, and carry out the research.

I must say, I think their argument has merit. I am not sure why transfer is the only option here and if they are willing to execute the program (and Steve seemed genuinely excited about it) I recommend proceeding down this road. It would also mean holding Varmus' feet to the fire for more funds than he seems to want to spring, but maybe that is good.

If you feel you need to jam Defense on this, which I do not recommend, it will probably require heavy lifting at the top. I must say, I do not see the merit of doing it.

To Gordon Adams
This is a rough
draft - I just
wrote some stuff
about DOD given
the time

October 24, 1996

NOTE FOR THE DIRECTOR

FROM: Nancy-Ann Min

RE: Calls to Dr. Harold Varmus (NIH) and DOD Secretary Perry

Purpose of Calls: To come up with a total of \$30 million in additional funding for genetic research devoted to breast cancer, which (together with the approximately \$3 million in additional FY 1997 funding NIH is devoting to this item) would represent a 50% increase in this initiative from FY 1996. This additional funding will be announced on Sunday, October 27, in a Rose Garden event.

1. Dr. Harold Varmus (NIH) (301/496-2433)

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

Suggested Outline of Call

- In FY 1996, NIH spent \$61,931 on genetic breast cancer research. A major discovery of two genes that appear to be related to breast cancer--BRCA-1 and BRCA-2--was announced by NIH scientists this spring.
- The President wants to highlight what we are doing to build upon the discovery of these two genes by devoting increased funding to additional research aimed at discovering other genetic links to breast cancer, as well as research to develop techniques to screen women for these genes and devise therapies for these particular forms of breast cancer.
- Although NIH received an \$830 million increase in FY 1997--\$420 million more than the President's FY 1997 request, which itself was \$410 more than FY 1996 enacted--it appears that Dr. Varmus has allocated only about \$3 million in new funding to genetic breast cancer research. The increase allocated for all breast cancer research at NIH is

disproportionally lower than the increase that NIH as a whole received (NIH received a 7% increase, while the amount allocated to breast cancer research is only 4%). This seems odd in view of (1) the strong priority the President has placed on combatting breast cancer, and (2) the recent breakthroughs in genetic breast cancer research.

- If you decide you want to pursue getting Dr. Varmus to devote additional funds to genetic breast cancer research from within NIH's FY 1997 funding increase of \$830 million: Dr. Varmus has around \$16 million in discretionary funds that he can use for research projects he deems worthy. He also has the ability to transfer up to 1% of NIH's total budget (\$12.7 billion) among the institutes, although this may require Congressional notification depending on how he goes about it.

2. DOD Official--Secretary Bill Perry (703/695-5261)
Deputy Secretary John White (703/695-6352)
Secretary of the Army Togo West (703/695-4211)

Background: For a number of years, DOD has received appropriations to be used for breast cancer research, although it has never requested this funding in its budget. In FY 1995, DOD received \$150 million for this purpose; in FY 1996, it received \$75 million, and in the most recent budget, FY 1997, DOD received \$112 million. After checking with DOD, OMB staff determined that these funds--most of which go to the Army--have not yet been obligated.

Suggested Outline of Call

- The President wants to announce a 50% increase in funding for genetic breast cancer research on Sunday.
- In order to come up with these funds without having to decrease funding for some other priority research area at NIH (e.g., AIDS), I need to use a small portion of the breast cancer research funds Congress appropriated to DOD.
- Of course, DOD has never requested these funds, although I understand that the Army has done a good job of using them in the past and has devoted them to high-quality research.
- What I need you to do is to transfer approximately \$27 million of the \$112 million DOD received to NIH to be devoted to genetic breast cancer research (i.e., following up on the discovery last year of the BRCA-1 and BRCA-2 genes to develop screening and therapies, and also to aid in the search for new genetic links).

Richard J. Turman

10/24/99 02:31:16
PM

Record Type: Record

To: Nancy A. Min/OMB/EOP, Sarah A. Bianchi/OMB/EOP

cc: Barry T. Clendenin/OMB/EOP, Victoria A. Wachino/OMB/EOP

Subject: URGENT -- DOD Breast Cancer Research Funding levels

Steve Dotson called to confirm that the funding levels appropriated in DoD for breast cancer research are as follows:

(\$ in millions)

FY95	FY96	FY97
150	75	112.5

Victoria A. Wachino

10/23/96 09:04:29
AM

Record Type: Record

To: Nancy A. Min/OMB/EOP

cc: Barry T. Clendenin/OMB/EOP, Richard J. Turman/OMB/EOP, Chin-Chin Ip/OMB/EOP, Gordon P. Agress/OMB/EOP

Subject: NIH Funding for Breast Cancer Research

Earlier today, you asked Richard whether NIH's estimated increase for breast cancer research in FY 1997 is consistent with the overall increase NIH received in final appropriations action. The short answer is: the increase for breast cancer research is slightly below the rate of increase for all of NIH. Here's a short table comparing increases in NIH breast cancer research with increases in NIH funding overall:

*FY 1997 Increases in NIH Breast Cancer Research Funding vs. NIH Total Funding
(\$ in millions)*

	FY96	FY97 Request	FY97 Enacted	% Increase Over 96	% Increase Over Request
NIH Total	\$11,927	\$12,376	\$12,747	6.9%	3%
NIH Breast Cancer Research	\$ 403	\$ 410	\$ 420	4.2%	2.4%

12747
11927

820



FACSIMILE TRANSMISSION

DATE: 10/23/96

FAX TO: Nancy-Ann Min**ADDRESS:** OMB**PHONE:** (202) 395-5178**FAX:** (202) 395-7289

FROM: Dennis Williams
Office of Budget, ASMB,
Department of Health and Human Services**ADDRESS:** Hubert H. Humphrey Building, Room 503-H
200 Independence Avenue, S.W.
Washington, DC 20201**PHONE:** (202) 690-7846**FAX:** (202) 690-6896

PAGES FOLLOWING COVER PAGE: 3**SUBJECT:** BRCA 1,2 and Breast Cancer Genetics - NIH Spending

MESSAGE:

Per your conversation with John, attached are NIH's revised estimates for BRCA 1,2 research for FYs 1995-1997, as well as an estimate of total breast cancer genetics research.

SENT BY:

10-23-96 : 6:04PM :

NIH OD/OFM-

202 690 6896:# 2/ 4

**National Institutes of Health
Resources Devoted to Genetic Research related to Breast Cancer
Dollars in Thousands**

	FY 1995		FY 1996		FY 1997	
	Actual	BRCA 1,2	Actual	BRCA 1,2	Estimate	BRCA 1,2
NCI	\$37,500		\$40,300	\$8,000	\$42,500	\$10,480
NHLBI	188		199		206	
NIDR						
NIDDK	3,550		3,700		3,900	
NINDS						
NIAID	0		0		0	
NIGMS	5,453		7,350		7,742	
NICHD						
NEI			867		900	
NIEHS	510	448	750	650	850	750
NIA	490		508		528	
NIAMS	0		0		0	
NIDCD	0		0		0	
NIMH	490	490	308	308	0	
NIDA	0		0		0	
NIAAA						
NINR	250	250	315	315		
NCRR						
NCHGR	6,764		7,534	4,500	7,911	4,700
FIC	0		0		0	
NLM	0		0		0	
OD			100	100		
TOTAL	\$55,195	\$1,188	\$61,931	\$13,873	\$64,537	\$15,930

approx. \$2m supported through National Cancer Genetics NetworkEs

These estimates represent minimal amounts for the areas above. NIH does not code for either of the areas, and if more time were available, with a coherent definition of the areas, a higher amount may be identified.

Oct 23, 1996

October 23, 1996

**National Cancer Institute
Examples of Genetic Research In Breast Cancer**

BRCA1 & BRCA2

Risk of breast and ovarian cancer related to mutations in both BRCA1 and BRCA2 are being explored in families at high risk of breast and ovarian cancer. The best way to counsel individuals in these families is also being evaluated as well as the impact such counselling has on their lives. In addition, we have conducted a large survey in the metropolitan Washington area to estimate the risk of breast, ovarian, and other cancers associated with alterations in BRCA1 and BRCA2 in the Jewish population because of an increased frequency of variants in both the BRCA1 and BRCA2 genes. The findings from this survey will have major impact on the decisions about who will benefit from genetic screening.

Radlogenic Breast Cancer

A number of different groups of individuals who have received radiation exposure have been assessed for risk of breast cancer related to dose and time of radiation exposure. These groups include radiation technologists, children treated for childhood cancers, women undergoing repeated fluoroscopies or X-rays as part of their clinical care of tuberculosis or scoliosis, and women treated for other primary cancers. In addition to careful radiation dosimetry, other risk factor information and genetic predisposition information is collected. Biologic specimens are also obtained to evaluate both germline and somatic mutations. To date studies have focussed on alterations in ATM, BRCA1, and p53.

Li-Fraumeni Syndrome

Families with a relatively rare syndrome, Li-Fraumeni syndrome, have been studied for many years. Individuals in these families are at increased risk of sarcomas, breast and brain cancer, adrenal cortical carcinoma in childhood, and possibly leukemia. Germline mutations in p53 were described in a number of families and linkage analyses are now being attempted. An international registry of cases and families is being established as a consortium effort among the groups working on the genetics and natural history of the disorder.

Genetic susceptibility

Although approximately 10% of breast cancer may be attributable to several major genes (including BRCA1 and BRCA2 plus others) other genes which control the metabolism of hormones, dietary substances, and fats may be important in the development of breast cancer. The new study will explore the gene-environment interactions in risk of breast cancer focusing on the polymorphic metabolic genes and their appropriate substrates.

Cowden syndrome

A very rare disorder, Cowden disease, is associated with an increased risk of gastrointestinal hamartomas, benign skin tumors, benign and malignant thyroid tumors, and breast cancer. The gene was recently localized to chromosome 10q22-23 by an international collaborative effort. Work continues to isolate the gene.

National Institutes of Health

National Center for Human Genome Research

Projects in BRCA1 and BRCA 2

Examples of Projects

- Detection of BRCA 1 Mutations by DNA Chip Hybridization
- The Role of the BRCA 1 gene in the pathogenesis of breast cancer
- Molecular Cytogenetics of Gene Amplification
- BRCA 1 Knock-out and Transgenic Mice
- Outcomes of Education and Counseling for BRCA 1 Testing
- Comparing Models of Pre-Test Education for BRCA 1 Testing
- Delineation of chromosomal aberrations during the progression of solid tumor
- Can Interactive Computers Effectively Inform Patients about a Genetic Test for Breast Cancer.

October 22, 1996

☐ Accept☐ Regret☐ Pending

To: Stephanie Streett
Anne Hawley

From: Betsy Myers

Request: For the President to hold a White House announcement of three initiatives which demonstrates the Administration's commitment to women business owners: (1) The expansion of the SBA Women's Pre-Qualification Pilot Loan Program from 16 locations to nationwide; (2) the launching of the Women's Business Intranet network; and (3) the release of the White House Interagency Committee on Women's Business Enterprise success story book honoring women business owners who have benefited from federal programs and policies.

Purpose: To amplify the President's commitment to growing the women's business sector.

Background: The President has a strong record on women's business ownership. Since coming to office, the number of women business owners has increased to almost 8 million. These businesses contribute more than \$2.3 trillion to the economy annually and employ 18.5 million Americans. Several of the Administration's efforts have helped foster the growth of women business ownership. The SBA has increased loans to women by 300 percent since 1992, awarding women more than \$3 billion in loans. In addition, the Administration has made the SBA Office of Women's Business Ownership permanent and has increased technical assistance to women business owners by launching 30 new demonstration sites.

This three-prong announcement would continue the Administration's efforts on behalf of women business owners.

(1)The Women's Prequalification Pilot Loan Program, currently only available in 16 sites, could be available nationwide. Under this program, women entrepreneurs receive technical assistance with writing business plans and loan applications and receive SBA pre-qualification letters which they can bring to lending institutions to further increase their ability to get a loan.

(2)The launching of the Women's Business Intranet is an ideal example of reinventing government to ensure better computer communication and coordination between the SBA's 54 Women's Business Centers. This improvement is being made possible through a public-private partnership with IBM which has donated more than 200 computers. With this increased communication, the sites will be able to share information on their activities and better serve women business owners. In addition, they will be able to hold on-line conferences to further improve services.

(3)The "Women Succeed in Business" booklet honors 12 women around the nation whose companies have benefited from federal agencies or policies. The book also includes a list of resources in the government which can assist women entrepreneurs. The booklet will be used to show how this Administration has successfully worked in partnership with women business owners. About 10,000 copies are being distributed around the country.

Previous Participation: In January released a report of the Interagency Committee on Women's Business Enterprise and National Women's Business Council which noted the dramatic increase in the number of women business owners

Date and Time: Sunday, Oct. 27 or anytime afterward

Duration: 30 minutes

Location: White House or anywhere

Participants: The President and women featured in the Women's Succeed in Business booklet.

Outline of Events: A woman entrepreneur introduces President. President speaks.

Remarks: Yes

Media Coverage: Open

Recommended by: Betsy Myers

Contact: Betsy Myers, 6-7300

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, Oct. 1, 1996

Contact: CDC Press Office
(404) 639-3286

Breast Cancer Screening Efforts Go Nationwide Secretary Shalala Launches Breast Cancer Awareness Month

Stressing the importance of routine breast cancer screening for all women, HHS Secretary Donna E. Shalala today announced the expansion of the Breast and Cervical Cancer Early Detection Program to all 50 states, with \$102 million in federal funding for the upcoming year.

Since its first year of operation in 12 states in 1991, this program has provided screening tests to nearly a million medically underserved women.

The announcement came as National Breast Cancer Awareness Month activities were launched nationwide.

"We know that regular mammograms can substantially reduce the chance of death from breast cancer," said Secretary Shalala. "It is important that we reach every American woman with this message. And it is especially important that we reach racial and ethnic minority women throughout our country, because breast cancer mortality among these women is disproportionately high."

The Breast and Cervical Cancer Early Detection Program, operated by the CDC, serves low income and minority women, older women and those who are uninsured or underinsured. Operating in an increasing number of states each year since 1991, it is going nationwide this month with the addition of programs in Alabama, Delaware, Hawaii, Idaho, Indiana, Kentucky, Mississippi, Montana, Nevada, New Hampshire, North Dakota, South Dakota, Tennessee, Virginia, Wyoming and Washington D.C., as well as the Northern Mariana Islands, Republic of Palau, Virgin Islands, Hopi Tribe, Native American Rehabilitation Association of the Northwest, the Navajo Nation, and Indian Community Health Service.

From its inception through May 1996, the program provided 457,600 mammograms to women. Breast cancer was diagnosed in 2,495 of them.

In addition, Papanicolaou (Pap) tests have been provided to 612,008 women, and 19,166 were found to have a precursor of cervical cancer called cervical intraepithelial neoplasia (CIN I, II or III, which can be treated successfully). Almost all deaths from cervical

cancer are preventable through widespread use of Pap testing and timely and appropriate treatment. Invasive cervical cancer has been diagnosed in 239 women through the CDC program.

The CDC program provides outreach screening and education programs through a broad array of facilities, including local health departments, community and migrant health centers, private physician offices, family planning and church sponsored clinics, YWCAs, women's shelters and senior centers.

"Public education and outreach have played important roles in the long-term success of this program," said CDC Director David Satcher, M.D. "CDC and its partners have successfully reached medically underserved women with screening through a variety of intensive community-based efforts."

Educating consumers and health professionals is the cornerstone of the National Breast Cancer Awareness Month (NBCAM) program which enters its second decade of public and professional educational outreach efforts. Two HHS agencies, the CDC and the National Cancer Institute, join with 15 other national organizations as co-sponsors of the October National Breast Cancer Awareness Month, which is dedicated to increasing awareness of the importance of early detection of breast cancer.

This year, National Mammography Day will be celebrated on Friday, October 18. On National Mammography Day, women across America are encouraged to receive or sign up for a screening mammogram or to make a commitment to get one.

Breast cancer research and screening have been high priorities for HHS under Secretary Shalala. In 1993, she convened a conference to develop a National Action Plan on Breast Cancer, and implementation of the plan is being carried out through a public-private partnership led by HHS' Office on Women's Health. Total HHS discretionary funding for breast cancer research and programs has increased from about \$90 million in 1990 to an estimated \$507 million in FY 1996.

Breast cancer is the most commonly diagnosed cancer among American women. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade, and that breast cancer will claim nearly half a million lives.

Death rates from the disease are highest among women aged 40 or older and black women as compared to white women for those aged less than 70 years. With proper screening and treatment, however, the chances of surviving breast cancer are improving. For women age 50-

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

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(NOTE: List of Breast and Cervical Cancer Early Detection Program grants to each state attached)

CDC's National Breast and Cervical Cancer Early Detection Program

Comprehensive Program

AWARDED

States and Territories

FY 96

Alabama	\$ 750,000
Alaska	\$ 1,751,104
Arizona	\$ 1,100,648
Arkansas	\$ 1,622,203
California	\$ 5,950,425
Colorado	\$ 2,131,985
Connecticut	\$ 1,400,000
Delaware	\$ 566,515
Florida	\$ 2,000,000
Georgia	\$ 2,516,273
Hawaii	\$ 750,000
Idaho	\$ 750,000
Illinois	\$ 3,050,000
Indiana	\$ 1,087,484
Iowa	\$ 1,700,000
Kansas	\$ 1,500,000
Kentucky	\$ 1,079,907
Louisiana	\$ 750,000
Maine	\$ 1,564,561
Maryland	\$ 3,705,108
Massachusetts	\$ 2,597,000
Michigan	\$ 4,908,000
Minnesota	\$ 1,488,245
Mississippi	\$ 750,000
Missouri	\$ 2,500,000
Montana	\$ 1,079,907
Northern Mariana Islands	\$ 200,000
Nebraska	\$ 1,000,000
Nevada	\$ 775,344
New Mexico	\$ 3,475,000
New Jersey	\$ 2,000,000
New Hampshire	\$ 1,000,000
New York	\$ 4,459,537
North Carolina	\$ 3,400,000
North Dakota	\$ 733,456
Ohio	\$ 4,088,387
Oklahoma	\$ 1,000,000
Oregon	\$ 2,250,847
Pennsylvania	\$ 2,010,000
Republic of Palau	\$ 227,145
Rhode Island	\$ 994,064
South Carolina	\$ 2,500,000
South Dakota	\$ 750,000

- More -

Tennessee	\$ 750,000
Texas	\$ 4,153,569
Utah	\$ 1,150,000
Vermont	\$ 1,052,889
Virgin Islands	\$ 721,894
Virginia	\$ 1,000,000
Washington	\$ 3,250,082
Washington, D.C.	\$ 500,000
West Virginia	\$ 2,881,438
Wisconsin	\$ 2,722,000
Wyoming	\$ 750,000

Subtotal States and Territories: \$98,845,017

American Indian/Alaska Native Organizations

Arctic Slope Native Association	\$ 300,000
Cherokee Nation	\$ 244,626
Cheyenne River Sioux	\$ 182,310
Eastern Band of Cherokee Indians	\$ 287,225
Hopi Tribe	\$ 282,429
Indian Community Health Service	\$ 282,429
Maniilaq Association	\$ 265,900
Native American Rehabilitation Association of the Northwest	\$ 152,714
The Navajo Nation, Division of Health	\$ 282,428
Pleasant Point Passamaquoddy	\$ 175,472
Poarch Band of Creek Indians	\$ 81,481
South Puget Intertribal Planning Agency	\$ 283,690
Southcentral Foundation	\$ 412,430

Subtotal AI/AN Organizations: \$ 3,233,134

TOTAL COMPREHENSIVE

PROGRAM AWARDS: \$102,078,151

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Friday, Oct. 18, 1996

Contact: HHS Press Office
(202) 690-6343

BREAST CANCER SCREENING PROMOTED FOR NATIONAL MAMMOGRAPHY DAY Toll-Free Information On Free and Reduced-Fee Mammograms

Encouraging women across America to receive routine breast cancer screening, HHS Secretary Donna E. Shalala promoted six, nationwide, toll-free numbers to locate accredited facilities offering free and reduced-fee screening mammograms in honor of National Mammography Day.

The numbers are:

National Cancer Institute's Cancer Information Service
(1-800-4-CANCER)

The American Cancer Society
(1-800-ACS2345)

National Alliance of Breast Cancer Organizations
(1-800-719-9154)

The Susan G. Komen Breast Cancer Foundation
(1-800-I'M AWARE)

Y-ME National Breast Cancer Organization
(1-800-221-2141)

Y-ME Spanish Language Hotline
(1-800-986-9505)

These numbers operate throughout the year providing information about breast cancer prevention, detection and treatment.

"We know that regular mammograms can substantially reduce the chance of death from breast cancer," said Secretary Shalala. "It is important that we reach every American woman with this message."

The telephone services are part of activities and outreach efforts during National Breast Cancer Awareness Month, aimed at increasing awareness of the importance of early detection of breast cancer.

The first National Mammography Day was officially recognized by President Clinton on Oct. 19, 1993 and will be observed on Oct. 18 this year. On Oct. 3, 1996 President Clinton officially proclaimed October 1996 as National Breast Cancer Awareness Month.

In his proclamation, he urged women to get mammograms as appropriate and to take advantage of preventive health services. He called upon government officials, businesses, communities, volunteers, educators, and the American public to work together to fight breast cancer.

Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings. Currently Medicare covers one mammogram every two years for women age 65 and older. In his balanced budget proposal, President Clinton proposes to increase Medicare coverage to one mammogram annually for beneficiaries over 50, with no copayment or deductible requirement.

Breast cancer is the most commonly diagnosed non-skin cancer among American women, accounting for 31 percent of all cancers among women. Although death rates from breast cancer have been declining in recent years, epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade, and that breast cancer will claim nearly half a million lives. There is no proven way to prevent breast cancer, so early detection, through mammography and clinical breast exams, and treatment are key to lowering the death rate.

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

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. HHS Secretary Shalala convened a conference in December 1993 to establish a National Action Plan on Breast Cancer and implementation of the plan is being carried out through a public, private and volunteer partnership led by HHS' Office of Women's Health. Total discretionary spending has increased from about \$90 million in FY 1990 to an estimated \$531 million in FY 1997.

On Oct. 1, 1996 Secretary Shalala announced the expansion of the CDC's National Breast and Cervical Cancer Early Detection Program to all 50 states, with \$102 million in federal funding for the upcoming year. The program provides screening services for low income and medically underserved women. Since its first year of operation in 12 states in 1991, this program has provided over a million screening tests.

In March 1996, the FDA issued proposed regulations to implement the Mammography Quality Standards Act (MQSA), to ensure that mammography facilities meet high quality standards for equipment and personnel.

And the PHS Office of Women's Health has initiated an innovative partnership with the Central Intelligence Agency and the Department of Defense to transfer defense imaging technologies to improve early detection of breast cancer.

Educating consumers and health professionals is the cornerstone of the National Breast Cancer Awareness Month (NBCAM) program, which is entering its second decade of public and professional outreach efforts. Two HHS agencies, the CDC and the National Cancer Institute, are working with 15 other national organizations as co-sponsors of the 1996 October National Breast Cancer Awareness Month.

In addition to National Mammography Day, activities, screenings, and media events will be held across the country throughout the month to improve breast cancer awareness.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

October 18, 1996

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

BREAST CANCER: NEW EFFORTS UNDERWAY

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

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

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

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

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

Background: More Women Can Survive Breast Cancer

- The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.
- In 1995 alone, approximately 182,000 new cases of breast cancer were diagnosed in women and 46,000 died from the disease. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- Death rates from the disease are highest among older, black, and low-income women. During the last 20 years, death rates from breast cancer for women over 65 increased by 35 percent for black women and 11 percent for white women. Mortality rates vary widely among racial and ethnic groups in the United States. Hispanic, Chinese, Filipino and Japanese women have annual rates at or below 15 per 100,000 women, while black, white and Native Hawaiian women have rates above 25 per 100,000 women.
- With proper screening and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. During the most recent 5-year period of available data (1989 to 1993), the age-adjusted breast cancer mortality rates fell approximately 6 percent among white women and rose about 1 percent among black women. By comparison, from 1980 to 1989, rates increased 3 percent among white women and 16 percent among black women.
- During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

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

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

HHS Action To Combat Breast Cancer

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

National Action Plan on Breast Cancer

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

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

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

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

National Breast and Cervical Cancer Early Detection Program

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

Breast Cancer Among the Elderly

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

New Frontiers In Breast Cancer Early Detection

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

Centers of Excellence

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

Mammography Clinical Practice Guidelines

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

Mammography Standards

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

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

Environmental Factors and Breast Cancer

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

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More breast
cancer
info from
Dennis Williams

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, Oct. 1, 1996

Contact: PHS Office on Women's Health
(202) 690-7650

HHS LAUNCHES "CENTERS OF EXCELLENCE IN WOMEN'S HEALTH"

The Department of Health and Human Services today announced establishment of six National Centers of Excellence in Women's Health, to serve as national models for improving the health care of American women.

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

"Our nation can't afford to give anything less than its best efforts for women's health," said HHS Secretary Donna E. Shalala. "These new Centers of Excellence are just one step in a broad cooperative effort to improve our health research and services for women, and to improve the career prospects for women in the health professions."

The national Centers of Excellence will be located at Allegheny University of the Health Sciences, Philadelphia; Magee-Womens Hospital, Pittsburgh, Pa.; Ohio State University Medical Center, Columbus, Ohio; University of California at San Francisco; University of Pennsylvania, Philadelphia; and Yale University, New Haven, Conn. They represent a public-private partnership between HHS and the academic institutions. The U.S. Public Health Service's Office on Women's Health developed the concept for the centers and is providing \$1 million to support the centers.

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

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

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

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

The Centers of Excellence will provide the following women's health resources and services:

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

The PHS Office on Women's Health provides national leadership in advancing women's health in public policy, research, service delivery and education. The office acts as a catalyst for developing new national and regional initiatives to improve women's health.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Monday, Sept. 30, 1996

Contact: PHS Office on Women's Health
(202) 690-7650

\$1.98 MILLION AWARDED TO BEGIN CLINICAL TRIALS ON NEW BREAST IMAGING TECHNOLOGIES

The Department of Health and Human Services, in a unique collaboration with the CIA, has awarded \$1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community -- originally used for missile guidance and target recognition -- to improve the early detection of breast cancer.

"These technologic innovations assist intelligence officers in finding targets camouflaged behind trees via satellite, said Health and Human Services Secretary Donna E. Shalala. "Now clinical trials will determine the safety and effectiveness of the same intelligence technologies to assist radiologists with finding small cancers camouflaged behind breast tissue."

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

- More -

Clinical trials are the crucial next step to test how effectively these new imaging procedures will work on women, with the intent of having the new technologies available to consumers as soon as possible.

"If we can image missiles in distant skies, and with the Hubble telescope see the surface of Mars, then surely we should be better able to detect small lumps in women's breasts right in front of us," said Susan J. Blumenthal, M.D., M.P.A., Deputy Assistant Secretary for Women's Health and Assistant Surgeon General.

Breast cancer is one of the most feared diseases among women. One in eight women will be diagnosed with the deadly disease during her lifetime. It is estimated that in 1996 more than 44,000 women will die from breast cancer.

Currently, mammography is the best method for detecting breast cancer and can decrease death rates by 30 percent. However, it is a 40-year-old technology that misses up to 15-20 percent of cancerous tumors. In addition, three out of four lesions detected by this technology are benign, leading to unnecessary and costly procedures, including biopsies.

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

The clinical trials will include testing in two major areas:

- Computer-aided diagnosis in digital x-ray mammography -- in which visual information is generated, displayed, enhanced, stored, and transmitted by computers instead of x-ray film -- has the potential to produce clearer, sharper images and may be especially helpful in viewing dense breast tissue where small cancers are harder to see.
- Computer-aided diagnosis for magnetic resonance imaging (MRI) -- in which three-dimensional images of breast tumors are created on computers, allowing doctors to view the actual volume, shape and size of the tumor -- has the potential to provide more detailed images to help doctors distinguish between benign and malignant breast tumors, and more accurately guide biopsy and to select the most effective treatment.

An extensive library, or digital image database, will also be created that will serve as a national resource for other researchers working in this exciting new area.

Other institutions and organizations that will participate in conducting this clinical trial include: Massachusetts General Hospital, University of Chicago, Brown University, University of Arkansas, University of California at Los Angeles, University of California at San Francisco, University of Virginia, National Naval Medical Center and David Sarnoff Research Institute.

In charge of the project for the University of Pennsylvania will be Mitchell Schnall, M.D., Ph.D., Chief of the Magnetic Resonance Imaging Section in the Department of Radiology.

The clinical trials are supported by the PHS Office on Women's Health, which provides national leadership in advancing women's health in public policy, research, service delivery and education, and acts as a catalyst for developing new national and regional initiatives to improve women's health.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

to 80 percent of a subtype of Alzheimer's that strikes before age 65. In searching for the functions of the proteins coded by the genes, investigators have detected a similarity between the PS1 and -2 proteins and a protein that is known to be involved in cell to cell communication and development. Accumulating evidence of the unexpectedly influential role of genetic factors in Alzheimer's disease adds urgency to the task of clarifying the molecular basis of the disease. In the interim, information about mutations in Alzheimer's-related genes likely will lead to diagnostic tests for at-risk members of affected families. Alzheimer's disease affects 4 million Americans today; that number will increase dramatically as baby boomers hit the age of highest risk.

Ataxia Telangiectasia (AT) — Researchers isolated the gene for AT, a rare disease of childhood that typically leads to death before adulthood. The disease is marked by progressive loss of coordination beginning between 1 and 2 years of age, growth retardation, immune deficiencies, high rates of cancer, radiation sensitivity, and premature aging. Although both parents must contribute a defective AT gene for a child to be affected, carriers — persons with one copy of the gene but who do not have the disease — are at increased risk for cancer and are highly sensitive to radiation. Identification of the gene paves the way to not only develop tests for prenatal diagnosis, but also to identify carriers, thus enabling carriers to choose to limit their use of radiation in cancer screening and treatment. Up to 8 percent of all breast cancers may be caused by mutations in the AT gene.

Breast Cancer — In an extension of the exciting 1994 finding of **BRCA1**, a gene that confers susceptibility to breast cancer, NIH scientists and collaborators discovered a specific mutation in the gene in nearly 1 percent of blood samples collected from women of Ashkenazi Jewish descent. This finding identifies a particular subgroup of the general population that may benefit from genetic testing for the BRCA1 mutation. Epidemiologists have hypothesized that this mutation may account for as much as 16 percent of breast and 39 percent of ovarian cancers among Ashkenazi Jewish women age 50 and under. The finding of the BRCA1 mutation within a discrete population makes consideration of genetic screening economically practical, and suggests the feasibility of targeted intervention and prevention efforts. In 1995, in this country alone, 182,000 new cases of breast cancer were diagnosed and 46,000 women died from the disease. Costs of breast cancer exceed \$12 billion per year.

With the scientific spotlight focused on the BRCA genes in the wake of the 1994 discovery of BRCA1, researchers last year discovered a "relative" of the gene that appears also to predispose women to inherited breast cancer. The newly isolated **BRCA2** gene may account for at least one-third of all cases of the disease. The function of the gene, which is found on chromosome 13, is not known; however, its DNA sequence suggests that it is related to BRCA1, which scientists believe produces a secreted protein that acts as a tumor suppressor. Defects in BRCA2 could cause the gene to fail to produce such a tumor suppressing protein, or to "misplace" it within a cell, rendering it ineffective. Either error could contribute to cancer. Ongoing research into the functions of these genes will increase our understanding of the genetic causes of breast cancer and promises to lead to improved screening tests and treatments.

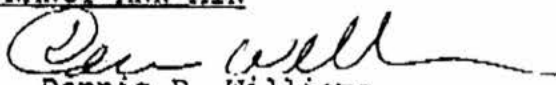


DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

OCT 22 1996

NOTE TO NANCY-ANN MINFrom:  Dennis P. Williams

Subject: Breast Cancer Information

Attached is some recent information about the Department's efforts on breast cancer research.

Attachments

Department of Health and Human Services

BREAST CANCER SPENDING

(Discretionary dollars in millions)

	FY 1995	FY 1996	FY 1997	FY 1997
			P.B.	Cong. Est.
NIH:				
NCI.....	\$309	\$337	\$341	\$349
NHLBI.....	1	1	1	1
NIDDK.....	18	19	19	20
NIGMS.....	11	15	15	16
NICHD.....	5	6	6	6
NEI.....	1	1	1	1
NIEHS.....	5	8	10	10
NIA.....	2	3	3	3
NIMH.....	1	1	1	1
NIAAA.....	1	1	1	1
NINR.....	2	2	3	3
NCRR.....	1	1	1	1
NCHGR.....	7	8	8	8
FIC.....	0	0	0	0
Total, NIH..	\$364	\$403	\$410	\$420
FDA:				
Mammography Quality Standards.....	20	26	26	26
IHS.....	3	3	3	3
CDC:				
Breast Cancer Screening.....	61	73	75	81
ANCPR.....	1	0	1	1
Subtotal....	\$449	\$505	\$515	\$531

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

October 18, 1996

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

BREAST CANCER: NEW EFFORTS UNDERWAY

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

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

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

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

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

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Background: More Women Can Survive Breast Cancer

- The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.
- In 1995 alone, approximately 182,000 new cases of breast cancer were diagnosed in women and 46,000 died from the disease. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- Death rates from the disease are highest among older, black, and low-income women. During the last 20 years, death rates from breast cancer for women over 65 increased by 35 percent for black women and 11 percent for white women. Mortality rates vary widely among racial and ethnic groups in the United States. Hispanic, Chinese, Filipino and Japanese women have annual rates at or below 15 per 100,000 women, while black, white and Native Hawaiian women have rates above 25 per 100,000 women.
- With proper screening and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. During the most recent 5-year period of available data (1989 to 1993), the age-adjusted breast cancer mortality rates fell approximately 6 percent among white women and rose about 1 percent among black women. By comparison, from 1980 to 1989, rates increased 3 percent among white women and 16 percent among black women.
- During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

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

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

HHS Action To Combat Breast Cancer

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

National Action Plan on Breast Cancer

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

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

- More -

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

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

National Breast and Cervical Cancer Early Detection Program

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

- More -

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Breast Cancer Among the Elderly

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

New Frontiers In Breast Cancer Early Detection

The Department of Health and Human Services has been working with the Department of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast

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

Centers of Excellence

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

Mammography Clinical Practice Guidelines

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

- More -

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Mammography Standards

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

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

Environmental Factors and Breast Cancer

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

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, Oct. 1, 1996

Contact: CDC Press Office
(404) 639-3286

Breast Cancer Screening Efforts Go Nationwide Secretary Shalala Launches Breast Cancer Awareness Month

Stressing the importance of routine breast cancer screening for all women, HHS Secretary Donna E. Shalala today announced the expansion of the Breast and Cervical Cancer Early Detection Program to all 50 states, with \$102 million in federal funding for the upcoming year.

Since its first year of operation in 12 states in 1991, this program has provided screening tests to nearly a million medically underserved women.

The announcement came as National Breast Cancer Awareness Month activities were launched nationwide.

"We know that regular mammograms can substantially reduce the chance of death from breast cancer," said Secretary Shalala. "It is important that we reach every American woman with this message. And it is especially important that we reach racial and ethnic minority women throughout our country, because breast cancer mortality among these women is disproportionately high."

The Breast and Cervical Cancer Early Detection Program, operated by the CDC, serves low income and minority women, older women and those who are uninsured or underinsured. Operating in an increasing number of states each year since 1991, it is going nationwide this month with the addition of programs in Alabama, Delaware, Hawaii, Idaho, Indiana, Kentucky, Mississippi, Montana, Nevada, New Hampshire, North Dakota, South Dakota, Tennessee, Virginia, Wyoming and Washington D.C., as well as the Northern Mariana Islands, Republic of Palau, Virgin Islands, Hopi Tribe, Native American Rehabilitation Association of the Northwest, the Navajo Nation, and Indian Community Health Service.

From its inception through May 1996, the program provided 457,600 mammograms to women. Breast cancer was diagnosed in 2,495 of them.

In addition, Papanicolaou (Pap) tests have been provided to 612,008 women, and 19,166 were found to have a precursor of cervical cancer called cervical intraepithelial neoplasia (CIN I, II or III, which can be treated successfully). Almost all deaths from cervical

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cancer are preventable through widespread use of Pap testing and timely and appropriate treatment. Invasive cervical cancer has been diagnosed in 239 women through the CDC program.

The CDC program provides outreach screening and education programs through a broad array of facilities, including local health departments, community and migrant health centers, private physician offices, family planning and church sponsored clinics, YWCAs, women's shelters and senior centers.

"Public education and outreach have played important roles in the long-term success of this program," said CDC Director David Satcher, M.D. "CDC and its partners have successfully reached medically underserved women with screening through a variety of intensive community-based efforts."

Educating consumers and health professionals is the cornerstone of the National Breast Cancer Awareness Month (NBCAM) program which enters its second decade of public and professional educational outreach efforts. Two HHS agencies, the CDC and the National Cancer Institute, join with 15 other national organizations as co-sponsors of the October National Breast Cancer Awareness Month, which is dedicated to increasing awareness of the importance of early detection of breast cancer.

This year, National Mammography Day will be celebrated on Friday, October 18. On National Mammography Day, women across America are encouraged to receive or sign up for a screening mammogram or to make a commitment to get one.

Breast cancer research and screening have been high priorities for HHS under Secretary Shalala. In 1993, she convened a conference to develop a National Action Plan on Breast Cancer, and implementation of the plan is being carried out through a public-private partnership led by HHS' Office on Women's Health. Total HHS discretionary funding for breast cancer research and programs has increased from about \$90 million in 1990 to an estimated \$507 million in FY 1996.

Breast cancer is the most commonly diagnosed cancer among American women. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade, and that breast cancer will claim nearly half a million lives.

Death rates from the disease are highest among women aged 40 or older and black women as compared to white women for those aged less than 70 years. With proper screening and treatment, however, the chances of surviving breast cancer are improving. For women age 50-

- More

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

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(NOTE: List of Breast and Cervical Cancer Early Detection Program grants to each state attached)

CDC's National Breast and Cervical Cancer Early Detection Program

Comprehensive Program AWARDED

<u>States and Territories</u>	<u>FY 96</u>
Alabama	\$ 750,000
Alaska	\$ 1,751,104
Arizona	\$ 1,100,640
Arkansas	\$ 1,622,203
California	\$ 5,950,425
Colorado	\$ 2,131,985
Connecticut	\$ 1,400,000
Delaware	\$ 566,515
Florida	\$ 2,000,000
Georgia	\$ 2,516,273
Hawaii	\$ 750,000
Idaho	\$ 750,000
Illinois	\$ 3,050,000
Indiana	\$ 1,087,484
Iowa	\$ 1,700,000
Kansas	\$ 1,500,000
Kentucky	\$ 1,079,907
Louisiana	\$ 750,000
Maine	\$ 1,564,561
Maryland	\$ 3,705,108
Massachusetts	\$ 2,597,000
Michigan	\$ 4,908,000
Minnesota	\$ 1,488,245
Mississippi	\$ 750,000
Missouri	\$ 2,500,000
Montana	\$ 1,079,907
Northern Mariana Islands	\$ 200,000
Nebraska	\$ 1,000,000
Nevada	\$ 775,344
New Mexico	\$ 3,475,000
New Jersey	\$ 2,000,000
New Hampshire	\$ 1,000,000
New York	\$ 4,459,537
North Carolina	\$ 3,400,000
North Dakota	\$ 733,456
Ohio	\$ 4,088,387
Oklahoma	\$ 1,000,000
Oregon	\$ 2,250,847
Pennsylvania	\$ 2,010,000
Republic of Palau	\$ 227,145
Rhode Island	\$ 994,064
South Carolina	\$ 2,500,000
South Dakota	\$ 750,000

- More -

Tennessee	\$ 750,000
Texas	\$ 4,153,569
Utah	\$ 1,150,000
Vermont	\$ 1,052,889
Virgin Islands	\$ 721,894
Virginia	\$ 1,000,000
Washington	\$ 3,250,082
Washington, D.C.	\$ 500,000
West Virginia	\$ 2,881,438
Wisconsin	\$ 2,722,000
Wyoming	\$ 750,000

Subtotal States and Territories: \$98,845,017

American Indian/Alaska Native Organizations

Arctic Slope Native Association	\$ 300,000
Cherokee Nation	\$ 244,626
Cheyenne River Sioux	\$ 182,310
Eastern Band of Cherokee Indians	\$ 287,225
Hopi Tribe	\$ 282,429
Indian Community Health Service	\$ 282,429
Maniilaq Association	\$ 265,900
Native American Rehabilitation	
Association of the Northwest	\$ 152,714
The Navajo Nation,	
Division of Health	\$ 282,428
Pleasant Point Passamaquoddy	\$ 175,472
Poarch Band of Creek Indians	\$ 81,481
South Puget Intertribal	
Planning Agency	\$ 283,690
Southcentral Foundation	\$ 412,430

Subtotal AI/AN Organizations: \$ 3,233,134

TOTAL COMPREHENSIVE

PROGRAM AWARDS: \$102,078,151

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Friday, Oct. 18, 1996

Contact: HHS Press Office
(202) 690-6343

BREAST CANCER SCREENING PROMOTED FOR NATIONAL MAMMOGRAPHY DAY Toll-Free Information On Free and Reduced-Fee Mammograms

Encouraging women across America to receive routine breast cancer screening, HHS Secretary Donna E. Shalala promoted six, nationwide, toll-free numbers to locate accredited facilities offering free and reduced-fee screening mammograms in honor of National Mammography Day.

The numbers are:

National Cancer Institute's Cancer Information Service
(1-800-4-CANCER)

The American Cancer Society
(1-800-ACS2345)

National Alliance of Breast Cancer Organizations
(1-800-719-9154)

The Susan G. Komen Breast Cancer Foundation
(1-800-I'M AWARE)

Y-ME National Breast Cancer Organization
(1-800-221-2141)

Y-ME Spanish Language Hotline
(1-800-986-9505)

These numbers operate throughout the year providing information about breast cancer prevention, detection and treatment.

"We know that regular mammograms can substantially reduce the chance of death from breast cancer," said Secretary Shalala. "It is important that we reach every American woman with this message."

The telephone services are part of activities and outreach efforts during National Breast Cancer Awareness Month, aimed at increasing awareness of the importance of early detection of breast cancer.

The first National Mammography Day was officially recognized by President Clinton on Oct. 19, 1993 and will be observed on Oct. 18 this year. On Oct. 3, 1996 President Clinton officially proclaimed October 1996 as National Breast Cancer Awareness Month.

In his proclamation, he urged women to get mammograms as appropriate and to take advantage of preventive health services. He called upon government officials, businesses, communities, volunteers, educators, and the American public to work together to fight breast cancer.

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Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings. Currently Medicare covers one mammogram every two years for women age 65 and older. In his balanced budget proposal, President Clinton proposes to increase Medicare coverage to one mammogram annually for beneficiaries over 50, with no copayment or deductible requirement.

Breast cancer is the most commonly diagnosed non-skin cancer among American women, accounting for 31 percent of all cancers among women. Although death rates from breast cancer have been declining in recent years, epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade, and that breast cancer will claim nearly half a million lives. There is no proven way to prevent breast cancer, so early detection, through mammography and clinical breast exams, and treatment are key to lowering the death rate.

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

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. HHS Secretary Shalala convened a conference in December 1993 to establish a National Action Plan on Breast Cancer and implementation of the plan is being carried out through a public, private and volunteer partnership led by HHS' Office of Women's Health. Total discretionary spending has increased from about \$90 million in FY 1990 to an estimated \$531 million in FY 1997.

On Oct. 1, 1996 Secretary Shalala announced the expansion of the CDC's National Breast and Cervical Cancer Early Detection Program to all 50 states, with \$102 million in federal funding for the upcoming year. The program provides screening services for low income and medically underserved women. Since its first year of operation in 12 states in 1991, this program has provided over a million screening tests.

In March 1996, the FDA issued proposed regulations to implement the Mammography Quality Standards Act (MQSA), to ensure that mammography facilities meet high quality standards for equipment and personnel.

And the PHS Office of Women's Health has initiated an innovative partnership with the Central Intelligence Agency and the Department of Defense to transfer defense imaging technologies to improve early detection of breast cancer.

- MORE -

Educating consumers and health professionals is the cornerstone of the National Breast Cancer Awareness Month (NBCAM) program, which is entering its second decade of public and professional outreach efforts. Two HHS agencies, the CDC and the National Cancer Institute, are working with 15 other national organizations as co-sponsors of the 1996 October National Breast Cancer Awareness Month.

In addition to National Mammography Day, activities, screenings, and media events will be held across the country throughout the month to improve breast cancer awareness.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Monday, Sept. 30, 1996

Contact: PHS Office on Women's Health
(202) 690-7650

\$1.98 MILLION AWARDED TO BEGIN CLINICAL TRIALS ON NEW BREAST IMAGING TECHNOLOGIES

The Department of Health and Human Services, in a unique collaboration with the CIA, has awarded \$1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community -- originally used for missile guidance and target recognition -- to improve the early detection of breast cancer.

"These technologic innovations assist intelligence officers in finding targets camouflaged behind trees via satellite, said Health and Human Services Secretary Donna E. Shalala. "Now clinical trials will determine the safety and effectiveness of the same intelligence technologies to assist radiologists with finding small cancers camouflaged behind breast tissue."

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

- More -

- 2 -

Clinical trials are the crucial next step to test how effectively these new imaging procedures will work on women, with the intent of having the new technologies available to consumers as soon as possible.

"If we can image missiles in distant skies, and with the Hubble telescope see the surface of Mars, then surely we should be better able to detect small lumps in women's breasts right in front of us," said Susan J. Blumenthal, M.D., M.P.A., Deputy Assistant Secretary for Women's Health and Assistant Surgeon General.

Breast cancer is one of the most feared diseases among women. One in eight women will be diagnosed with the deadly disease during her lifetime. It is estimated that in 1996 more than 44,000 women will die from breast cancer.

Currently, mammography is the best method for detecting breast cancer and can decrease death rates by 30 percent. However, it is a 40-year-old technology that misses up to 15-20 percent of cancerous tumors. In addition, three out of four lesions detected by this technology are benign, leading to unnecessary and costly procedures, including biopsies.

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

- More -

The clinical trials will include testing in two major areas:

- Computer-aided diagnosis in digital x-ray mammography -- in which visual information is generated, displayed, enhanced, stored, and transmitted by computers instead of x-ray film -- has the potential to produce clearer, sharper images and may be especially helpful in viewing dense breast tissue where small cancers are harder to see.
- Computer-aided diagnosis for magnetic resonance imaging (MRI) -- in which three-dimensional images of breast tumors are created on computers, allowing doctors to view the actual volume, shape and size of the tumor -- has the potential to provide more detailed images to help doctors distinguish between benign and malignant breast tumors, and more accurately guide biopsy and to select the most effective treatment.

An extensive library, or digital image database, will also be created that will serve as a national resource for other researchers working in this exciting new area.

Other institutions and organizations that will participate in conducting this clinical trial include: Massachusetts General Hospital, University of Chicago, Brown University, University of Arkansas, University of California at Los Angeles, University of California at San Francisco, University of Virginia, National Naval Medical Center and David Sarnoff Research Institute.

In charge of the project for the University of Pennsylvania will be Mitchell Schnall, M.D., Ph.D., Chief of the Magnetic Resonance Imaging Section in the Department of Radiology.

The clinical trials are supported by the PHS Office on Women's Health, which provides national leadership in advancing women's health in public policy, research, service delivery and education, and acts as a catalyst for developing new national and regional initiatives to improve women's health.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, Oct. 1, 1996

Contact: PHS Office on Women's Health
(202) 690-7650

HHS LAUNCHES "CENTERS OF EXCELLENCE IN WOMEN'S HEALTH"

The Department of Health and Human Services today announced establishment of six National Centers of Excellence in Women's Health, to serve as national models for improving the health care of American women.

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

"Our nation can't afford to give anything less than its best efforts for women's health," said HHS Secretary Donna E. Shalala. "These new Centers of Excellence are just one step in a broad cooperative effort to improve our health research and services for women, and to improve the career prospects for women in the health professions."

The national Centers of Excellence will be located at Allegheny University of the Health Sciences, Philadelphia; Magee-Womens Hospital, Pittsburgh, Pa.; Ohio State University Medical Center, Columbus, Ohio; University of California at San Francisco; University of Pennsylvania, Philadelphia; and Yale University, New Haven, Conn. They represent a public-private partnership between HHS and the academic institutions. The U.S. Public Health Service's Office on Women's Health developed the concept for the centers and is providing \$1 million to support the centers.

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

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

- 2 -

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

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

The Centers of Excellence will provide the following women's health resources and services:

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

The PHS Office on Women's Health provides national leadership in advancing women's health in public policy, research, service delivery and education. The office acts as a catalyst for developing new national and regional initiatives to improve women's health.

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Note: HHS press releases are available on the World Wide Web at:
<http://www.dhhs.gov>.

to 80 percent of a subtype of Alzheimer's that strikes before age 65. In searching for the functions of the proteins coded by the genes, investigators have detected a similarity between the PS1 and -2 proteins and a protein that is known to be involved in cell to cell communication and development. Accumulating evidence of the unexpectedly influential role of genetic factors in Alzheimer's disease adds urgency to the task of clarifying the molecular basis of the disease. In the interim, information about mutations in Alzheimer's-related genes likely will lead to diagnostic tests for at-risk members of affected families. Alzheimer's disease affects 4 million Americans today; that number will increase dramatically as baby boomers hit the age of highest risk.

Ataxia Telangiectasia (AT) — Researchers isolated the gene for AT, a rare disease of childhood that typically leads to death before adulthood. The disease is marked by progressive loss of coordination beginning between 1 and 2 years of age, growth retardation, immune deficiencies, high rates of cancer, radiation sensitivity, and premature aging. Although both parents must contribute a defective AT gene for a child to be affected, carriers — persons with one copy of the gene but who do not have the disease — are at increased risk for cancer and are highly sensitive to radiation. Identification of the gene paves the way to not only develop tests for prenatal diagnosis, but also to identify carriers, thus enabling carriers to choose to limit their use of radiation in cancer screening and treatment. Up to 8 percent of all breast cancers may be caused by mutations in the AT gene.

Breast Cancer — In an extension of the exciting 1994 finding of **BRCA1**, a gene that confers susceptibility to breast cancer, NIH scientists and collaborators discovered a specific mutation in the gene in nearly 1 percent of blood samples collected from women of Ashkenazi Jewish descent. This finding identifies a particular subgroup of the general population that may benefit from genetic testing for the **BRCA1** mutation. Epidemiologists have hypothesized that this mutation may account for as much as 16 percent of breast and 39 percent of ovarian cancers among Ashkenazi Jewish women age 50 and under. The finding of the **BRCA1** mutation within a discrete population makes consideration of genetic screening economically practical, and suggests the feasibility of targeted intervention and prevention efforts. In 1995, in this country alone, 182,000 new cases of breast cancer were diagnosed and 46,000 women died from the disease. Costs of breast cancer exceed \$12 billion per year.

With the scientific spotlight focused on the **BRCA** genes in the wake of the 1994 discovery of **BRCA1**, researchers last year discovered a "relative" of the gene that appears also to predispose women to inherited breast cancer. The newly isolated **BRCA2** gene may account for at least one-third of all cases of the disease. The function of the gene, which is found on chromosome 13, is not known; however, its DNA sequence suggests that it is related to **BRCA1**, which scientists believe produces a secreted protein that acts as a tumor suppressor. Defects in **BRCA2** could cause the gene to fail to produce such a tumor suppressing protein, or to "misplace" it within a cell, rendering it ineffective. Either error could contribute to cancer. Ongoing research into the functions of these genes will increase our understanding of the genetic causes of breast cancer and promises to lead to improved screening tests and treatments.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

OCT 22 1996

NOTE TO NANCY-ANN MIN

From:  Dennis P. Williams

Subject: Breast Cancer Information

Attached is some recent information about the Department's efforts on breast cancer research.

Attachments

Department of Health and Human Services

BREAST CANCER SPENDING

(Discretionary dollars in millions)

	FY 1995	FY 1996	FY 1997 P.B.	FY 1997 Cong. Est.
<u>NIH:</u>				
NCI.....	\$309	\$337	\$341	\$349
NHLBI.....	1	1	1	1
NIDDK.....	18	19	19	20
NIGMS.....	11	15	15	16
NICHD.....	5	6	6	6
NEI.....	1	1	1	1
NIEHS.....	5	8	10	10
NIA.....	2	3	3	3
NIMH.....	1	1	1	1
NIAAA.....	1	1	1	1
NINR.....	2	2	3	3
NCRR.....	1	1	1	1
NCHGR.....	7	8	8	8
FIC.....	0	0	0	0
Total, NIH..	\$364	\$403	\$410	\$420
<u>FDA:</u>				
Mammography Quality Standards.....	20	26	26	26
IHS.....	3	3	3	3
<u>CDC:</u>				
Breast Cancer Screening.....	61	73	75	81
AHCPR.....	1	0	1	1
Subtotal....	\$449	\$505	\$515	\$531



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

October 15, 1996

NOTE FOR DON BAER

FROM: Nancy-Ann Min

RE: Ideas for Possible Breast Cancer Event

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

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

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

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

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

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

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

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

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

THE WHITE HOUSE

WASHINGTON

National Breast Cancer Awareness Month, 1996

By the President of the United States of America

A Proclamation

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

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

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

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

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

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

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

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

William J. Clinton

Richard J. Turman

10/11/98 07:09:37 PM

Record Type: Record

To: Nancy A. Min/OMB/EOP, Sarah A. Bianchi/OMB/EOP

cc: Barry T. Clendenin/OMB/EOP

Subject: Breast Cancer -- NIH Information

⇒ specific mutation →
Askenazi
aspect /
inappropriate

⇒ new technologies

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

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

Cancer Genetics Network

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

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

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

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

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

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

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

Human Genome Project -
"maps" - where are genes? that are most
likely to be involved in disease. 10,000 genes -
on xref map - Web page. next some for PC
best over

24th

uncommon childhood
disorder caused by
mutation

15-20% of
3-4 yrs with up

BRCA1 diag. testing -
mktr -

sample
down
center

vicinity

1995

He also tried to explain how the additional information they're finding about the genetic basis of breast cancer could be of help in isolating what environmental factors play a role in breast cancer, but I had a hard time following his reasoning.

He is quite enthusiastic about the progress that has been made, and he believes will continue to be made, in this area, and would be happy to discuss it further this weekend, if need be. His home phone is 301-468-5672. He won't be at home on Sunday, but should be around the rest of the time.



OFFICE ON WOMEN'S HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

OFFICE OF PUBLIC HEALTH AND SCIENCE

OFFICE ON WOMEN'S HEALTH

Humphrey Building

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Number of Pages being transmitted (including cover): 15

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TO: Sarah Bianchi

OFFICE: _____

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If this facsimile is not received in its entirety, please contact _____
at the number stated above.

NOTE: I hope this will help.
Sund.

Detecting Changes in Serial Mammograms for Early Detection of Breast Cancer

A dual use application of two-dimensional image alignment technology

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

Comparison of mammograms enables a physician to detect change that signals the early start of cancer. The physician currently views two mammograms side by side, mentally matching key features to align and compare the mammograms. Change detection is a challenging task because soft tissue takes on different shapes at different imaging sessions, resulting in misaligned mammograms. At the early start of cancer, important change may be quite subtle and difficult to detect.



Original Mammogram



Mammogram 1 Year Later



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



Difference After Alignment
(suspicious region is easily identified)

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

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

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

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Private Sector Partners: Dr. D.B. Kopans, Harvard Medical School;
Dr. M.D. Schnall/Dr. R.S. Mezrich, University of Pennsylvania Medical Center



Detecting Lesions in Magnetic Resonance Breast Scans

A dual use application of three-dimensional volume alignment technology

National Information Display Laboratory • Princeton, New Jersey

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

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

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

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



Slice of "Pre" MR



Slice of "Post" MR



Change before alignment



Change after alignment

Figure represents alignment of Pre and Post MR data sets

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

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

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Dr. M.D. Schnall/Dr. R.S. Mezhich, University of Pennsylvania Medical Center



Pattern Recognition Tools to Assist Early Detection of Breast Cancer

A dual use application for learning image context in mammography

National Information Display Laboratory • Princeton, New Jersey

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

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

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

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



Figure 1

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



Figure 2

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

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

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

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Fact Sheet

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

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



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

BREAST CANCER

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

BACKGROUND

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

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

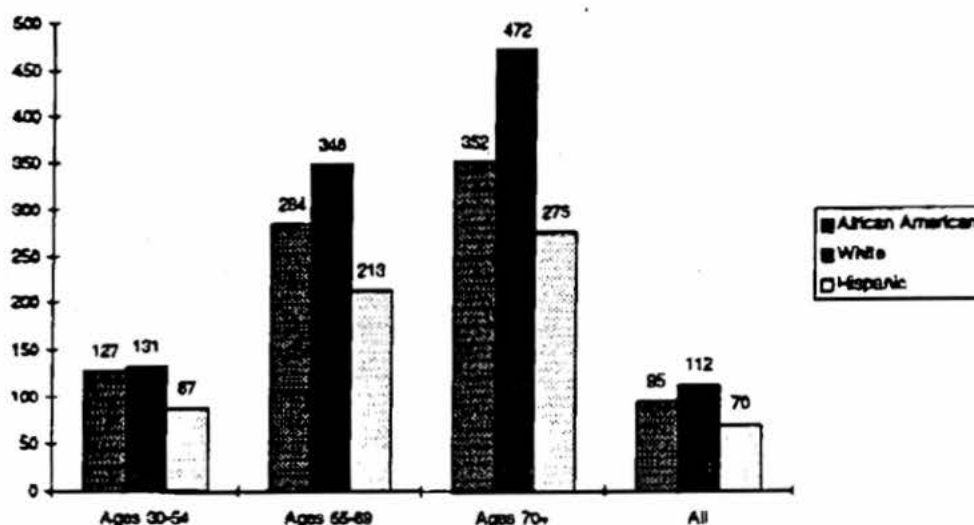
Despite the increasing incidence of breast cancer since 1940, the overall death rate (mortality rate) in American women has been declining in the 1990s. Among white women, the mortality rate has dropped approximately 6 percent between 1989 and 1993. For African-American women, increases in mortality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

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

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



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



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

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

ETIOLOGY OF BREAST CANCER

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

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

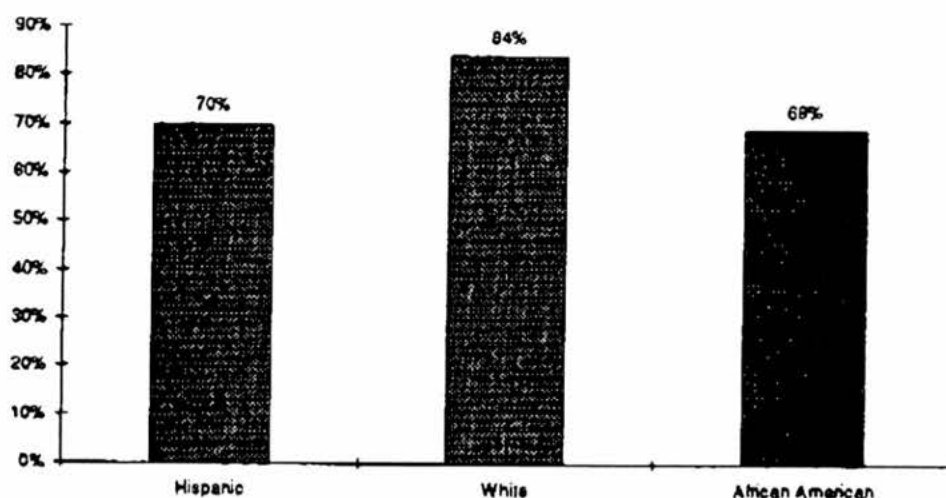
RISK FACTORS

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

Other risk factors include:

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

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



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

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

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

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

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

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

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

DETECTION AND DIAGNOSIS OF BREAST CANCER

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

CONVENTIONAL MAMMOGRAPHY

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

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

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

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

surgical biopsies, reduce costs, and eliminate scarring.

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

ULTRASOUND

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

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

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

NEW DIAGNOSTIC TECHNOLOGIES

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

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

Digital Mammography

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

Computer-Aided Diagnosis (CAD)

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

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

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

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

BREAST CANCER TREATMENT

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

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

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

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

PREVENTION OF BREAST CANCER

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

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

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

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

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

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

DHHS BREAST CANCER INITIATIVES

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

PHS OFFICE ON WOMEN'S HEALTH

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

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

National Action Plan on Breast Cancer

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

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

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

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

Federal Coordination of Breast Cancer Programs

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

Initiative to Develop New Breast Cancer Imaging Techniques

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

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

Older Women Mammography Initiative

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

AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR)

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

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

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

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

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

FOOD AND DRUG ADMINISTRATION (FDA)

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

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

NATIONAL INSTITUTES OF HEALTH (NIH)

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

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

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

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

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

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

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

INDIAN HEALTH SERVICE (IHS)

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

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

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

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

SUMMARY

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

For Further Information:**U.S. Public Health Service's Office on
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October 11, 1996

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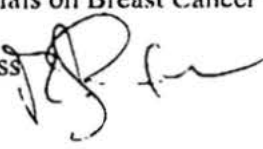
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Subject: Further Materials on Breast Cancer

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Room: #7026

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Here are some materials on breast cancer funding and statistics. We have included:

- a May 7 National Cancer Institute press release announcing that the breast cancer death rate continued to decline in 1993;
- an October 4 CDC MMWR article showing that the death rate has decreased through 1992 while incidence (the number of new cases) has *increased*;

Most of the CDC's FY 1997 Breast Cancer Program Increase Will Go to States

Congress has appropriated \$140 million for CDC breast and cervical cancer screening programs in FY 1997, \$15 million more than the President requested (and than was appropriated in FY96). CDC staff tell us that they have not yet made final decisions about the use of those funds, but they expect to send more than 80% of the funds to States for their screening programs.

CDC staff say that all the States currently have "comprehensive" breast and cervical cancer screening programs, but the 15 States that received comprehensive programs in FY 1996 received smaller grants than the previous 35 -- CDC plans to use the additional funds in FY 1997 to even out these disparities. CDC tell us that in FY 1995 (when their funding was \$100 million) they screened about 142,000 women.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, May 7, 1996

Contact: NCI Press Office
(301) 496-6641

NCI Reports Improvements in Breast Cancer Death Rate

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

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

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

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

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

(more)

2

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

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

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

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

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

(more)

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

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

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

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

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

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

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

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

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

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

(more)

5

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

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

###

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

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

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

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

Highlights

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

Funding in FY 1997

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



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MNWR

MORBIDITY AND MORTALITY WEEKLY REPORT

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

National Breast Cancer Awareness Month — October 1996

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

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

Breast Cancer Incidence and Mortality — United States, 1992

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

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

Breast Cancer — Continued

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

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

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

Breast Cancer Incidence

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

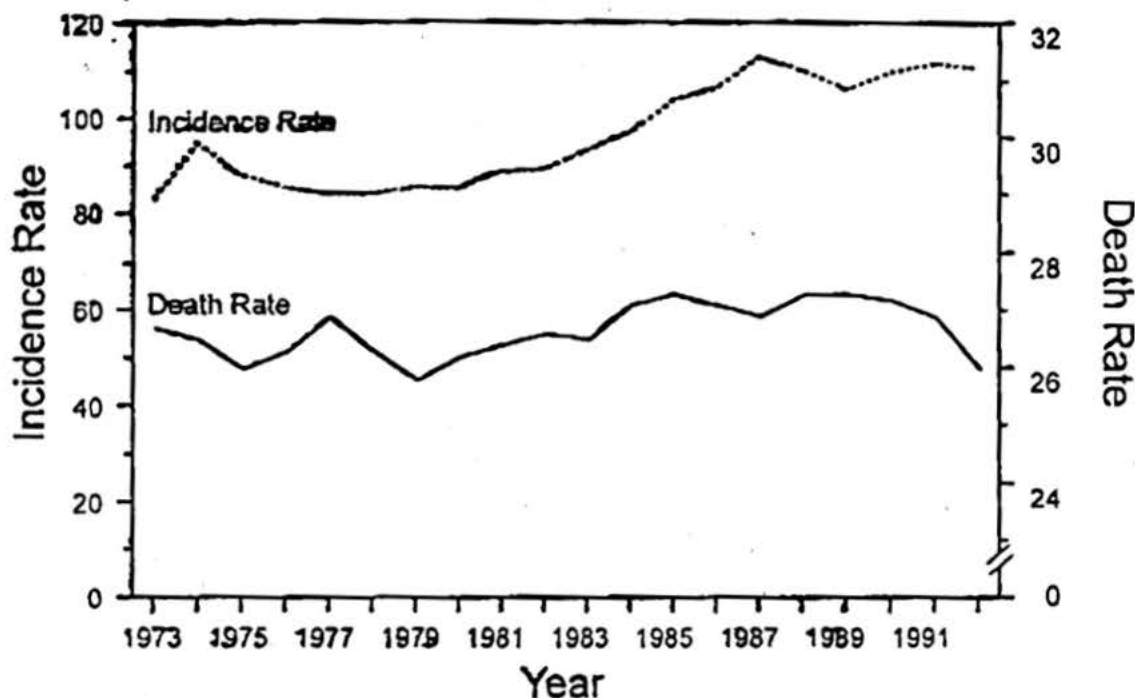
During 1973–1992, the overall incidence rate increased from 82.5 to 110.6; rates increased steadily during 1973–1987, and stabilized during 1988–1992 (Figure 1). During 1988–1992, incidence rates increased directly with age until age 75–79 years for whites and age 80–84 years for blacks (2); the rates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

Breast Cancer Mortality

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

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

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

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

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

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

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

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

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

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

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

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

Breast Cancer — Continued

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

State	No. deaths			Rate			Black-to-white ratio
	White	Black	Total	White	Black	Total	
Alabama	2,440	871	3,318	23.5 [§]	31.5	25.2	1.3
Alaska	158	..	190	26.3	..	23.8	..
Arizona	2,509	..	2,707	24.6	..	24.0 [§]	..
Arkansas	1,668	298	1,972	22.9 [§]	30.3	23.8 [§]	1.3
California	18,702	1,579	21,121	28.9	32.1	28.0 [§]	1.2
Colorado	2,169	..	2,280	24.9	..	24.7	..
Connecticut	2,897	181	3,089	28.7	30.0	26.9	1.1
Delaware	593	..	692	32.0	..	32.5	..
District of Columbia	197	509	712	29.3	38.0	35.3 [§]	1.3
Florida	11,859	1,158	13,044	25.2 [§]	29.0	25.5 [§]	1.2
Georgia	3,419	1,118	4,547	24.3 [§]	27.4	24.9 [§]	1.1
Hawaii	177	..	548	25.4	..	18.2 [§]	..
Idaho	712	..	717	25.0	..	24.7	..
Illinois	9,467	1,353	10,853	28.3 [§]	32.8	29.5 [§]	1.1
Indiana	4,513	365	4,888	26.7	33.9	27.2	1.3
Iowa	2,728	..	2,758	26.5	..	26.4	..
Kansas	2,078	..	2,191	25.7	..	25.8	..
Kentucky	2,823	231	3,062	25.4	33.0	25.8	1.3
Louisiana	2,324	1,046	3,386	25.0	33.2	27.2	1.3
Maine	1,110	..	1,116	26.7	..	26.7	..
Maryland	3,188	859	4,073	28.0	32.0	28.6	1.1
Massachusetts	6,110	201	6,335	30.1	31.2	30.0 [§]	1.0
Michigan	6,959	1,071	8,070	27.5	33.7	28.1	1.2
Minnesota	3,686	..	3,744	27.1	..	26.9	..
Mississippi	1,290	631	1,922	22.7	27.8	24.2 [§]	1.2
Missouri	4,271	449	4,734	26.1	32.0	26.6	1.2
Montana	626	..	646	24.8	..	24.8	..
Nebraska	1,431	..	1,463	26.9	..	26.8	..
Nevada	803	..	861	26.7	..	26.3	..
New Hampshire	1,021	..	1,025	30.8	..	30.7	..
New Jersey	7,474	894	8,423	31.5 [§]	34.7	31.6 [§]	1.1
New Mexico	963	..	1,000	24.6	..	23.6	..
New York	16,211	2,292	18,643	31.1 [§]	29.6	30.5 [§]	1.0
North Carolina	4,307	1,160	5,518	25.3	30.5	26.3	1.2
North Dakota	564	..	575	27.3	..	27.2	..
Ohio	9,404	987	10,409	28.3	32.2	28.8	1.1
Oklahoma	2,259	136	2,468	24.9	24.7	24.0 [§]	1.0
Oregon	2,339	..	2,389	25.7	..	25.4	..
Pennsylvania	12,081	1,089	13,200	29.2 [§]	34.8	29.6 [§]	1.2
Rhode Island	1,103	..	1,141	31.5	..	31.6	..
South Carolina	1,995	745	2,744	25.5	29.0	26.3	1.1
South Dakota	606	..	624	26.5	..	26.3	..
Tennessee	3,358	688	4,056	24.1 [§]	34.2	25.4	1.4
Texas	9,638	1,412	11,100	23.5 [§]	30.3	24.0 [§]	1.3
Utah	883	..	897	23.3	..	23.2	..
Vermont	494	..	494	28.0	..	27.9	..
Virginia	4,035	983	5,057	27.2	33.4	27.9	1.2
Washington	3,713	..	3,851	27.1	..	26.5	..
West Virginia	1,564	..	1,631	24.7	..	24.9	..
Wisconsin	4,312	130	4,455	27.3	33.1	27.3	1.2
Wyoming	320	..	324	25.9	..	25.6	..
Total	189,639	23,114	215,039	27.0	31.3	27.1	1.2

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

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

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

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

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

$$\frac{215039}{5} = 43007.8$$

Breast Cancer — Continued

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

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

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Suffocations in Grain Bins — Minnesota, 1992–1995

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

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



To Richard
Tanner

FACSIMILE TRANSMISSION

DATE: 10/22/96

FAX TO: Nancy-Ann Min

ADDRESS: OMB

PHONE: (202) 395-5178

FAX: (202) 395-7289

FROM: Dennis Williams
Office of Budget, ASMB,
Department of Health and Human Services

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FAX: (202) 690-6896

PAGES FOLLOWING COVER PAGE: 2

SUBJECT: Breast Cancer

MESSAGE:

Additional information specific to research on BRCA genes.

Breast
Cancer

BREAST CANCER GENES

Discovery of BRCA1 and BRCA 2 Genes for Breast Cancer

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

WHAT THE DEPARTMENT IS DOING

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

Page 2

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



National Cancer Institute

FOR IMMEDIATE
RELEASE

June 23, 1997

Press Release

Office of Cancer
Communications

Building 31, Room
10A24

Bethesda, MD 20892

FOR RESPONSE TO

INQUIRIES

Lori Psillidis

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Breast Cancer Prevention Trial Completes Recruitment: Answers Expected in Two to Three Years

After five years, recruitment for the Breast Cancer Prevention Trial (BCPT) ended May 30, 1997, and results are expected in two to three years. The 13,000th woman joined the study on May 20. Women who have qualified to participate, but who have not completed pre-entry tests and examinations, have until Sept. 1, 1997 to enroll.

"Reaching this milestone is a tremendous accomplishment for the oncology community," said Leslie Ford, M.D., associate director for early detection and community oncology at the National Cancer Institute (NCI), and NCI coordinator for the study. "Finding a way to prevent breast cancer is one of the most important research questions we have to answer. Each and every woman who has chosen to participate has my gratitude for their trust and conviction in seeing this study through."

Norman Wolmark, M.D., chairman of the Pittsburgh-based National Surgical Adjuvant Breast and Bowel Project (NSABP), the NCI-sponsored research network conducting the BCPT, also thanked and praised the participants. "Reaching this point in the study represents an achievement of unprecedented dimension. Everyone recognizes that breast

Centers for Disease Control and Prevention

Breast and Cervical Cancers

An estimated 2 million American women will be diagnosed with breast or cervical cancer in the 1990s, and half a million will lose their lives. A disproportionate number of deaths will be among minorities and women of low income.

Breast cancer is the most common nondermatologic cancer among American women and is second only to lung cancer as a cause of cancer-related deaths. An estimated 180,200 new cases of breast cancer among women will be diagnosed in 1997, and 43,900 women will die from the disease.

The incidence of invasive cervical cancer has decreased significantly over the last 40 years, due in large part to early detection efforts. Still, an estimated 14,500 new cases of invasive cervical cancer will be diagnosed in 1997, and 4,800 women will die from the disease. Virtually all of these deaths can be prevented by making these lifesaving screening services available to all women at risk.

The Program

"This initiative will remove many of the financial barriers women face in getting timely mammograms and Pap tests."

--Donna E. Shalala, Secretary
U.S. Department of Health and Human
Services

The Breast and Cervical Cancer Mortality Prevention Act of 1990 authorized the CDC to implement a national program to ensure that every woman for whom it is deemed appropriate receives regular screening for breast and cervical cancers, prompt follow-up if necessary, and assurance that the tests are performed in accordance with current recommendations for quality assurance. CDC implements many of these activities through partnerships with state and territorial health agencies, American Indian/Alaska Native organizations, and other national organizations. In Fiscal Year 1997, CDC entered into the seventh year of this landmark national program that brings critical breast and cervical cancer screening services to underserved women, including older women, women with low income, uninsured or underinsured women, or women of racial/ethnic minority groups.

Appropriations of \$140 million in 1997 enable CDC to establish greater access to screening and follow-up services, increased education and outreach programs for women and health care providers, and improved quality assurance measures for mammography and cervical cytology.

Fifty states, five territories, the District of Columbia, and 13 American Indian/Alaska Native organizations now participate in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). CDC provides national program leadership in collaboration with other federal agencies and professional, national, voluntary, and consumer organizations.

The National Breast and Cervical Cancer Early Detection Program

Comprehensive Screening Programs

- ☐ All 50 States
- ☐ District of Columbia
- ☐ Northern Mariana Islands
- ☐ Republic of Palau
- ☐ U.S. Virgin Islands
- ☐ American Indian/Alaska Native organizations
 - ☐ Arctic Slope Native Association, AK
 - ☐ Cherokee Nation, OK
 - ☐ Cheyenne River Sioux Tribe, SD
 - ☐ Eastern Band of Cherokee Indians, NC
 - ☐ Hopi Tribe, AZ
 - ☐ Indian Community Health Service, AZ
 - ☐ Maniilaq Association, AK
 - ☐ Native American Rehabilitation Association of the Northwest, OR
 - ☐ Navajo Nation, NM & AZ
 - ☐ Pleasant Point Passamaquoddy Tribe, ME
 - ☐ Poarch Band of Creek Indians, AL
 - ☐ Southcentral Foundation, AK
 - ☐ South Puget Intertribal Planning Agency, WA

Capacity-Building Programs

- ☐ American Samoa
- ☐ Puerto Rico

Screening and Follow-up Services

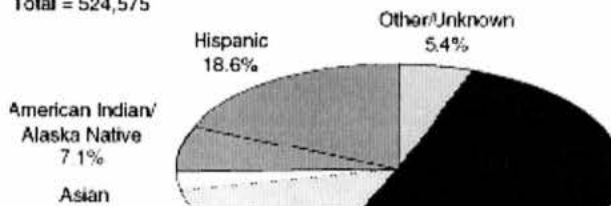
Why Get Screened?

Breast cancer screening by mammography is the most effective method of detecting breast cancer in its earliest, most treatable stage. Mammography detects cancer an average of 1.7 years before the woman can feel the lump herself and locates cancers too small to be felt during a breast examination. Generally, survival has an inverse relationship with the stage of breast

Percent Distribution of Mammograms and Papanicolaou Tests Provided to NBCCEDP Participants, by Race/Ethnicity, 1991–1996

Mammograms by Race/Ethnicity

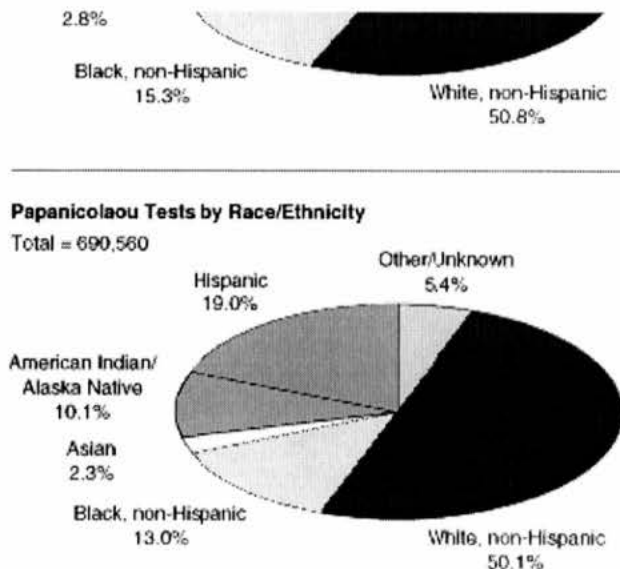
Total = 524,575



relationship with the stage of breast cancer at detection --- the more advanced the cancer stage, the lower the survival rate. When breast cancer is diagnosed at a local stage, the 5-year survival rate is 97%. When breast cancer is diagnosed at a distant stage (metastasized), the 5-year survival rate decreases to 20%.

The intended outcome of cervical cancer screening differs from that of breast cancer screening: the primary goal is not to find cancer, but to find precancerous lesions. Detection and treatment of precancerous cervical lesions (dysplasia) identified by Papanicolaou (Pap) screening can actually prevent cervical cancer.

Additionally, if cervical cancer is detected while in its earliest in situ stage, the likelihood of survival is almost 100 percent with timely and appropriate treatment and follow-up.



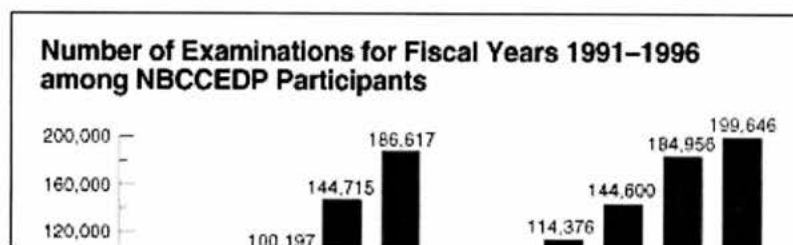
Source: NBCCEDP data through 9/30/96

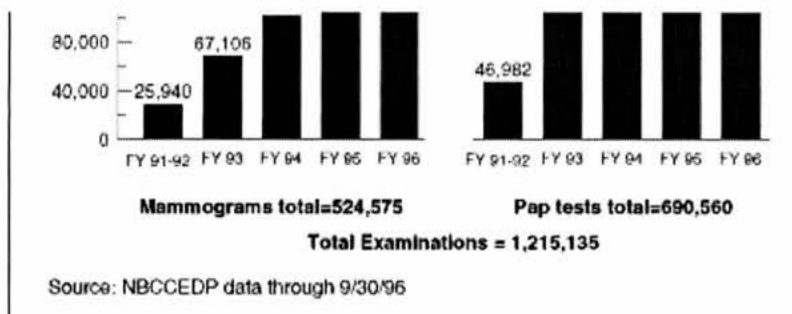
Common Barriers to Screening

- ❑ **Fear.** Women do not want to discover that they have cancer.
- ❑ **Cost.** Many women cite cost as the reason they do not use early detection programs. Many are not aware of the availability of low-cost programs.
- ❑ **Transportation.** Because many women lack transportation, the location of screening facilities is important.
- ❑ **Communication Barriers.** Communication styles and methods are sometimes inappropriate to the needs of the women seeking services.
- ❑ **Lack of Physician Referral.** Studies have shown that women are more likely to be screened if their physician recommends screening.
- ❑ **Lack of Child Care.** Some women need assistance with arranging child care to be able to use screening.

Treatment

The NBCCEDP legislative mandate does not permit payment for treatment with CDC funds. However, funded programs have shown creativity and determination in identifying and securing treatment services for women diagnosed with breast cancer or cervical abnormalities. These treatment sources reflect the extent of state and local government support, medical provider generosity, and community commitment. Examples of these resources include county programs for the indigent, state-funded cancer clinics, and in one state, a legislative mandate to use cigarette tax revenue to pay for treatment. The Indian Health Service has funded treatment for many American Indian/Alaska Native organizations. Medical providers and hospitals in communities have also donated treatment services.



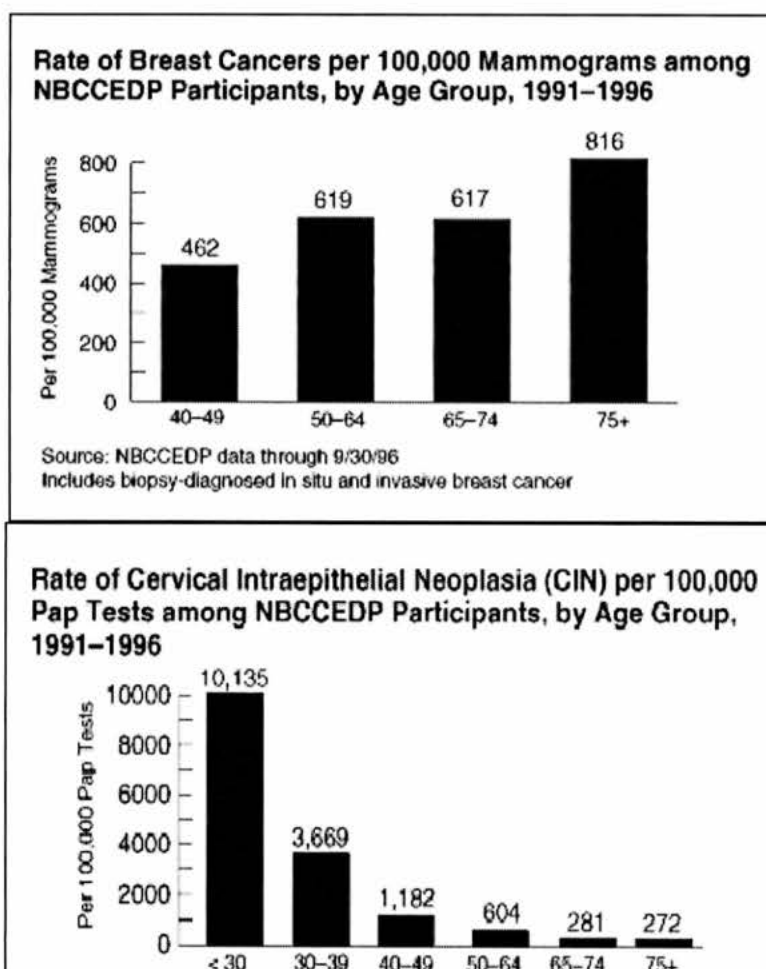


Surveillance

How the Program Has Helped

Through September 1996, more than 1,200,000 screening tests were provided by the program. Of the 506,673 mammograms provided to women aged 40 years and older, 33,218 (6.5 percent) were abnormal, and 2,918 led to a diagnosis of breast cancer. As depicted below, the rates of breast cancer increased with increasing age.

Of the 690,560 Pap tests provided, 27,135 (4 percent) were abnormal. A total of 21,257 cases of cervical intraepithelial neoplasia (CIN) I, II, or III, a precursor of invasive cervical cancer that can be successfully treated, were diagnosed. A total of 258 cases of invasive cervical cancer were diagnosed, a rate of 39 per 100,000. As depicted below, the rates of CIN decreased with increasing age.



CIN

Source: NBCCEDP data through 9/30/96
Includes biopsy-diagnosed CIN I, CIN II, CIN III

Public Education and Outreach

***"Comprehensive strategies will be needed
to educate and motivate women to seek
screening services."***

--Donna E. Shalala, Secretary
U.S. Department of Health and Human
Services

Innovative Program Strategies

The program has made significant progress in building state and community partnerships to serve women. Various outreach activities have been designed to educate women and motivate them to be screened.

- In Anchorage, Alaska, the Southcentral Foundation's Alaska Native Women's Wellness Project and many other partners collaborate to bring breast and cervical cancer screening and community outreach to medically underserved women. Alaska Native women face many barriers in seeking health care that require the development of culturally specific outreach strategies and educational materials. This partnership reaches out to many organizations that can bring special competencies and skills to provide women with breast health education and screening services. The project is managed by Alaska Natives, who are close to the community and who understand Native ways of communicating and interacting.
 - Glendale, California is a multi-ethnic Los Angeles suburb where non-English speaking underserved populations include Eastern Europeans, Asians, and Hispanics. The California Department of Health's Breast and Cervical Cancer Early Detection Program joined forces with the YWCA of Glendale, the Mission City Clinic, University of California Los Angeles, and numerous community-based organizations to deliver comprehensive screening services. Through these partners' combined efforts, a high volume of women from a large and diverse community receive high quality breast screening services and education.
 - The Nebraska Breast and Cervical Cancer Early Detection Program is concerned about Vietnamese women for whom cervical cancer is the leading cancer site. In Hastings, Nebraska, the program determined that Vietnamese women were not returning for their annual clinic visits because reminders were in English. In July 1996, letters in Vietnamese were mailed to all Vietnamese women aged 18 years and over in Hastings. This letter invited them to attend a program at the YWCA in Vietnamese that provided education about and referrals for screening services. Because Vietnamese women may be more comfortable accessing health care with other women, the women who are scheduled for clinic visits have an interpreter with them and go as a group. These efforts illustrate Nebraska's commitment to culturally sensitive outreach.
-

Partnerships and Coalition Development

National Organizations

Since 1992, CDC has awarded funds to national organizations to educate their constituents about breast and cervical cancers, to increase access to breast and cervical cancer screening among underserved women, and to develop strategies for reaching women in collaboration with state and territorial health agencies and American Indian/Alaska Native organizations. These organizations include

- ☐ American Association of Retired Persons
- ☐ American Federation of Teachers Education Foundation
- ☐ American Indian Healthcare Association
- ☐ Mayo Foundation, Inc.
- ☐ National Caucus and Center on Black Aged, Inc.
- ☐ National Center for Farmworker Health, Inc.
- ☐ National Coalition of Hispanic Health and Human Service Organizations
- ☐ National Education Association
- ☐ National Hispanic Council on Aging
- ☐ Susan G. Komen Breast Cancer Foundation
- ☐ World Education
- ☐ YWCA of the U.S.A.

National Center for Farmworker Health, Inc.

The Traveling Lay Health Advisors (TLHA) program was developed to address the need for comprehensive and culturally sensitive early detection of cancer among mostly Hispanic migrant and seasonal farmworkers. TLHAs provide basic education on women's health, referrals to breast and cervical cancer screening sites, tracking and follow-up services, and translation of service information for farmworkers. TLHAs help assure continuity of care, assisting health centers and clinics in arranging follow-up care and referrals and in locating patient medical records. These activities contribute to the mission of the health centers by reaching a greater percentage of the target population while strengthening NBCCEDP efforts to decrease barriers to breast and cervical cancer screening.

National Center for Farmworker Health, Inc. collaborated on developing a community media guide for advocates who are interested in health promotion with a focus on breast and cervical cancers. This step-by-step guide on how to use media channels to reach Hispanic audiences is available in Spanish and English from the National Center for Farmworker Health, Inc.

Other National Collaborations

The ability to implement a national program to control breast and cervical cancers depends largely on the involvement of various partners in state and local governments, physicians, national and private sector organizations, and consumers. CDC relies heavily on these partnerships to build the necessary infrastructure to provide screening services for all women who need them.

- American Cancer Society. The CDC and ACS collaboration combines the resources of national ACS divisions with CDC and its strong ties to the departments of health in every state. ACS assists in developing and delivering CDC-funded programs. ACS divisions serve as partners with state health agencies to increase screening services to medically underserved women. CDC collaborates with ACS staff in all programmatic areas, including establishing early detection programs, provider education efforts, and special demonstration projects.
 - Avon. In 1993, a unique public-private partnership was established among CDC, Avon Products Inc., YWCA of the U.S.A., the National Alliance of Breast Cancer Organizations (NABCO), and the National Cancer Institute to educate women about breast health and to improve access to early detection services. Avon's Breast Cancer Awareness Crusade has raised more than \$18 million for breast cancer programs nationwide through the sale of its Breast Cancer Awareness pink ribbon products. Avon has funded more than 200 programs through NABCO and YWCA of the U.S.A.
 - National Breast Cancer Teleconference. In April 1996, the NBCCEDP, Avon's Breast Cancer Awareness Crusade, the New York State Department of Health, and WQED Pittsburgh, conducted a national teleconference at 650 locations. The teleconference highlighted five case studies, which addressed successful partnerships and proven outreach strategies for reaching low-income, minority and older women. A package is available to help in the implementation of breast health outreach programs in communities. CDC continues to support partnership development as an important component of successful cancer prevention and control efforts.
-

Quality Assurance

Quality assurance is essential if breast and cervical cancer early detection is to be an effective cancer control tool. CDC has supplied all participating programs with screening guidelines, assisted the Food and Drug Administration (FDA) in conducting quality assurance training programs, teamed with the American College of Radiology to improve and assure the quality of mammography screening, and developed guidelines on the evaluation of common breast problems.

The Mammography Quality Standards Act of 1992

The Mammography Quality Standards Act established a nationwide program to regulate the quality assurance practices in all mammography facilities throughout the United States and authorized FDA to carry out this program. CDC has assisted FDA in formulating a training program for officials responsible for regulating facilities. CDC's activities in quality assurance have also included the creation of educational programs for appropriate professionals.

Quality Assurance in Cytology

CDC has funded the Association of State and Territorial Public Health Laboratory Program Directors to write recommendations regarding the impact of closing laboratories that are found to provide inferior cytology services. This report is focusing on the responsibilities and roles of the health department in notifying patients and physicians who have received services and diagnostic tests from these facilities. A working group of state laboratory directors and national experts has been convened to study and recommend policies concerning these issues.

Professional Education

The National Training Center for the Prevention and Early Detection of Cancers

CDC's Division of Cancer Prevention and Control has established a National Training Center for the Prevention and Early Detection of Cancer through a contract with R.O.W. Sciences, Inc. This center will provide training programs, educational opportunities, and educational materials for practicing health care professionals of state and territorial health agencies and tribal organizations. The target audience will include program managers, administrative staff and data managers, health educators, physicians, nurses, radiologists, radiological technologists, cytotechnologists, and outreach workers. Training will be skills-based and will use new and creative approaches, including live, interactive satellite courses.

Other Key Partners

- ☐ American College of Physicians
 - ☐ American College of Radiology
 - ☐ American Public Health Association
 - ☐ Association of State and Territorial Chronic Disease Program Directors
 - ☐ Association of State and Territorial Directors of Health Promotion and Public Health Education
 - ☐ Association of State and Territorial Health Officials
 - ☐ Association of Teachers of Preventive Medicine
 - ☐ Food and Drug Administration
 - ☐ Health Care Financing Administration
 - ☐ Health Resources and Services Administration
 - ☐ Indian Health Service
 - ☐ National Alliance of Breast Cancer Organizations
 - ☐ National Association of County Health Officials
 - ☐ National Cancer Institute
 - ☐ National Governors' Association
 - ☐ National Medical Association
-

For more information, please contact the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Mail Stop K-64, 4770 Buford Highway NE, Atlanta, GA 30341-3724, (770) 488-4751.

E-mail to cancerinfo@cdc.gov

World Wide Web at <http://www.cdc.gov/nccdphp/dpc>

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**To download the .pdf version of CDC's *Diabetes At-A-Glance*,
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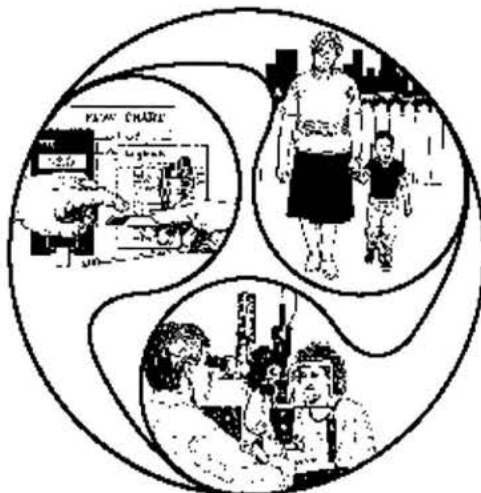
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Diabetes

A Serious Public Health Problem

AT-A-GLANCE

1996



Translating Science Into Care

*"Those who suffer losses due to diabetes are not just statistics on a chart.
They are people whose talents and wisdom are needed and whose problems deserve our unified efforts.
Together we can join to make life more just and more joyful for generations to come."*

David Satcher, MD, PhD, Director, Centers for Disease Control and Prevention

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

Is Diabetes a Serious Public Health Problem?

In 1995, about 16 million people in the United States had diabetes, but only 8 million had been diagnosed with the condition. The number of persons with diagnosed diabetes has increased from 1.6 million in 1958 to 8 million in 1995 - a fivefold increase. Diabetes is the seventh leading cause of death in the United States, and it contributes to thousands of deaths each year. Individuals with diabetes are at

in the United States, and it contributes to thousands of deaths each year. Individuals with diabetes are at increased risk for

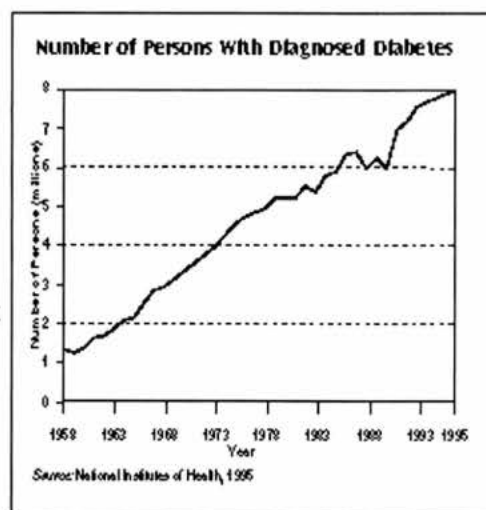
- ☐ heart disease
- ☐ blindness
- ☐ kidney failure
- ☐ lower extremity amputations not related to injury

Diabetes and its complications occur among Americans of all ages and racial and ethnic groups. The burden of this disease is heavier among elderly Americans and certain racial and ethnic populations, including African Americans, Hispanics/Latinos, and American Indians. For example, more than 10% of elderly adults have been diagnosed with diabetes, and the prevalence of diabetes among various American Indian tribes ranges from 5% to 50%. A number of studies have also shown increased rates of the disease among certain Asian and Pacific Islander populations.

What Is Diabetes?

The term diabetes describes either a deficiency of insulin or a decreased ability of the body to use insulin, which is a hormone secreted by the pancreas. Insulin allows glucose (sugar) to enter body cells and be converted to energy. Insulin is also needed to synthesize protein and store fats. In uncontrolled diabetes, glucose and lipids (fats) remain in the bloodstream and, with time, damage the body's vital organs and contribute to heart disease.

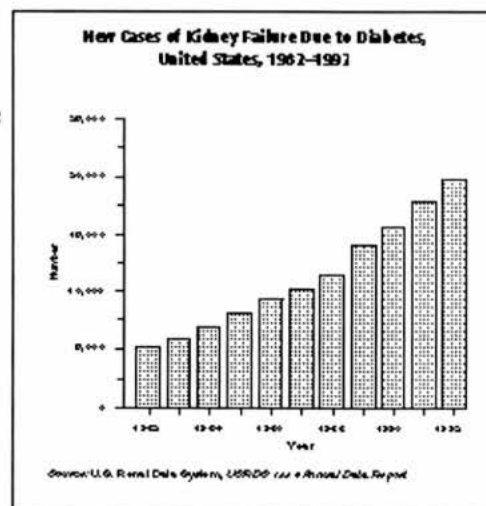
Diabetes is classified into two main types: non-insulin-dependent diabetes mellitus (NIDDM) and insulin-dependent diabetes mellitus (IDDM). The most common type is NIDDM. It affects 90% of those with diabetes and usually appears after the age of 40. The other type - IDDM - affects less than 10% of those with diabetes. Although this type of diabetes can occur at any age, it most often appears in childhood or the teen years. The primary focus of the Centers for Disease Control and Prevention (CDC) is to translate scientific information about diabetes into strategic plans that help people prevent the complications of diabetes.



What Are the Economic Costs of Diabetes?

Diabetes imposes a heavy economic burden upon the nation each year. In 1992, an estimated \$92 billion in direct and indirect costs were spent on diabetes. Contributing substantially to these costs are the complications of diabetes. For example, in 1992, the cost of treating kidney failure for 56,000 Americans with diabetes exceeded \$2.1 billion. This figure did not include the costs associated with disabilities and premature death. In this same year, Medicare expenditures per person with diabetes on kidney dialysis averaged \$38,700. Because kidney failure is increasing at an alarming rate, these costs are expected to rise.

More than 60% of lower extremity amputations that are not related to injury occur among persons with diabetes. Approximately 57,000 diabetes-related amputations were performed in 1993. The direct costs of diabetes-related amputations are about \$600 million annually.



The full burden of diabetes in terms of death, complications, and costs is not easy to measure. In fact, many hidden costs are associated with diabetes. These costs include a failure to recognize the role of diabetes in premature deaths and the unknown costs related to undiagnosed diabetes. Furthermore, for

families and communities, the loss of human lives and abilities transcends numerical measures.

What Are the Benefits of Prevention?

The increasing burden of diabetes is alarming, but the good news is that much of the burden of this major public health problem can be prevented with early detection, improved delivery of care, and diabetes self-management education. For example,

- ❑ Currently, screening and treatment for eye disease among persons with diabetes is saving the federal government about \$248 million annually. If all persons with diabetes received recommended screening and treatment, the annual savings to the federal budget could exceed \$470 million.
- ❑ Women with preexisting diabetes deliver more than 18,000 babies each year. For every \$1.00 invested in preconception care for these mothers, \$1.86 can be saved by preventing birth defects.
- ❑ The Diabetes Control and Complications Trial, a national 10-year study that involved 1,441 volunteers with insulin-dependent diabetes, confirmed that good control of blood sugar prevented the onset or delayed the progression of eye, kidney, and nerve damage by at least 50%.

What Does CDC Do To Reduce the Burden?

CDC strives to increase awareness and education about diabetes, support early detection and treatment of complications, improve the quality of diabetes care, and enhance access to diabetes care by improving and expanding services.

To advance a common mission to reduce the burden of diabetes, CDC joins with state and territorial health departments in establishing partnerships for populations at increased risk for diabetes and its complications. CDC and its partners use the following approaches:

They define the burden and develop surveillance systems to-

- ❑ identify high-risk groups
- ❑ monitor health outcomes and indicators of the quality of health care recommended for persons with diabetes
- ❑ provide data that can be used to formulate health care policy
- ❑ evaluate progress in disease prevention and control

They develop new approaches such as innovative community-based programs-

- ❑ **Project DIRECT-CDC** is collaborating with the state of North Carolina to evaluate the effectiveness of community-based public health approaches in reducing the burden of diabetes.
- ❑ **Diabetes Today**-This program provides health professionals and community leaders with the skills to mobilize communities and to develop appropriate interventions. One of the outcomes of this course is a strategic plan that is community owned and culturally relevant to the local population.
- ❑ **Latino Diabetes Initiative for Action (Latino DIA)**- In 1995, CDC launched this initiative to develop culturally relevant diabetes prevention strategies for Latino communities. CDC enlisted the National Latino Expert Workgroup to collaborate in planning, prioritizing, implementing, promoting, and evaluating strategic Latino DIA activities to narrow the disparity of diabetes in the Latino community.

They implement effective programs-

CDC works with state- and territorial-based diabetes control programs to reduce the complications associated with diabetes. The following are just a few examples of such activities:

- ❑ **The Maine Diabetes Control Program** implemented a diabetes outpatient education program in more than 30 hospitals and health centers throughout the state. In a 3-year period, this state

education program resulted in a 32% reduction in hospital admissions - a savings of \$293 per participant.

- ❑ **The Michigan Diabetes Control Program's Upper Peninsula Diabetes Outreach Network (UPDON)** established a program with hospitals, health departments, and home care agencies that improved the quality of diabetes care and education. The participants in the program experienced a 45% lower rate of hospitalizations, a 31% drop in lower extremity amputations, and a 27% lower death rate than did nonparticipants. This program has been replicated in five new outreach networks throughout the state.
- ❑ **The Texas Diabetes Control Program** recently formed the Managed Care Work Group to establish minimum standards of care and outcome measures for Texans with diabetes. A cost-benefit analysis by one of the collaborating partners determined a break-even point in 2 years with savings to result thereafter. Other partners are joining as they consider the quality of care issues and realize the cost benefit.

National Partnerships

CDC joins with government agencies, voluntary and professional organizations, academic institutions, and community groups to

- ❑ provide data for sound public health decisions
- ❑ inform the public about the burden of diabetes
- ❑ ensure that current research findings are translated into effective clinical and public health strategies to reduce the burden of diabetes
- ❑ promote assurance of optimal diabetes care and education for all persons living with diabetes in the United States

Diabetes presents both a challenge to and an opportunity for public policymakers, health care providers, community leaders, and individuals with diabetes to apply prevention strategies known to make a significant impact. Recent studies in diabetes have confirmed that prevention of complications of diabetes is a strategy that works. Such strategies benefit individuals, families, communities, health organizations, and all those who are financially and economically concerned about the impact of diabetes and its complications.

For more information, please contact:

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For release November 1, 1997

National Diabetes Fact Sheet

National estimates and general information on diabetes in the United States

- ☐ [What is Diabetes?](#)
- ☐ [Prevalence of Diabetes](#)
- ☐ [Incidence of Diabetes](#)
- ☐ [Deaths Among Persons With Diabetes](#)
- ☐ [Prevalence of Diabetes by Age](#)
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What is diabetes?

Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. Diabetes can be associated with serious complications and premature death, but persons with diabetes can take measures to reduce the likelihood of such occurrences.

Prevalence of diabetes*

Total: 15.7 million people -- 5.9% of the population -- have diabetes.

- ☐ **Diagnosed:** 10.3 million people
- ☐ **Undiagnosed:** 5.4 million people

* For further information on prevalence, see the [Appendix](#).

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Incidence of diabetes

New cases diagnosed per year: 798,000

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Deaths among persons with diabetes

- ☐ Studies have found death rates to be twice as high among middle-aged people with diabetes as among middle-aged people without diabetes.
- ☐ Based on death certificate data, diabetes contributed to 187,800 deaths in 1995.
- ☐ Diabetes was the seventh leading cause of death listed on U.S. death certificates in 1995, according to CDC's National Center for Health Statistics.
- ☐ Diabetes is believed to be underreported on death certificates, both as a condition and as a cause of death.

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Prevalence of diabetes by age

- ☐ **Age 65 years or older:** 6.3 million. *18.4% of all people in this age group have diabetes.*
- ☐ **Age 20 years or older:** 15.6 million. *8.2% of all people in this age group have diabetes.*
- ☐ **Under age 20:** 123,000. *0.16% of all people in this age group have diabetes.*

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Prevalence of diabetes by sex in people 20 years or older*

- ☐ **Men:** 7.5 million. *8.2% of all men have diabetes.*
- ☐ **Women:** 8.1 million. *8.2% of all women have diabetes.*

* These figures do not include the approximately 123,000 cases of diabetes in children and teenagers in the United States.

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Prevalence of diabetes by race/ethnicity in people 20 years or older*

Non-Hispanic whites: 11.3 million. *7.8% of all non-Hispanic whites have diabetes.*

- ❑ **Non-Hispanic whites:** 11.3 million. *7.8% of all non-Hispanic whites have diabetes.*
- ❑ **Non-Hispanic blacks:** 2.3 million. *10.8% of all non-Hispanic blacks have diabetes.*
On average, non-Hispanic blacks are 1.7 times as likely to have diabetes as non-Hispanic whites of similar age.
- ❑ **Mexican Americans:** 1.2 million. *10.6% of all Mexican Americans have diabetes.*
On average, Mexican Americans are 1.9 times as likely to have diabetes as non-Hispanic whites of similar age.
- ❑ **Other Hispanic/Latino Americans:** On average, Hispanic/Latino Americans are almost twice as likely to have diabetes as non-Hispanic whites of similar age. (Sufficient data are not currently available to derive more specific estimates for 1997.)
- ❑ **American Indians and Alaska Natives:** Prevalence varies among tribes, bands, pueblos and villages, and ranges from <5% to 50% for diagnosed diabetes. There are more than 550 federally recognized tribes, bands, pueblos, and villages in the United States.
- ❑ **Asian Americans and Pacific Islanders:** Prevalence data for diabetes among Asian Americans and Pacific Islanders are limited. Some groups within this population are at increased risk for diabetes. For example, data collected from 1988 to 1995 suggest that Native Hawaiians are twice as likely to have diagnosed diabetes as white residents of Hawaii.

** These figures do not include the approximately 123,000 cases of diabetes in children and teenagers in the United States.*

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The four types of diabetes

- ❑ **Type 1 diabetes** was previously called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. Type 1 diabetes may account for 5% to 10% of all diagnosed cases of diabetes. Risk factors are less well defined for type 1 diabetes than for type 2 diabetes, but autoimmune, genetic, and environmental factors are involved in the development of this type of diabetes.
- ❑ **Type 2 diabetes** was previously called non-insulin dependent diabetes mellitus (NIDDM) or adult-onset diabetes. Type 2 diabetes may account for about 90% to 95% of all diagnosed cases of diabetes. Risk factors for type 2 diabetes include older age, obesity, family history of diabetes, prior history of gestational diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity. African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Pacific Islanders are at particularly high risk for type 2 diabetes.
- ❑ **Gestational diabetes** develops in 2% to 5% of all pregnancies but disappears when a pregnancy is over. Gestational diabetes occurs more frequently in African Americans, Hispanic/Latino Americans, American Indians, and persons with a family history of diabetes. Obesity is also associated with higher risk. Women who have had gestational diabetes are at increased risk for later developing type 2 diabetes. In some studies, nearly 40% of women with a history of gestational diabetes developed diabetes in the future.
- ❑ **"Other specific types"** of diabetes result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. Such types of diabetes may account for 1% to 2% of all diagnosed cases of diabetes.

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Complications of diabetes

Heart disease

Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes have heart disease death rates about 2 to 4 times as high as that of adults without diabetes.

Stroke

The risk of stroke is 2 to 4 times higher in people with diabetes.

High blood pressure

An estimated 60% to 65% of people with diabetes have high blood pressure.

Blindness

- Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old.
- Diabetic retinopathy causes from 12,000 to 24,000 new cases of blindness each year.

Kidney disease

- Diabetes is the leading cause of end-stage renal disease, accounting for about 40% of new cases. 27,851 people with diabetes developed end-stage renal disease in 1995.
- In 1995, a total of 98,872 people with diabetes underwent dialysis or kidney transplantation.

Nervous system disease

- About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage (which often includes impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems).
- Severe forms of diabetic nerve disease are a major contributing cause of lower extremity amputations.

Amputations

- More than half of lower limb amputations in the United States occur among people with diabetes.
- From 1993 to 1995, about 67,000 amputations were performed each year among people with diabetes.

Dental disease

Periodontal disease (a type of gum disease that can lead to tooth loss) occurs with greater frequency and severity among people with diabetes. Periodontal disease has been reported to occur among 30% of people aged 19 years or older with type 1 diabetes.

Complications of pregnancy

- The rate of major congenital malformations in babies born to women with preexisting diabetes varies from 0% to 5% among women who receive preconception care to 10% among women who do not receive preconception care.
- Between 3% to 5% of pregnancies among women with diabetes result in death of the newborn; the rate for women who do not have diabetes is 1.5%.

Other complications

- Diabetes can directly cause acute life-threatening events, such as diabetic ketoacidosis* and hyperosmolar nonketotic coma.*
- People with diabetes are more susceptible to many other illnesses. For example, they are more likely to die of pneumonia or influenza than people who do not have diabetes.

** Diabetic ketoacidosis and hyperosmolar nonketotic coma are medical conditions that can result from biochemical imbalance in uncontrolled diabetes.*

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Cost

- ❑ **Total (direct and indirect):** \$92 billion (United States, 1992)
- ❑ **Direct medical costs:** \$45 billion
- ❑ **Indirect costs:** \$47 billion (disability, work loss, premature mortality)

This estimate is in contrast to higher estimates cited elsewhere that are based on all health care costs incurred by people with diabetes, including costs not resulting from diabetes. New cost estimates are expected to be released within 6 months.

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New diagnostic criteria for diabetes*

The new diagnostic criteria for diabetes include the following changes:

- ❑ The routine diagnostic test for diabetes is now a fasting plasma glucose test rather than the previously preferred oral glucose tolerance test. (However, in certain clinical circumstances, physicians may still choose to perform the more difficult and costly oral glucose tolerance test.)
- ❑ A confirmed** fasting plasma glucose value of greater than or equal to 126 milligrams/deciliter (mg/dL) indicates a diagnosis of diabetes. Previously, a value of greater than or equal to 140 mg/dL had been required for diagnosis.
- ❑ In the presence of symptoms of diabetes, a confirmed** nonfasting plasma glucose value of greater than or equal to 200 mg/dL indicates a diagnosis of diabetes.
- ❑ When a doctor chooses to perform an oral glucose tolerance test (by administering 75 grams of anhydrous glucose dissolved in water, in accordance with World Health Organization standards, and then measuring the plasma glucose concentration 2 hours later), a confirmed** glucose value of greater than or equal to 200 mg/dL indicates a diagnosis of diabetes.
- ❑ In pregnant women, different requirements are used to identify the presence of gestational diabetes.

* For further information about the new diagnostic criteria for diabetes, please refer to the Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, as referenced in the Appendix.

** Except in certain specified circumstances, abnormal tests must be confirmed by repeat testing on another day.

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Treatment of diabetes

Diabetes knowledge, treatment, and prevention strategies advance daily. Treatment is aimed at keeping blood glucose near normal levels at all times. Training in self-management is integral to the treatment of diabetes. Treatment must be individualized and must address medical,

psychosocial, and lifestyle issues.

- Treatment of type 1 diabetes: Lack of insulin production by the pancreas makes type 1 diabetes particularly difficult to control. Treatment requires a strict regimen that typically includes a carefully calculated diet, planned physical activity, home blood glucose testing several times a day, and multiple daily insulin injections.
- Treatment of type 2 diabetes: Treatment typically includes diet control, exercise, home blood glucose testing, and in some cases, oral medication and/or insulin. Approximately 40% of people with type 2 diabetes require insulin injections.

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Impaired fasting glucose

Impaired fasting glucose is a new diagnostic category in which persons have fasting plasma glucose values of 110-125 mg/dL. These glucose values are greater than the level considered normal but less than the level that is diagnostic of diabetes. It is estimated that 13.4 million persons, 7.0% of the population, have impaired fasting glucose. Scientists are trying to learn how to predict which of these persons will go on to develop diabetes and how to prevent such progression.

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Appendix

How were the estimates in this fact sheet derived?

Periodically, the federal government conducts surveys to determine the health of Americans. Such surveys involve questionnaires and medical tests. The diabetes prevalence and incidence estimates presented in this fact sheet were developed by analyzing the newest available national survey data and then adjusting for changes in the population based on 1997 census estimates. The prevalence of diagnosed diabetes represents the number who said they had diabetes. The prevalence of undiagnosed diabetes represents the number of people who said they did not have diabetes, but when given a fasting plasma glucose test, they did in fact have abnormally elevated blood glucose levels (defined as fasting plasma glucose levels greater than or equal to 126 mg/dL). Other estimates presented in this fact sheet were based on individual surveys, research projects, and registry data. A listing of references and additional data sources are at the end of this fact sheet.

Has the number of persons with diabetes changed since the previous National Diabetes Fact Sheet, which was issued in 1995?

Between the 1995 and 1997 fact sheets, the number of persons with diagnosed diabetes increased from 8 million to 10.3 million, but the number of persons with undiagnosed diabetes decreased. For the 1995 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the oral glucose tolerance test to identify undiagnosed diabetes. In contrast, for the 1997 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the fasting plasma glucose test, according to recently enacted recommendations. These tests are not equivalent, however, and fewer cases of undiagnosed diabetes are identified using the fasting plasma glucose test under current recommendations.

An enhanced national effort to identify previously undiagnosed persons may also have contributed to a decrease in the number of persons with undiagnosed diabetes. Continued efforts to identify persons with undiagnosed diabetes, the implementation of new guidelines for screening, and the use of an easier and less expensive diagnostic test are all likely to lead to even further decreases in the number of persons with undiagnosed diabetes and increases in the number of persons with diagnosed diabetes.

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MD: National Institutes of Health, 1995. NIH Publication No. 95-1468.

- Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997 July;20(7):1183-97.
- Valway S, Freeman W, Kaufman S, Welty T, Helgersen SD, Gohdes D. Prevalence of diagnosed diabetes among American Indians and Alaska Natives, 1987. *Diabetes Care* 1993;16 (Suppl 1):271-276.
- U.S. Department of Health and Human Services. Physical activity and health: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.
- U.S. Renal Data System. USRDS 1997 Annual Data Report. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, 1997.

Additional sources

- Calculations were performed by the National Institutes of Health and the Centers for Disease Control and Prevention using data from various surveys including the Third National Health and Nutrition Examination Survey (NHANES III), the National Health Interview Survey (NHIS), and U.S. Census estimates for current population. The national prevalence estimates for diabetes were based on Harris MI, Unpublished Data from NHANES III, 1988-1994.
- Information about Native Hawaiians was provided by the Hawaii Diabetes Control Program and is based on Wen M, Unpublished Analysis of Data from the Behavioral Risk Factor Surveillance System (BRFSS) from 1988-1995.

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Acknowledgments

The following organizations collaborated in compiling the information for this fact sheet:

American Association of Diabetes Educators

<http://www.diabetesnet.com/aade.html>

American Diabetes Association

<http://www.diabetes.org>

Centers for Disease Control and Prevention

<http://www.cdc.gov/diabetes>

Department of Veterans Affairs

<http://www.va.gov/health/diabetes/>

Health Resources and Services Administration

<http://www.hrsa.dhhs.gov>

Indian Health Service

<http://www.ihs.gov/IHSMAN.html>

Juvenile Diabetes Foundation International

<http://www.jdfcure.com>

National Diabetes Education Program

Internet page under construction

National Institute of Diabetes and Digestive and Kidney Disease of the National Institutes of Health

<http://www.niddk.nih.gov>

U.S. Department of Health and Human Services, Office of Minority Health

<http://www.omrhc.gov>

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estimated at \$2.1 billion by the Congressional Budget Office. The goal is to help Medicare beneficiaries better control their blood sugar levels and reduce expensive complications of diabetes such as cardiovascular disease and renal failure.

- **Expanded Research:** The Act also provides \$150 million over five years for research on type 1 diabetes. The new initiative will enable HHS to increase its annual funding for total diabetes research by approximately 10 percent.
- **Indian Health Initiative:** Funding under the Act provides HHS' Indian Health Service and other agencies with \$150 million for five years for expanded and more intensive diabetes prevention and treatment services in partnership with tribes and Urban Indian Health Centers. The program will include earlier testing for diabetes and community-based intervention efforts to increase knowledge.

Total HHS discretionary spending on diabetes research and prevention was \$345 million in FY 1997.

Diabetes is a serious disease and, if left uncontrolled, it can cause serious complications for an individual, including strokes and blindness. More than half of lower limb amputations in the United States are among people with diabetes. Diabetes is the seventh leading cause of death in the United States. This disease also takes a high financial toll on the United States, costing more than \$92 billion in medical expenses, disability, and lost wages each year, according to the estimate of the American Diabetes Association.

Type 2 diabetes, which accounts for more than 90 percent of all cases of diabetes, is associated with older age, race, ethnicity, and a family history of diabetes. In addition, CDC reports that obesity and physical inactivity are strongly associated with increased risk of diabetes.

Type 1 diabetes, formerly known as Insulin-Dependent or Juvenile Onset Diabetes, occurs when the body does not produce any insulin, most often occurring in children and young adults. It accounts for 5 to 10 percent of diabetes.

Many clinical trials are underway, including the NIH's Diabetes Prevention Program, to test whether lifestyle changes and/or pharmacological treatments can prevent onset of diabetes.

Serious complications of diabetes can be controlled by properly identifying and treating people with the disease.

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NOTE: A "National Diabetes Fact Sheet" is available from the Centers for Disease Control and Prevention press office.

HHS press releases are available on the World Wide Web at: <http://www.hhs.gov>.

Date: Saturday, October 25, 1997

FACT SHEET

Contacts: HHS Press Office (202) 690-6343
NCI Press Office (301) 496-6641
FDA Press Office (301) 827-6242

BREAST CANCER: NEW EFFORTS UNDERWAY

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

For women age 50-69, having regular mammograms can reduce the chance of death from breast cancer by one-third or more. Despite these numbers, 33 percent of women ages 50-64, and 45 percent of women age 65 and older reported not receiving a mammogram during the past two years.

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

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

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

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

Background: More Women Can Survive Breast Cancer

- The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 13 women just two decades ago. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.
- Approximately 180,000 new cases of breast cancer will be diagnosed in 1997, and about 44,000 women are expected to die from breast cancer. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- Death rates from the disease are highest among older, black, and low-income women. With proper screening and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. Between 1982 and 1987, breast cancer incidence for women increased about 4 percent per year, but recently has leveled off.

The death rate for women with breast cancer declined 6.3 percent between 1991 and 1995. The

greatest reductions in death rates were among younger women (9.3 percent) and white women (6.6 percent), with more modest reductions among African Americans (1.6 percent) and women age 65 and older (2.8 percent).

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

HHS Spending On Breast Cancer

HHS discretionary funding for breast cancer research, prevention and treatment has increased from approximately \$274 million in FY 1993 to an estimated \$513 million in FY 1997. As the Centers for Disease Control and Prevention (CDC) have worked to increase access for all women to mammography screening and follow up services, the resources devoted to breast cancer services have increased from an estimated \$42 million in FY 1993, to \$81 million in FY 1997. Cancer research is vital to our understanding of how to prevent, detect and treat breast cancer. The Clinton Administration has invested in breast cancer research at the National Institutes of Health by increasing funding from \$229 million in FY 1993, to \$401 million in FY 1997, and a President's budget request of \$408 million in FY 1998. HHS also helps provide treatment for breast cancer through the Medicare and Medicaid programs and through the Indian Health Service.

HHS Action To Combat Breast Cancer

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

New Mammography Benefit

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

Mammography Quality Standards

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

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

National Action Plan on Breast Cancer

HHS' Office on Women's Health is coordinating the National Action Plan on Breast Cancer. This first-ever national plan was developed in 1993 under Secretary Shalala's leadership. The Plan has

awarded over \$9 million in grants for 99 innovative research and outreach projects, with a special emphasis on the development of public-private partnerships targeted in the six priority areas:

- ❑ *The Information Action Council Working Group* is working to improve access to information about breast cancer for consumers, scientists, and practitioners via the Internet and other information technologies.
- ❑ *The Etiology Working Group* is focusing on efforts to expand the scope and breadth of biomedical, epidemiological and behavioral research on breast cancer. The group has identified four priority areas: chemicals and hormones, viruses, radiation and electromagnetic fields, and lifestyle factors.
- ❑ *The National Biological Resources Banks Working Group* (NAPBC) has focused on the development of a national mechanism and standard for obtaining and storing tissue for multiple areas of breast cancer research. The NAPBC has awarded funds to establish a national biological resources bank and is now conducting a survey of tissue banks throughout the country to identify and determine the accessibility of all available biological resources.
- ❑ *The Working Group to Ensure Consumer Involvement* has defined several specific activities to help ensure consumer involvement at all levels in the development of national research, education, and service delivery programs related to breast cancer.
- ❑ *The Clinical Trial Accessibility Working Group* has identified a series of initiatives to address four types of barriers to participation in clinical trials, including barriers associated with the informed consent process, patient and physician misperceptions about clinical trials, lack of information about the availability of trials, and cost.
- ❑ *The Working Group on Heredity Susceptibility* is evaluating the ethical, legal and policy issues of individuals carrying breast cancer susceptibility genes.

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

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

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

Privacy of Genetic Information and Breast Cancer

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

National Breast and Cervical Cancer Early Detection Program

CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. Resources devoted to breast cancer screening services have grown from an estimated \$42 million in FY 1993 to \$81 million in FY 1997. The program, which has been operating in an increasing number of states over the past six years, has provided screening tests to almost one million medically underserved women. In October 1996, the program went nationwide, with funding for all 50 states.

Breast Cancer Among the Elderly

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

New Frontiers In Breast Cancer Early Detection

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

Centers of Excellence

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

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, AHCPR in October 1994 developed a Clinical Practice Guideline--Quality Determinants of Mammography--with separate versions for mammography providers, health care professionals, and consumers. The guidelines provide information on the roles and responsibilities of each health care professional involved in mammography services, as well as information and recommendations for women.

Mammography for Women with Addictive and Mental Disorders

Women who are in need or who receive substance abuse or mental health services often lack appropriate

primary health care, including breast cancer education, detection, and treatment. Women-focused substance abuse and mental health programs funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) are designed to be comprehensive, delivering primary health care services to women who often are medically underserved. These services include education on breast self-examination and mammography services, and counseling on risks for breast cancer.

Environmental Factors and Breast Cancer

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

Office of Cancer Survivorship

On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

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Date: Saturday, October 25, 1997

FACT SHEET

Contacts: HHS Press Office (202) 690-6343

NCI Press Office (301) 496-6641

BREAST CANCER AND MAMMOGRAPHY

Overview: *The Department of Health and Human Services supports a wide variety of programs in research, treatment and screening for breast cancer. Total HHS discretionary spending on breast cancer in FY 1997 was estimated to be \$513 million for public health programs, in addition to an estimated \$280 million for mammography services paid for by Medicare and Medicaid. Within the FY 1998 President's budget request, HHS discretionary spending on public breast cancer programs would rise to \$522 million.*

Early detection of breast cancer is crucial for successful treatment, and HHS programs promote mammography and clinical breast exams. This is especially true for older women: about 80 percent of breast cancers occur in women age 50 or older, yet 33 percent of women age 50 to 64, and 45 percent of women age 65 and older, have reported not receiving a mammogram in the past two years. HHS agencies support a number of efforts to inform women about mammography, assure high quality service, and help provide access:

- ☐ *The National Cancer Institute, and other NIH institutes, provide information outreach and support broad research on breast cancer and on new breast imaging technologies*
- ☐ *The Food and Drug Administration establishes quality standards for mammography facilities and certifies facilities*
- ☐ *The Agency for Health Care Policy and Research has issued guidelines on the quality and delivery of mammography, and does research on mammography services*
- ☐ *The Centers for Disease Control and Prevention supports an early detection program providing access to mammography for uninsured and low-income women*
- ☐ *Medicare and Medicaid cover treatment for breast cancer and for screening services in most states. President Clinton proposed, and Congress adopted, the expansion of Medicare coverage which will help pay for annual mammograms for all Medicare beneficiaries age 40 and over. This new benefit will be available starting January 1, 1998.*

The National Cancer Institute provides science-based guidance on the use of mammography. NCI now recommends that women age 40 and over be screened every one to two years. In addition, the institute recommends that women at higher risk of breast cancer get expert medical advice about when to begin screening and about the frequency of their screening.

Breast Cancer

Breast cancer is the most frequently diagnosed non-skin cancer in women in the United States. It is second only to lung cancer in cancer-related deaths. Approximately 180,000 new cases of breast cancer will be diagnosed in 1997, and about 44,000 women are expected to die from the disease.

Between 1982 and 1987, breast cancer incidence (rate of new cases) for women increased about 4 percent per year, but recently has leveled off. The death rate for women with breast cancer declined 6.3 percent between 1991 and 1995. The greatest reductions in death rates were among younger women (9.3 percent) and white women (6.6 percent), with more modest reductions among African Americans (1.6

percent) and women age 65 and older (2.8 percent).

There are a variety of effective treatments for breast cancer, including surgery, radiotherapy, hormonal therapy, and chemotherapy.

Risk Factors

Elevated risk of breast cancer is associated with the following conditions:

- ☐ Having had a previous breast cancer.
- ☐ Laboratory evidence that the woman is carrying a specific genetic mutation or change that increases susceptibility to breast cancer.
- ☐ Having a mother, sister, or daughter with a history of breast cancer or having two or more close relatives, such as cousins, with a history of breast cancer.
- ☐ Having had a diagnosis of other types of breast disease (not cancer but a condition that may predispose to cancer) or having had two or more breast biopsies for benign disease.
- ☐ Having so much dense breast tissue on a previous mammographic examination that clear reading was difficult.
- ☐ Having a first birth at age 30 or older.

Breast cancer is more prevalent in older age groups. The risk of breast cancer increases with age. About 80 percent of breast cancers occur in women age 50 or older. The risk is especially high in women over age 60. Breast cancer is uncommon under age 40. Present rates project that each year, out of 100,000 women:

- ☐ in their 30s, 43 women will be diagnosed with breast cancer and 8 will die of the disease;
- ☐ in their 40s, 163 women will be diagnosed with breast cancer and 29 will die of the disease;
- ☐ in their 50s, 263 women will be diagnosed with breast cancer and 59 will die of the disease;
- ☐ in their 60s, 374 women will be diagnosed with breast cancer and 91 will die of it.

Early Detection

Screening is a means to detect breast cancer before the onset of symptoms. High-quality mammography, with clinical breast exams, is the most effective technology presently available to detect breast tumors.

Several studies have shown that regular mammography screening can decrease the chance of dying from breast cancer. In addition, early detection may prevent the necessity of removing lymph nodes and in some cases may prevent the need for removing the entire breast or for undergoing chemotherapy.

Current NCI Guidance on Mammography

The National Cancer Institute, following the advice of the National Cancer Advisory Board, recommends:

- ☐ Women in their 40s who are at average risk of breast cancer should be screened every one to two years with mammography
- ☐ Women aged 50 and older should be screened every one to two years
- ☐ Women who are at higher risk of breast cancer should seek expert medical advice about when and how often they should get screened.

Along with mammograms, a clinical breast examination by a health care provider should be included as part of regular, routine health care.

Limitations of Mammography

While mammography is the best screening tool available now, early detection does not necessarily mean lives will be saved. Mammography may not help a woman with a small but fast growing tumor that has already spread at the time of detection. And about 50 percent of women whose breast cancer is detected by mammography would not have died from the cancer even if they had waited until a lump could be felt because the tumors are slow-growing and easy to treat.

Breasts of younger women contain many glands and ligaments that appear dense on a mammogram, so it is sometimes difficult to spot tumors in their breasts. About 25 percent of breast tumors are missed in women in their 40s compared to 10 percent for women in their 50s. Also, between 5 percent and 10 percent of mammograms are abnormal. Of those in younger women that are followed up with additional tests (another mammogram, fine needle aspiration, ultrasound, or biopsy) most will not be cancer. Over the past 30 years, mammography has been able to detect a higher proportion of small tissue abnormalities called ductal carcinoma in situ (DCIS), abnormal cells confined to the milk ducts of the breast. Some believe these tumors are not life threatening, while others think they are. Because there is so little data to support either view, the abnormalities are commonly removed surgically.

HHS is supporting a variety of research projects aimed at improving breast cancer detection.

HHS Programs Supporting Mammography

Mammography Quality Standards. Under the final rules of the Mammography Quality Standards Act (MQSA), published October 1997, the FDA sets high standards for mammography facilities and certifies those which meet the standards. The roughly 10,000 mammography facilities nationwide certified by the FDA must meet quality standards for both equipment and personnel, and are inspected annually. MQSA regulations require facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled interpreting physicians to interpret the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that any follow-up testing or treatment can begin immediately. Resources devoted to the MQSA total \$26.4 million for FY 1997, and the proposed budget for FY 1998 is \$27 million.

The names and locations of FDA certified mammography facilities are available by calling the Cancer Information Service at 1-800-4-CANCER. In addition, the FDA has included a list of all FDA certified mammography facilities in the United States on its internet home page. The address is <http://www.fda.gov/cdrh/faclist.html>

Research To Develop Better Screening. New imaging technologies under development for breast cancer screening include magnetic resonance imaging, breast ultrasound, and breast-specific positron emission tomography. In addition to imaging technologies, NCI-supported scientists are exploring methods to detect breast cancer using simple tests of the blood, urine, or nipple aspirates, and to detect genetic alterations that place women at increased risk for breast cancer.

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

Mammography Clinical Practice Guidelines. Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, HHS' Agency for Health Care Policy and Research developed a Clinical Practice Guideline - *Quality Determinants of Mammography* - with separate

versions for mammography providers, health care professionals, and consumers. The guideline provides information on the roles and responsibilities of each health care professional involved in mammography services, as well as information and recommendations for women.

Medicare and Medicaid Coverage of Mammography. Since 1991, Medicare has covered mammography screening for the early detection of breast cancer. For women age 40-49, Medicare currently covers one screening mammogram every two years, except for women with a high risk (for example, a woman with a mother, sister or daughter who has had breast cancer), in which case annual mammograms are covered. For women age 50-64, annual screening mammograms are covered; and for women 65 and older, Medicare covers one screening mammogram every two years.

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

Under Medicaid, diagnostic mammograms are a mandated service and states must cover them. Screening mammograms, however, are provided by states as an optional service, with most states covering screening mammograms in fee-for-service Medicaid. In addition, virtually all Medicaid managed care plans offer preventive services, including mammography, to their enrollees.

The Health Care Financing Administration has urged states to provide annual mammography screening to Medicaid beneficiaries at age 40; HCFA will continue to provide federal matching payments for annual mammography screening services.

National Breast and Cervical Cancer Early Detection Program. The CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. The resources devoted to breast cancer screening services are estimated to have increased from \$42 million in FY 1993, to \$81 million in FY 1997. The program, which has been operating in an increasing number of states over the past six years, has provided screening tests to almost one million medically underserved women. In October, 1996, the program went nationwide, with funding for all 50 states.

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

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

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About the Program

Colorectal Cancer Prevention and Control Initiatives

You may also download a [PDF version \(183K\)](#) for [Adobe Acrobat Reader](#) or a [PostScript version \(1468K\)](#).

Colorectal Cancer: The Importance of Early Detection

AT-A-GLANCE
1997



Photo courtesy of the Winship Cancer Center of Emory University

"We now have clearer insight into the natural history of colorectal cancer, better understanding of its biologic features, and clinical skills with which to intervene and make a difference for many people. Colorectal cancer screening has come of age."

Sidney J. Winawer, MD, Memorial Sloan-Kettering Cancer Center, New York

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention**

Colorectal Cancer

Colorectal Cancer

Colorectal cancer is the second leading cause of cancer-related death in the United States. In 1997, approximately 131,200 new cases of colorectal cancer will be diagnosed, and an estimated 54,900 deaths will be caused by the disease. When skin cancer is excluded, colorectal cancer follows prostate and lung cancers in incidence among men; among women, it follows breast and lung cancers. Approximately 6 percent of Americans will develop colorectal cancer within their lifetime.

Who Is at Risk?

After the age of 40, a person begins to have an increased risk of developing colorectal cancer, and this risk generally increases with advancing age. Men are more likely than women to develop colorectal cancer. African Americans are more likely than whites to be diagnosed with colorectal cancer and are more likely to die of the disease; incidence and mortality trends indicate that this gap is widening. Also at increased risk of developing colorectal cancer are those having inflammatory bowel disease, those having a family history of colorectal cancer or adenomatous polyps, and those having either of two hereditary syndromes (familial adenomatous polyposis syndrome or hereditary nonpolyposis colorectal cancer syndrome). Other factors contributing to a person's increased risk include a history of colorectal cancer or polyps; a history of ovarian, endometrial, or breast cancer; and low levels of physical activity. Low fruit and vegetable intake, diets low in fiber and high in fat, obesity, and alcohol consumption are possible additional risk factors.

Early Detection

When colorectal cancer is detected early and patients are followed up with appropriate treatment, survival is greatly enhanced. Survival rates vary significantly by stage at diagnosis: persons with colorectal cancer diagnosed at a localized stage have a 5-year relative survival rate of 91 percent, and those with colorectal cancer diagnosed at a regional stage have a 5-year survival rate of 63 percent. For persons with a diagnosis at an advanced stage of colorectal cancer (distant metastases), the 5-year survival rate drops to 7 percent, despite advances in surgical technique and postoperative therapies such as chemotherapy, radiation, and immunotherapy. Only 37 percent of colorectal cancers are diagnosed while the disease is still in a localized stage. For African Americans, the 5-year relative survival rates are lower than those for whites, and a smaller proportion of cases are diagnosed at an early stage.

Cancerous polyps and their precursors, benign adenomatous polyps, may be present in the colon for years before invasive cancer develops. Reducing the number of deaths from colorectal cancer depends on detecting and removing precancerous polyps and detecting and providing treatment for invasive cancer in its earliest stages. Colorectal cancer can actually be prevented by the removal of precancerous polyps.

Several tests are currently available for colorectal cancer screening:

- ☐ **Fecal Occult Blood Testing (FOBT)** is a chemical test for blood in a stool sample. A positive test can indicate bleeding from a precancerous growth or from colorectal cancer. However, FOBT has the potential for false positive and false-negative results. Some noncancerous gastrointestinal lesions cause bleeding, which creates a false positive result on an FOBT for colorectal cancer. False-negative results can occur because some polyps and cancers may not cause bleeding or may do so only intermittently. Certain foods, food supplements, and drugs may affect test results;

intermittently. Certain foods, food supplements, and drugs may affect test results; therefore, patients should adhere to restrictions as specifically recommended by test manufacturers.

The health benefits derived from colorectal cancer screening by FOBT are supported by a randomized control trial in the United States that showed a 33 percent reduction in mortality in the group chosen to undergo annual screening by FOBT. Two European trials have also shown benefits from the use of FOBT for screening.

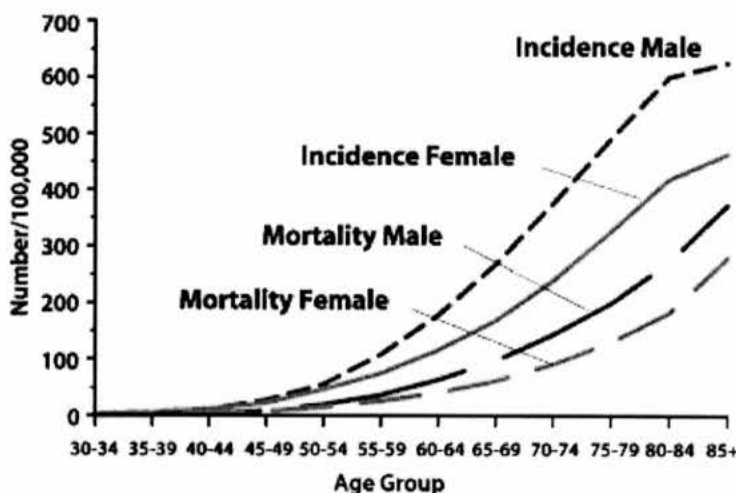
- **Sigmoidoscopy** uses a hollow, lighted tube to visually inspect the wall of the rectum and distal colon. The 35-centimeter flexible sigmoidoscope can detect about 50-55 percent of polyps; the longer 60-centimeter flexible scope is capable of detecting about 65-75 percent of polyps and 40-65 percent of colorectal cancers.

The efficacy of sigmoidoscopy has not been tested in a randomized control trial, but it is supported by two case-control studies.

Three other tests for colorectal cancer are commonly used in clinical practice, although no direct evidence, as yet, supports their efficacy in reducing morbidity and mortality. **Colonoscopy**, which is similar to sigmoidoscopy, can be used to visually inspect the entire colon and allows for the detection, removal, and biopsy of polyps during a single medical procedure. The **double contrast barium enema (DCBE)** procedure uses barium sulfate, air, and X-ray technology for examining the interior wall of the colon. Colonoscopy and DCBE are also used as follow-up diagnostic tools when the results of another

screening test are positive. **Digital rectal examination (DRE)** is the most commonly used screening test for colorectal cancer because it can be easily incorporated into a routine physical examination and is commonly performed to check the prostate in men as well. However, it can detect only those tumors within about 10 centimeters of the anus.

Cancers of the Colon and Rectum: Average Annual Age-Specific SEER Incidence and U.S. Mortality Rates by Gender, 1988-1992



Source: Cancer Statistics Review, 1973-1992

Guidelines for Screening

Because of recent evidence that screening reduces mortality from colorectal cancer, three scientific organizations have released new guidelines that call for the screening of all people at average risk beginning at age 50.

- **U.S. Preventive Services Task Force (USPSTF):** On the basis of a systematic and rigorous review of new data, the USPSTF, an independent, expert advisory panel convened by the U.S. Public Health Service, has concluded that sufficient evidence now exists to recommend colorectal cancer screening. The USPSTF recommends that clinicians include colorectal cancer screening, with periodic flexible sigmoidoscopy

and/or annual FOBT, in the periodic health examination of all persons aged 50 and older.

- ❑ **The American Cancer Society (ACS):** For those persons aged 50 and older and of average risk, the ACS recommends screening by one of the two following methods: annual FOBT, along with flexible sigmoidoscopy every 5 years; or a total colon examination, either by colonoscopy every 10 years or DCBE every 5-10 years. The ACS recommends that a DRE be conducted along with sigmoidoscopy or total colon examination. The ACS also provides separate guidelines for screening those at increased risk.
- ❑ **Interdisciplinary Task Force:** An interdisciplinary task force, originally convened by the federal Agency for Health Care Policy and Research, and supported by five major gastroenterological societies, has released guidelines very similar to those established by the ACS. Extensive documentation and rationale accompany these recommendations for colorectal cancer screening.

Although the guidelines vary, they all emphasize the health benefits derived from colorectal cancer screening-finding and removing precancerous polyps and thus preventing the development of cancer, or detecting cancer at an early stage.

Colorectal Cancer Screening Guidelines Available on the Internet:

- ❑ U.S. Preventive Services Task Force
<http://text.nlm.nih.gov>
- ❑ American Cancer Society
<http://www.cancer.org/colorectal/crearly.html>
- ❑ Interdisciplinary Task Force
<http://www.gastro.org/colcancer>

The preceding links are provided as a service to our users. Links to these Internet sites do not indicate endorsement of these sites or their contents by CDC.

Screening Usage

Results from recent studies and the new guidelines highlight the need to increase screening for colorectal cancer. Currently, screening for colorectal cancer lags far behind screening for breast and cervical cancers, perhaps because the effectiveness of screening has only recently been documented. In the 1992 National Health Interview Survey, almost 17 percent of persons aged 50 or older had never heard of an FOBT for screening, and more than 32 percent had never heard of sigmoidoscopy. About 26 percent reported having had an FOBT for screening in the past 3 years, and only about 9 percent reported having had screening sigmoidoscopy in the past 3 years. These statistics underscore the need for greater effort to educate health care providers about colorectal cancer screening guidelines and to inform the public, especially the targeted older population, about the availability and advisability of

screening.

CDC Program Activities

The Centers for Disease Control and Prevention (CDC) has initiated a number of activities related to colorectal cancer screening:

- CDC is collaborating with the ACS in the establishment of a national coalition of public, private, and voluntary organizations to educate medical providers and the public about the importance of colorectal cancer screening. Potential partners include state health departments, professional digestive disease organizations (such as the American Digestive Health Foundation and the Digestive Disease National Coalition), medical societies, federal agencies, consumers, cancer survivors, managed care organizations, private industry, health educators, and the medical media. In July 1997, CDC and ACS hosted an initial National Colorectal Cancer Round Table of potential partners to discuss strategies for identifying barriers to screening, assessing current public awareness of and interest in screening, and developing and disseminating health messages to promote screening.
- CDC hosted a meeting in July 1997 to bring together representatives from state health departments that are implementing colorectal cancer initiatives. This meeting provided a forum for CDC and state staff to share current and future plans, and to identify challenges and opportunities in developing state-based colorectal cancer efforts.
- CDC is providing support for a 3-year program at the University of North Carolina Prevention Center to develop standards for performing and reporting results of sigmoidoscopies. Having such standards is important because of the anticipated increased use of sigmoidoscopy.
- CDC is providing support for two multiyear studies on patient compliance with screening regimens. In cooperation with the Kaiser Permanente Medical Care Program of Northern California, CDC is supporting a study of determinants of patient compliance with ongoing, no-cost flexible sigmoidoscopy screening. CDC is also collaborating with the Imperial Cancer Research Fund in Great Britain to examine factors that predict interest and participation in sigmoidoscopy screening in a randomly selected, population-based sample in Glasgow, Scotland.
- CDC is supporting analysis of data obtained from a randomized trial of FOBT at the University of Minnesota. The analysis includes determining whether the benefits of FOBT screening are limited to certain population subgroups.
- CDC is collaborating with the Group Health Cooperative of Puget Sound on a study of preventive services for older women. The study includes surveys of female members aged 50 or older and of providers to determine their knowledge, attitudes, and practices related to screening for colorectal cancer.
- CDC's National Center for Environmental Health, National Center for Health Statistics, and National Center for Chronic Disease Prevention and Health Promotion are collaborating to properly maintain specimens collected for the National Health and Nutrition Examination Survey III DNA bank. The Centers are facilitating extraction of DNA and development of study procedures in molecular genetic research to allow use of the specimens by scientific investigators, including those conducting studies for colorectal cancer susceptibility genes.

For more information, please contact the Centers for Disease Control and Prevention,
National Center for Chronic Disease Prevention and Health Promotion,
Mail Stop K-64, 4770 Buford Highway NE, Atlanta, GA 30341-3724, (770) 488-4751.

E-mail to cancerinfo@cdc.gov

World Wide Web at <http://www.cdc.gov/nccdphp/dpc>

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About the Program

The National Breast and Cervical Cancer Early Detection Program

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The National Breast and Cervical Cancer Early Detection Program

AT-A-GLANCE
1997



"As we move into the 21st century, public health organizations, private agencies, and professional and voluntary organizations must form partnerships to support and enrich services to the public."

David Satcher, MD, PhD, Director
Centers for Disease Control and Prevention

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Post-it* Fax Note 7671		Date 4/25	# of pages 4
To Mary Dixon		From Sharon Ford Watkins	
Co./Dept.		Co. NBCC	
Phone #		Phone #	
Fax # 936-7311		Fax #	

BREAST CANCER LEGISLATION IN THE 105TH CONGRESS

Endorsed by NBCC

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. 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 Rep. Louise Slaughter).
- **H.R. 418—Breast Cancer Early Detection Act of 1997**—provides coverage for annual screening mammography for women enrolled in the Medicare program (introduced by Reps. Maloney and Ensign).
- **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. 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, Falcomavaega, and Christian-Green).

- **H.R. 1069—Improved Patient Access to Clinical Studies Act of 1997**—permits individuals to continue their health plan coverage of services while participating in a clinical study (introduced by Rep. Nita Lowey).
- **H.R. 1070—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 Reps. Lowey and Morella/companion bill to Sen. Snowe).
- **H.R. 1352—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 Rep. Lowey/companion bill to Sen. Snowe)

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/companion bill to Rep. Lowey).
- **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/companion bill to Rep. Lowey).
- **S. 89—Genetic Information Non-discrimination 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 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 (introduced by Sen. Snowe/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/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**—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).
- **S. 381—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 (introduced by Senators Rockefeller and Mack).

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:

National Institutes of Health	\$590 million
Department of Defense	
Breast Cancer Research Program	\$175 million
Other Agencies (EPA, VA, etc.)	<u>\$ 20 million</u>
Total	\$785 million

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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<http://www.eshoo.house.gov/>

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(408) 245-2339

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

April 23, 1997

COMMITTEE ON COMMERCE
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CO-CHAIR,
MEDICAL TECHNOLOGY CAUCUS

**Until a cure is found, our mothers and
daughters with breast cancer still need our
help . . .**

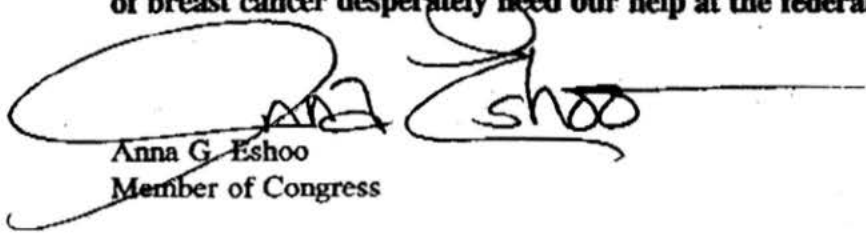
Dear Colleague:

On May 6th, hundreds of breast cancer survivors and advocates organized by the National Breast Cancer Coalition will arrive on Capitol Hill to deliver petitions containing **2.6 million signatures** -- one for each woman living with breast cancer today -- calling on the President and Congress to spend \$2.6 billion on breast cancer research between now and the year 2000.

As part of the national battle against breast cancer, I have introduced the ***Reconstructive Breast Surgery Benefits Act (HR 164)*** to ensure that insurance plans that cover mastectomies will also provide coverage for breast reconstruction. Although 17 states have passed similar laws guaranteeing breast reconstruction coverage, women in other states or in federally qualified health plans remain at risk.

The ***Reconstructive Breast Surgery Benefits Act*** is endorsed by the National Breast Cancer Coalition and nineteen other prominent cancer and health care organizations. On April 17th, Senator Edward Kennedy introduced the Senate companion (S. 609).

Please direct any questions or cosponsorship requests to Kristin Holman at 225-8104. A list of current cosponsors is provided on the back of this letter. I encourage you to join with your colleagues to ensure the full mental and physical recovery of breast cancer survivors. **Victims of breast cancer desperately need our help at the federal level.**



Anna G. Eshoo
Member of Congress

HR 164 Cosponsors (Rep. Eshoo)

Rep. Rosa DeLauro
Rep. Edolphus Towns
Rep. Patsy Mink
Rep. Louise Slaughter
Rep. Martin Frost
Rep. James McGovern
Rep. Linsey Graham
Rep. Eleanor Holmes-Norton
Rep. George Miller
Rep. Jack Quinn
Rep. Ellen Tauscher
Rep. Julia Carson
Rep. Zoe Lofgren
Rep. John Lewis
Rep. Eni Faleomavaega
Rep. Carolyn Maloney
Rep. Bobby Rush
Rep. William D. Delahunt
Rep. Sam Gejdenson
Rep. Maurice D. Hinchey
Rep. James A. Traficant
Rep. David Bonior
Rep. Vic Fazio
Rep. Sidney Yates
~~Rep. Lane Evans~~
Rep. Nancy Pelosi
Rep. Henry Waxman
Rep. Sheila Jackson-Lee
Rep. James L. Oberstar
Rep. Loretta Sanchez
Rep. Steve Rothman
Rep. Ronald Dellums
Rep. Gary Ackerman
Rep. Jon Fox
Rep. Bart Gordon
Rep. Robert Menendez
Rep. Bart Stupak
Rep. Robert Matsui
Rep. Dale E. Kildee
Rep. William J. Coyne
Rep. David McIntosh
Rep. Mike McIntyre
Rep. Sherrod Brown
Rep. Nick Lampson

S 609 Cosponsors (Sen. Kennedy)

Sen. Barbara Mikulski
Sen. Thomas Daschle
Sen. Christopher Dodd
Sen. Tom Harkin
Sen. Paul Wellstone
Sen. Patty Murray
Sen. Barbara Boxer
Sen. Carol Moseley-Braun
Sen. Diane Feinstein
Sen. Wendell H. Ford
Sen. Daniel K. Inouye



File Breast Cancer
NIH NEWS RELEASE Nt67c

NATIONAL INSTITUTES OF HEALTHNational Cancer Institute

FOR RELEASE
Tuesday, July 15, 1997NCI Press Office
(301) 496-6641

New Statistical Methodology Suggests Elevated Breast Cancer Mortality in Large Parts of Northeastern United States

Using an innovative statistical technique, scientists at the National Cancer Institute (NCI) have discovered that women living in a broad stretch of the metropolitan northeastern United States are slightly more likely to die from breast cancer than women in other parts of the Northeast. The study does not explain why these women are at higher risk of death, and the researchers note that the increase may be due to geographic differences in well-established risk factors for breast cancer which they were unable to include in the analysis.

"The breast cancer mortality rate along a section of the East Coast stretching from New York City to Philadelphia is 7.4 percent higher than the rest of the Northeast," said Martin Kulldorff, Ph.D., who led the study. "This is a statistically significant finding, indicating that elevated risk of breast cancer mortality in that area is not a random occurrence, but may be due to some underlying reason."

Kulldorff adds that "great caution should be exercised in interpreting the study of geographic clusters in cancer mortality." In particular, ascribing the cause of a mortality cluster to some local environmental exposure may be difficult or impossible.

Previous studies have shown that the northeastern United States (including Conn., Del., Md., Maine, Mass., N.H., N.J., N.Y., Pa., R.I., Vt. and D.C.) has about a 16 percent higher breast cancer mortality rate than the rest of the country. However, even within this region, there is substantial variation. Delaware, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Washington D.C. have higher breast cancer mortality rates than the national average. Breast cancer mortality rates in four other northeastern states -- Maryland, Vermont, Connecticut and Maine -- are very close to the national average of 26.4 per 100,000 women.

During the five years (1988-1992) covered by the analysis, 24,044 women in the New York/Philadelphia region died of breast cancer. This was about 200 more deaths per year than researchers would have expected to find if this area had the same breast cancer mortality rate as the rest of the 11-state northeastern region of the U.S. The study also showed the existence of four smaller clusters of increased mortality within the larger New York/Philadelphia area: northeast New Jersey, central New Jersey, Philadelphia, and Long Island, N.Y.

Long Island has been a major focus of research on breast cancer, following a June 1993 Congressional mandate to initiate a comprehensive study to ascertain whether environmental factors might be related to elevated breast cancer rates there. In light of this new study, Long

Island's elevated breast cancer mortality rate should be seen as part of a larger geographical trend in the New York/Philadelphia area.

In the new study, published in the July 15, 1997 *American Journal of Epidemiology*, researchers used a specially designed computer program that places a circular "window" on a map of the 11 most northeastern states and the District of Columbia.* They then calculated breast cancer mortality rates for the area inside the window's circumference and for the remainder of the northeastern United States.

A newly developed statistical method, called the spatial scan statistic, was used to compare these two rates. By resizing and moving the window across the entire map, the researchers were able to systematically scan for possible breast cancer mortality clusters and identify approximate boundaries for areas where mortality was elevated. The moveable window freed researchers from having to preselect which states or parts of states they would examine. Instead, they were able to let the data define the area for them.

Researchers also found a higher breast cancer mortality rate among women under 50 in the District of Columbia, but this cluster was explained by its proportionately larger African-American population. On average, African-American women have a higher mortality rate from breast cancer than do white women. In a paper published in the Feb. 5, 1997 *Journal of the National Cancer Institute*, NCI epidemiologist Robert E. Tarone, Ph.D., reported that breast cancer mortality rates for black women in the northeastern U.S. are no higher than those for black women in other regions. It is thus unlikely that widespread environmental exposures explain the elevated breast cancer mortality rates among white women in the Northeast.

The new study found that age, race, urbanization and average number of children born could not explain the elevated mortality rates for the larger New York/Philadelphia region, or for the four smaller clusters. However, the researchers could not include in their analysis other important risk factors for breast cancer such as age at first birth, menarche, or menopause, or factors that are known to affect mortality, including access to health care and regular mammography screening.

A study published in the July 2, 1997 *Journal of the National Cancer Institute* demonstrated that elevated breast cancer incidence in the San Francisco Bay Area could be entirely explained in terms of such known risk factors. Results of another study led by NCI epidemiologist Susan Sturgeon, Dr.P.H., and published in the Dec. 20, 1995 *Journal of the National Cancer Institute* showed that a large part of the regional differences in breast cancer death rates among white women in the United States would be explained by known factors such as age at first birth and mammography screening.

In 1997, there will be an estimated 180,200 new cases of invasive breast cancer among women in the United States, and an estimated 44,190 women will die from the disease. Breast cancer mortality rates vary widely from state to state. Hawaii's rate is 32 percent lower than the national age-adjusted average of 26.4 per 100,000 women, and Washington D.C.'s rate is 28 percent higher.

The new technique used in the study will help researchers overcome a major problem in "cancer cluster" investigations: the fact that the areas studied as clusters have generally been selected based on public concern rather than systematic comparison of rates in different areas.

NCI, in collaboration with the National Institute of Environmental Health Sciences, has undertaken two large initiatives to investigate reasons for elevated breast cancer death rates in the

Northeast/Mid-Atlantic regions. These studies are being conducted by investigators at major medical institutions in the East. Six studies, which comprise the Northeast/Mid-Atlantic Study, are focusing on organochlorine compounds, which are commonly used as pesticides. The Long Island Breast Cancer Study Project is investigating whether environmental factors are responsible for breast cancer risk in Nassau and Suffolk counties. This research includes assessments of exposure to organochlorines and other chemicals, magnetic fields, contaminated drinking water, air pollution, and hazardous and municipal waste.

*The study is titled "Breast Cancer Clusters in the Northeast United States: A Geographic Analysis." The authors are M. Kulldorff, E.J. Feuer, B.A. Miller, L.S. Freedman. *American Journal of Epidemiology*, Vol. 146, No. 2, 1997.

Cancer Information from the Office of Cancer Communications

National Cancer Institute news releases are available via the Internet through the World Wide Web (<http://rex.nci.nih.gov>). Click on Mass Media.

Cancer Information Service

The Cancer Information Service (CIS), a national information and education network, is a free public service of the National Cancer Institute (NCI), the Nation's primary agency for cancer research. The CIS meets the information needs of patients, the public, and health professionals. Specially trained staff provide the latest scientific information in understandable language. CIS staff answer questions in English and Spanish and distribute NCI materials.

Toll-free phone number: 1-800-4-CANCER (1-800-422-6237)

TTY: 1-800-332-8615

CancerFax ®

For NCI information by fax, dial (301) 402-5874 from the telephone on a fax machine and listen to recorded instructions.

CancerNet™

For NCI information by computer:

CancerNet Mail Service (via E-mail):

To obtain a contents list, send E-mail to cancernet@icicc.nci.nih.gov with the word "help" in the body of the message.

Internet:

Information is also accessible via the Internet through the World Wide Web at (<http://cancernet.nci.nih.gov>) and Gopher ([gopher://gopher.nci.nih.gov](http://gopher.nci.nih.gov)) servers.

*Breast Cancer.
Notebook*

Date: Wednesday, June 11, 1997

FACT SHEET

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BREAST CANCER: NEW EFFORTS UNDERWAY

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

For women age 50-69, having regular mammograms can reduce the chance of death from breast cancer by one third or more. Despite these numbers, 40 percent of women age 50 and older have reported not having a mammogram in the past two years, while 54 percent of women age 65 and older have a mammogram every two years.

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

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

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

Background: More Women Can Survive Breast Cancer

- ☐ The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.
- ☐ Approximately 180,200 new cases of breast cancer will be diagnosed in 1997, and about 44,000 women are expected to die from breast cancer. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.
- ☐ Death rates from the disease are highest among older, black, and low-income women. During the last 20 years, death rates from breast cancer for women over 65 increased by 35 percent for black women and 11 percent for white women. Mortality rates vary widely among racial and ethnic groups in the United States. Hispanic, Chinese, Filipino and Japanese women have annual rates at or below 15 per 100,000 women, while black, white and Native Hawaiian women have rates above 25 per 100,000 women.

- ☐ With proper screening and treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. Between 1982 and 1987, breast cancer incidence (rate of new cases) for women increased about 4 percent per year, but recently has leveled off. The death rate for women with breast cancer declined 6.3 percent between 1991 and 1995. The greatest reductions in death rates were among younger women (9.3 percent) and white women (6.6 percent), with more modest reductions among African Americans (1.6 percent) and women age 65 and older (2.8 percent).
- ☐ During the most recent 5-year period, death rates among white women declined for all decades of age from 30 to 79 years. Among black women, rates were down for all decades of age from 30 to 69 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women aged 30 to 39 years, rates dropped about 13 percent among whites and 5 percent among blacks. For women aged 40 to 49 years, rates dropped 9 percent among whites and 2 percent among blacks.

HHS Spending On Breast Cancer

HHS discretionary funding for breast cancer research, prevention and treatment has increased from approximately \$276 million in FY 1993 to an estimated \$513 million in FY 1997. As the Centers for Disease Control and Prevention (CDC) are working to increase access for all women to mammography screening and follow up services, the resources devoted to breast cancer services have increased from \$42 million in FY 1993, to \$81 million in FY 1997. Cancer research is vital to our understanding of how to prevent, detect and treat breast cancer. The Clinton Administration has invested in breast cancer research at the National Institutes of Health by increasing funding from \$229 million in FY 1993, to \$401 million in FY 1997. HHS also helps provide treatment for breast cancer through the Medicare and Medicaid programs and through the Indian Health Service.

HHS Action To Combat Breast Cancer

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

National Action Plan on Breast Cancer

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

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

areas of breast cancer research. The NAPBC has awarded funds to establish a national biological resources bank and is now conducting a survey of tissue banks throughout the country to identify and determine the accessibility of all available biological resources.

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

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

Discovery of BRCA1 and BRCA2 Genes for Breast Cancer

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

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

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

National Breast and Cervical Cancer Early Detection Program

The CDC's National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. The resources devoted to breast cancer screening services have increased from \$42 million in FY 1993, to \$81 million in FY 1997. The program, which has been operating in an increasing number of states over the past six years, has provided screening tests to almost one million medically

underserved women. In October, 1996, the program went nationwide, with funding for all 50 states.

Breast Cancer Among the Elderly

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

New Frontiers In Breast Cancer Early Detection

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

Centers of Excellence

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

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, the AHCPR in October 1994, developed a Clinical Practice Guideline--Quality Determinants of Mammography--with separate versions for mammography providers, health care professionals, and consumers. The guidelines provide information on the roles and responsibilities of each health care professional involved in mammography services, as well as information and recommendations for women.

Mammography Standards

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

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

Environmental Factors and Breast Cancer

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

Office of Cancer Survivorship

On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

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