

NLWJC - Kagan

DPC - Box 029 - Folder 010

Health - Mammograms

THE WHITE HOUSE AT WORK

Saturday, October 25, 1997

PRESIDENT AND THE FIRST LADY ANNOUNCE NEW INITIATIVES TO IMPROVE PREVENTION AND EARLY DETECTION OF BREAST CANCER

"Until [we find a cure], we know that early detection is the most potent weapon we possess in our battle against breast cancer, and we know that mammography is the best way to detect breast cancer so that it can be treated before it's too late. The First Lady and I have worked hard to make mammograms available to more women and to encourage more women to get mammograms."

-- President Clinton, Saturday Radio Address. 10/25/97

In the Saturday Radio Address, the President and the First Lady announced new steps to ensure that more women get regular, high quality mammograms. Early detection, followed by prompt treatment, can reduce the risk of death by as much as 30 percent. However, a mammogram can fail to do its job because of poor medical techniques, processing or reading of the films; inadequate record keeping and reporting of results, and lack of effective quality assurance controls. In 1995, about 35 percent of mammography facilities that sought accreditation initially failed the quality requirements. Moreover, far too few women get regular mammograms. Thirty-three percent of women ages 50 to 64, and 45 percent of women over age 65 reported not receiving a mammogram in the last two years. The initiatives the President and the First Lady are announcing include:

Improving Quality Standards of the Mammography Facilities Nationwide. The new FDA regulations that were announced, authorized by the Mammography Quality Standards Act (MQSA), set new high standards for mammography facilities, including requiring facilities to hire capable technologists, to use equipment that produces clear and accurate images, and to ensure that physicians have the skills to interpret the rules. It also requires facilities to display their FDA certification and requires that patients be fully informed of results of a mammogram so that follow up testing and treatment can begin immediately. The National Breast Cancer Coalition applauded the implementation of the final regulations stating that "this Rule will ensure that every woman in America will receive the highest quality mammography."

Initiating a New Mammography Education Campaign at the National Cancer Institute (NCI). The NCI is initiating a new national education campaign that provides women and their families and health professionals clear, up-to-date information about steps they should take to detect mammography and breast cancer. The NCI materials provide information about the risk factors for breast cancer, the benefits and limitations of mammography, and the importance of regular mammograms for women in their 40s and older. They also highlight breast cancer incidence and mortality rates for women in different racial/ethnic groups.

Launching the First Lady's National Annual Medicare Mammography Campaign. Each year the First Lady has launched a mammography campaign to encourage older women to get mammograms. To encourage more older women to get regular mammograms, this year the First Lady's campaign includes:

- **New Nationwide Public Service Announcements to Encourage More Older Women to Get Mammograms.** The First Lady is announcing two new public service announcements to encourage older women to get mammograms. One of the PSAs features Candice Bergen of the Murphy Brown Show and the second PSA includes breast cancer survivor and spokesperson Carol Baldwin and her sons, Alec, William, Daniel and Stephen. In addition to these PSAs, a number of corporations have made important new commitments to educate women about the importance of regular mammography and screening.
- **HORIZON Grants to Improve Mammography Rates Among Minority Women.** This year the Health Care Financing Administration has focused the Medicare mammography campaign to reach minority Medicare beneficiaries who are even less likely to get mammography screenings.

BUILDING ON THE PRESIDENT'S STRONG RECORD IN THE FIGHT AGAINST BREAST CANCER.

- **A Long Record in Fighting Breast Cancer.** The President has taken a number of important steps to fight breast cancer. Since the President took office funding for breast cancer research, prevention and treatment has nearly doubled to over \$500 million in 1997. The Balanced Budget Act took steps to encourage more women to get regular mammograms by waiving deductibles for all mammograms and covering mammograms on an annual basis. In addition, the balanced budget also expanded coverage to pay for annual screening mammograms all Medicare beneficiaries age 40 and over, making coverage consistent with the new recommendations of national experts.



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

October 1, 1997

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

MEMORANDUM FOR ERSKINE BOWLES

THROUGH: Franklin D. Raines

FROM: Sally Katzen

SUBJECT: Heads-up on FDA Final Rule on Quality Mammography Standards

We have just concluded review of an FDA final rule that establishes nationwide quality and safety standards for mammography facilities. The final rule, which implements the Mammography Quality Standards Act (MQSA), combines five proposed regulations addressing accreditation, facilities, personnel, equipment, and performance standard alternatives.

The rule strikes an appropriate balance between imposing new costs on mammography facilities (which can limit patient access to mammography services) and improving our ability to protect women's health. Although the provisions of the rule are highly prescriptive, FDA pushed the performance standards as far as they could given the state of the art in this area.

As part of the White House's efforts to promote breast cancer awareness, the President is expected to announce the rule this Saturday in his radio address. While FDA received over 19,000 comments on the proposal, the final rule is generally expected to be well-received by the public, including physicians, mammography facilities, and advocacy groups.

Please call me if you have any questions.

*Health -
Mammograms*

President's Mammography Announcements

Today President Clinton is announcing actions to encourage women to begin receiving regular mammograms in their forties in response to the National Cancer Institute's (NCI) recommendation that women should begin undergoing regular mammography screening at forty. The President is taking action to bring Medicare, Medicaid, and federal employee health plans in line with the NCI's new recommendations, and is calling on private health plans to do the same.

- **Medicare.** President Clinton is proposing that Medicare cover annual screening mammograms for women beginning at age forty.
- **Medicaid.** The President is announcing that HCFA is sending a letter today to every State Medicaid director to encourage them to cover annual mammography screening beginning at age 40 and to make clear that the federal government will provide federal matching payments for these services.
- **Federal Employee Health Plans.** President Clinton is announcing that the Office of Personnel Management will require all federal employee health plans to cover annual mammograms beginning at age 40 by January 1, 1998.

*Health -
mammograms*

Pauline M. Abernathy

03/27/97 01:43:15 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
Subject: 1997-03/27 RBTP AT MAMMOGRAM ANNOUNCEMENT

----- Forwarded by Pauline M. Abernathy/OPD/EOP on 03/27/97 01:44 PM -----



SUNTUM_M @ A1
03/27/97 01:11:00 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
Subject: 1997-03/27 RBTP AT MAMMOGRAM ANNOUNCEMENT

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 27, 1997

REMARKS BY THE PRESIDENT
IN MAMMOGRAM ANNOUNCEMENT

The Oval Office

12:17 P.M. EST

THE PRESIDENT: Secretary Shalala has just briefed me on the National Cancer Institute's new recommendations on mammography. These recommendations, based on the latest and best medical evidence, give clear, consistent guidance to women in our national fight

against breast cancer. Breast cancer is the most commonly diagnosed cancer among women. It affects one in eight women in their lifetimes, and has touched the families of nearly every American, including my own.

We may not yet have a cure for breast cancer, but we do know that early detection and early treatment are our most potent weapons against this dread disease and we know that mammography can save lives. That is why it's important to send a clear, consistent message to women and to their families about when to start getting mammograms and how often to repeat them.

After careful study of the science, the National Cancer Advisory Board has now concluded that women between the ages of 40 and 49 should get a mammography examination for breast cancer every one or two years, in consultation with their doctors. The National Cancer Institute has now accepted these recommendations. Now women in their 40s will have clear guidance based on the best science, and action to match it.

Today I am taking action to bring Medicare, Medicaid and the federal employee health plans in line with the National Cancer Institute's recommendations. First, in the Medicare budget I am sending to Congress today I am making annual screening mammography exams, beginning at age 40, a covered expense without co-insurance or deductibles. Second, Secretary Shalala is sending a letter to state Medicare directors urging them to also cover annual mammograms beginning at 40, and assuring them that the federal government will pay its matching share if they do so. And today, I am directing the Office of Personnel Management to require all federal health benefit plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings, beginning next year.

The federal government is doing its part to make sure women have both coverage and access to this potentially lifesaving test. I want to challenge private health insurance plans to do the same. They, too, should cover regular screening mammograms for women 40 and over.

Finally, we know there has been much discussion on this issue and a lot of confusion. That is why we are launching a major public education campaign to make sure every woman and every health care professional in America, that all of them are aware of these new recommendations. This is a major step forward in our fight against breast cancer.

In addition to Secretary Shalala, I want to thank National Cancer Advisory Board Chairperson, Dr. Barbara Rimer, and

all the member of the Board, along with the NCI Director, Dr. Richard Klausner, for the fine job that they did in producing these recommendations. I also want to thank the First Lady, who could not be with us here because of her visit to Africa. She has devoted

countless hours to educating women about the importance of mammography, and this is a happy day for her.

She has especially tried to educate older women to take advantage of the Medicare coverage of mammograms, because we know that too few of them still do. And that's the last point I would like to make. These guidelines and this coverage, it's all very good, but unless women are willing to actually take advantage of the coverage, we won't have the full benefit of the recommendations and the findings that have been made.

Now I'd like to turn the microphone over to Secretary Shalala to make a few comments.

SECRETARY SHALALA: Thank you, Mr. President. Thank you, Mr. President, for your leadership. One of the biggest fears that women have about breast cancer is the fear of not knowing what to do or when to do it. But today years of confusion have been replaced by a clear, consistent scientific recommendation for women between the ages of 40 and 49. According to a joint statement released today, the National Cancer Institute and the American Cancer Society agree that mammography screening of women in their 40s is beneficial and supportable with the current scientific evidence. We can now tell all women over 40, talk to your doctor because regular mammography can save your life.

In fact, current evidence based on clinical trials finds that regular mammograms can reduce the death rate from breast cancer by about 17 percent for women between 40 and 49.

Now, to get the word out, we are developing materials and using our 1-800 number. It's 1-800-4-CANCER. The guidance we offer today to women in their 40s is a step forward, but it's only one piece of the Clinton administration overall strategy to fight breast cancer. Under the President's leadership, we have doubled the funding for breast cancer research, for treatment and prevention to more than \$500 million since 1993.

The President signed the landmark Kennedy-Kassebaum bill to ensure that all Americans, including those with preexisting conditions like breast cancer, can keep their insurance even if they lose or change their jobs. We're working hard to improve the quality of mammograms and improve access to quality mammograms. And that's why we're reaching out to women in every state, especially low-income women and women of color, to make certain that they know about and have access to mammograms.

And that's why, as the President indicated, the First Lady has led mammography awareness campaigns aimed at women over 65. Those women are the most at risk, and that's why, under the Mammography Quality Standards Act, American women can now have greater confidence in the safety and accuracy of their mammograms.

We also have created the first ever national action plan

on breast cancer, a true public-private partnership that supports research and outreach and has a goal of the eradication of breast cancer. Let me say that all of us owe a huge debt and a lot of gratitude to the activists and survivors, leaders who have used their voices and their pain to stop breast cancer and to heal those for whom it strikes.

All of us should be very proud of the fact that mortality rates for breast cancer are falling, not nearly enough, but they are finally going down in this country -- and all of us should

be proud that with this announcement today, we have replaced confusion with clarity, and moved another step closer to the day when our grandchildren will have to turn to the history books to learn about a disease called breast cancer. Working together, we can and will make it happen. Thank you very much.

Q Mr. President, do you have any comment on the mass suicide in California?

THE PRESIDENT: Well, of course, all I know is what I read about it this morning and what I saw last night reported. But it's heartbreaking, it's sickening, it's shocking. I think it's important that we get as many facts as we can about this and try to determine what, in fact, motivated those people, and what all of us can do to make sure that there aren't other people thinking in that same way out there in our country, that aren't so isolated that they can create a world for themselves that may justify that kind of thing. It's very troubling to me. But I don't think I know enough to make a definitive comment about it.

Q Mr. President, switching gears on another subject, the Democratic Party emerged from this most recent election in the aftermath of all of these fundraising problems -- it seems to be in pretty bad shape financially -- enormous debt that they can't repay. What, if anything, can you do about this, and how much responsibility do you have to try to get the Democratic Party back into shape?

THE PRESIDENT: Oh, a lot, and I have been doing a lot and I will do more. We knew that we would have to spend -- last year when it became obvious that our congressional candidates were going to be outspent, massively, we did everything we could to raise a good deal of money at the end. But the committees and the Democratic Committee went into debt with money that they could legally borrow in the hope of trying to be competitive. They actually did a pretty good job. They were still outspent, I figure, in the last 10 days, two weeks, probably four or five to one, in all of the contested races. But we knew that would happen and we knew it would take some time to pay it back. But I'm not particularly concerned about it; I think we will pay it back. And it was, I thought, important.

Keep in mind, we were at the bottom of the barrel in November of '94, and in 1995 we did a good job, I think, of building

March 26, 1997

MAMMOGRAM ANNOUNCEMENT

DATE: March 27, 1997
LOCATION: Oval Office
BRIEFING TIME: 11:30 am - 12:00 pm
EVENT TIME: 12:00 pm - 12:30 pm
FROM: Bruce Reed

I. PURPOSE

You will be announcing several new steps to encourage women to undergo regular mammograms beginning at age 40 as recommended by the National Cancer Institute in a morning press conference. This will highlight your continued commitment to making mammograms more readily available to women of all ages and the Administration's ongoing efforts to prevent, detect and treat breast cancer more effectively.

II. BACKGROUND

At 10:30am on Thursday, the Presidentially appointed National Cancer Advisory Board will announce that they are now recommending mammograms every one or two years for women in their forties. At this event, Richard Klausner, the Director of the National Cancer Institute, will also announce that he is accepting their recommendations. Since 1993, the National Cancer Institute has not recommended regular mammograms for women in their forties; the decision had been left up to women and their doctors.

This decision by the National Cancer Institute means there is now consensus in the medical community on regular mammogram screening. However, the American Cancer Society recommends screening every year and the National Cancer Institute is recommending them every one or two years. In practice the National Cancer Institute informs us that there will be little to no difference between the recommendations.

You will be responding to these new recommendations by announcing the following steps that will expand coverage of mammograms to women in their

forties and to provide clearer educational information to women on this issue:

- MEDICARE LEGISLATION - You will announce that as you forward the health portion of the balanced budget to Congress on Thursday, the Medicare provisions will be amended to include annual mammograms for women age 40 and over. (This expansion will be added to reforms already in your budget that improve the mammography benefit by eliminating the copayment.)
- MEDICAID
You will be announcing that the Health Care Financing Administration (HCFA) is sending a letter to state Medicaid directors to urge states to provide annual mammography screening to Medicaid beneficiaries over age 40, and to assure them that HCFA will provide federal matching payments for these screenings
- FEDERAL EMPLOYEES
You will announce that starting January 1, 1988, the Office of Personnel Management will require all federal health benefits plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings.
- PUBLIC INFORMATION CAMPAIGN
You will announce that the Administration is launching a public education campaign to provide information to women about breast cancer screening. Secretary Shalala will announce in her remarks that the 1-800-4-CANCER hotline will begin immediately to provide information consistent with the recommendations of the National Cancer Institute.
- CHALLENGE TO PRIVATE SECTOR HEALTH PLANS
You will call on the private sector health plans to follow the federal government lead to require federal health plans to provide coverage consistent with the National Cancer Institute's recommendations.

III. PARTICIPANTS

Briefing Participants:

Secretary Shalala
Erskine Bowles
Rahm Emanuel
Bruce Reed
Chris Jennings
Kitty Higgins

Betsy Myers
Terry Edmonds
Mike McCurry

Event Participants:
Secretary Shalala

There will be no invited guests to this event.

IV. PRESS PLAN

Pool Press.

V. SEQUENCE OF EVENTS

- You will enter the Oval Office, accompanied by Secretary Shalala, and walk directly to the podium.
- You will make remarks and then introduce Secretary Shalala.
- Secretary Shalala will make remarks.
- The Pool will ask questions, and then you will depart.

VI. REMARKS

Remarks Provided by Terry Edmonds in Speechwriting.

Health -
Mammograms

TO: Elena and Bruce
FR: Pauline and Christa

Attached please find the following Mammogram Announcement background documents:

- Event Memo
- 1 page fact sheet
- 1 page of breast cancer accomplishments
- Letter HCFA is sending to State Medicaid Directors
- NCI Press Release (to be released at 10:00 am tomorrow.)
- Draft of POTUS remarks
- Draft of Secretary Shalala's remarks
- Internal Q&A from HHS

Chris Jennings has reviewed these documents.

THE WHITE HOUSE
WASHINGTON

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(This expansion will be added to reforms already in your budget that improve the mammography benefit by eliminating the copayment.)

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- FEDERAL EMPLOYEES

You will announce that starting January 1, 1988, the Office of Personnel Management will require all federal health benefits plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings.

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You will call on the private sector health plans to follow the federal government lead to require federal health plans to provide coverage consistent with the National Cancer Institute's recommendations.

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VI. REMARKS

Remarks Provided by Terry Edmonds in Speechwriting.

PRESIDENT CLINTON ANNOUNCES MAMMOGRAPHY ACTIONS

March 27, 1997

Today President Clinton announced actions to encourage women to begin receiving regular mammograms in their forties in response to the National Cancer Institute's (NCI) recommendation that women should begin undergoing regular mammography screening at forty. The President is taking action to bring Medicare, Medicaid, and federal employee health plans in line with the NCI's new recommendations, and is calling on private health plans to do the same.

With the NCI's recommendation, women now have clear and consistent science-based advice that they should begin regular mammography screening in their forties. The Clinton Administration has strived to make high quality mammograms more readily available to women of all ages and to improve efforts to prevent, detect, and treat breast cancer, which currently affects 1 in 8 American women in their lifetime.

The President announced the following actions today in response to the NCI's recommendation:

- **Medicare.** President Clinton is proposing that Medicare cover annual screening mammograms for women beginning at age forty without coinsurance and deductibles. Currently, Medicare does not cover annual screening mammograms for women in their forties, and covered mammograms can be subject to coinsurance and deductibles. The proposed changes are included in the President's overall Medicare and Medicaid budget proposals, which the Administration is sending to Congress today.
- **Medicaid.** The President announced that the Health Care Financing Administration at HHS is sending a letter today to every State Medicaid director to encourage them to cover annual mammography screening beginning at age 40 and to make clear that the federal government will provide federal matching payments for these services. States currently have the option of covering mammography screening, but not all States cover annual mammography screening beginning at age 40.
- **Federal Employee Health Plans.** President Clinton is directing the Office of Personnel Management to require all federal employee health plans to cover annual mammograms beginning at age 40. Current Federal Employee Health Benefits program policy only covers one mammogram screening every two years for women in their forties. The new policy will take effect in January 1998, the start of the FEHB's next contract year.
- **Challenge to Private-Sector Health Plans.** President Clinton called on private-sector health plans to follow his lead in making the federal health plans consistent with the NCI's recommendations by covering annual screening mammograms beginning at age 40.
- **Public Education Campaign.** The Administration announced that it will lead a national public education campaign to provide women with clear information about when they should begin regular mammography screening. The NCI will also work with health organizations and associations to communicate the latest and most accurate information. Information will be available through the NCI's toll-free Cancer Information Service at 1-800-4-CANCER and on the web at <http://rex.nci.nih.gov>.

A Strong Record on Breast Cancer

The Clinton Administration has worked hard to combat breast cancer, the second leading cause of death from cancer for women. This year over 180,000 women will be newly diagnosed with breast cancer and more than 40,000 will die of this disease. The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. The following are examples of new initiatives undertaken since 1993:

- **Nearly Doubling Breast Cancer Research, Prevention, and Treatment.** Since the Clinton Administration has taken office, funding for breast cancer research, prevention and treatment at HHS has nearly doubled, from about \$276 million in FY 1993 to an estimated \$513 million in FY 1997.
- **Signed the Kassebaum-Kennedy Legislation into Law, Ending Pre-existing Condition Exclusions.** As a result of this legislation, no American will live in fear of being denied coverage just because they have a pre-existing condition such as breast cancer. This legislation is particularly helpful for the millions of cancer victims who will no longer face the dilemma of hesitating to go to a new and better job for fear of losing their health insurance.
- **Medicare Mammography Campaign.** The Clinton Administration has made it a priority to educate older women about the importance of detecting breast cancer early and to inform them about Medicare coverage of mammography services. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings. Breast cancer is more prevalent in older age groups and the risk of breast cancer increases with age. About 80 percent of breast cancers occur in women age 50 or older. Yet, only 65 percent of women age 50-64 have had a mammogram in the past two years, and only 45 percent of women age 65 and older have a mammogram every two years.
- **Mammography Quality Standards.** In 1992, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA). The rules ensure that the roughly 10,000 mammography facilities nationwide accredited by the FDA meet high quality standards for equipment and personnel.
- **National Breast and Cervical Cancer Early Detection Program.** The Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, and minority women. Since the program's inception, it has provided screening tests to almost one million medically underserved women. In October 1996, the program went nationwide, with funding for all 50 states.
- **Research on Using Imaging Technologies from the Defense, Space, and Intelligence Communities to Detect Cancer Earlier and with Greater Accuracy.** 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.

DRAFT

Dear State Medicaid Director:

I am writing to encourage States to provide coverage for annual screening mammograms for women age 40 and older. We are sensitive to the fiscal effect this may have on States, and want to assure you that Federal financial participation (FFP) will continue to be available for this service.

Breast cancer is the second leading cause of cancer deaths in American women. While all States provide some coverage for screening mammography, coverage limitations for women in this age group may reduce early detection of breast cancer.

Recent announcements concerning the appropriate age and frequency at which women should receive screening mammograms have heightened public interest in this critical issue. There is a particular focus on women from age 40 to 49. The National Cancer Board, a presidentially-appointed committee that advises and consults with the Director of the National Cancer Institute (NCI) and the Secretary of Health and Human Services, recently considered an updated finding from breast cancer studies. The new data show that regular screening mammograms for women in their 40s reduces death from breast cancer by about 17 percent. Today, March 27, the Board recommended to the Director of the NCI that women over age 40 get screening mammograms every one to two years. The NCI adopted the Board's recommendations. (See attachment.)

As you know, all State Medicaid programs must cover diagnostic mammograms. These services are included under one of the mandated service categories and are determined to be medically necessary as a result of a sign, symptom, or complaint. However, States have flexibility in choosing whether, and on what basis, to cover screening mammograms as an optional service.

In light of the new recommendation, we urge you to consider providing annual coverage for screening mammograms for women over age 40. Regular screening mammograms for these women should lead to decreasing morbidity and mortality rates from breast cancer. Medicaid coverage of screening mammograms will eliminate financial impediments to this important service for Medicaid beneficiaries in this age category, and providing coverage for annual screens assures, consistent with the NCI recommendations, that women choosing to have annual mammograms will be able to obtain this service. Again, we ~~reassure you~~ that we will provide federal matching payments for service expansions in this area. *want to reiterate*

In recent years, State have made aggressive efforts to ensure that Medicaid beneficiaries have access to preventive health measures. As partners with the States in Medicaid, we appreciate your commitment to ensuring the best possible preventive health services for Medicaid beneficiaries.



Office of Cancer
Communications Building 31 Room 10A24
Bethesda, Maryland 20892

For Response to Inquiries

National Institutes of Health

March 27, 1997

NCI Press Office
(301) 496-6641

**Statement from the National Cancer Institute on the
National Cancer Advisory Board Recommendations on Mammography**

The National Cancer Institute (NCI) accepts the recommendations of the National Cancer Advisory Board on screening mammography.

As a result, NCI will recommend that:

- Women in their 40s 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 than average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and the frequency of screening.

The board also stated that because of mammography's limitations, it is important that a clinical breast examination by a health care provider be included as part of regular, routine health care. NCI will include that statement in its recommendations.

Richard Klausner, M.D., NCI director, expressed his gratitude to the board for coming to closure on the issue quickly and for helping to bring clarity to this important issue. He said the board also made important recommendations for future research on breast cancer screening and education, and that NCI would address those research recommendations.

Klausner said the institute will immediately begin to develop new educational materials to communicate the screening recommendations and to help women and health professionals determine an individual's breast cancer risk. He said that NCI also will work with the American Cancer Society, other government agencies, advocacy organizations, cancer centers, and other

(more)

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groups to educate the public and health professionals about the benefits, limitations, and risks of screening mammography.

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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 federal government'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://tex.nci.nih.gov>) and (<http://cancernet.nci.nih.gov>) servers.

PRESIDENT WILLIAM J. CLINTON
MAMMOGRAPHY ANNOUNCEMENT
THE WHITE HOUSE
MARCH 27, 1997

Good afternoon. Secretary Shalala has just briefed me on the National Cancer Institute's new recommendations on mammography. These recommendations, based on the latest and best medical evidence, give clear, consistent guidance to women in our national fight against breast cancer. Breast cancer is the most commonly diagnosed cancer among women. It affects one in eight women in their lifetimes. My own mother fell victim to this terrible disease. We may not yet have a cure -- but we do know that early detection and early treatment are our most potent weapons in this battle. And we know that mammography can save lives.

That is why it is so important to send a clear, consistent message to women and their families about when to start getting mammograms and how often to repeat them. Today, we are offering women and their families that clear guidance, based on solid science.

After careful study of the science, the National Cancer ^{Advisory Board} ~~Institute~~ has now concluded that women between the ages of 40 and 49 should get a mammogram examination for breast cancer every one or two years in consultation with their doctors. ~~These new recommendations should end the debate.~~ ^{confusion.} The medical community is now in agreement -- regular mammograms starting at age 40 are the best way women can protect themselves against breast cancer.

The National Cancer Institute has helped these women.

In addition to Secretary Shalala, I want to thank National Cancer Advisory Board chairperson, Dr. Barbara Rimer [RHYMER] and all the members of the Board, along with NCI Director, Dr. Richard Klausner for the fine and speedy job you did in producing these recommendations. I also want to thank the First Lady, who could not be here today because of her historic visit to Africa. Hillary has devoted countless hours to educating women about the importance of mammography. She has particularly tried to educate older women to take advantage of Medicare coverage of mammograms because we know that too few of them do. ~~She is a part of this achievement and~~ I want to thank her for all she has done in the fight against breast cancer.

Now that medical experts agree on the need for regular mammograms for women beginning at age 40, we have to take steps to see that they get them and that they and their doctors understand the benefits of the procedure. So today, I am taking action to bring Medicare, Medicaid and federal ~~health~~ ^{screening} employee health plans in line with the National Cancer Institute's recommendations. First, in the Medicare budget I am sending to Congress today, I am making annual mammography exams, beginning at age 40, a covered expense, without ~~co-payments~~ ^{co-insurance} and deductibles. Second, Secretary Shalala is sending a letter to state Medicaid Directors urging them to also cover ~~an~~ ^{an} annual mammogram and assuring them that the federal government will pay its matching share. And today, I am directing the Office of Personnel Management to require all

federal health benefits plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings beginning next year.

Finally, we all know that there has been much discussion on this issue and a lot of confusion. ~~But we should all remember that there is not one prescription for all women. That is why women should make this decision in consultation with their doctors. We want to make sure that every woman who decides to have a mammogram has both coverage and access to this potentially life saving test.~~ That is why we are launching a major public education campaign to make sure every woman and every health professional in America is aware of these new recommendations. We all should know that regular mammograms are a critical weapon in our fight against breast cancer.

Now, I'd like to turn it over to Secretary Shalala.

SHIALALA

Thank you Mr. President for your leadership – and for once again showing your deep and personal commitment to lifting the ugly shadow of breast cancer that hangs over every American woman.

One of the biggest fears women have about breast cancer is the fear of not knowing what to do, or when to do it.

But today years of confusion have been replaced by a clear and consistent scientific recommendation for women between 40 and 49.

We can now tell them talk to your doctor because regular mammograms can save your life.

To get the word out, we are developing written materials, and using our 1-800-4-CANCER number to reach out to insurance companies, medical associations, advocacy groups and women themselves.

The guidance we offer today to women in their forties is a step forward.

But it is only one piece of our overall strategy to fight breast cancer and win.

We know that around 80 percent of breast cancers occur in women over 50; and that regular mammography reduces their risk of death by at least one-third.

And we know that breast cancer is the second leading cause of cancer death among American women.

But, thanks to the President, behind this pain and loss lies hope and real progress.

Under the President's leadership, we have almost doubled funding for breast cancer research, treatment and prevention to more than \$500 million dollars since 1993.

And we're working hard to improve access to quality mammograms.

That's why we're reaching out to women in all 50 states – especially low income women and women of color – to make sure they know about and have access to mammograms.

That's why the First Lady has led a mammography awareness campaign aimed at women over 65 – those women most at risk.

And that's why under the Mammography Quality Standards Act, American women can now have greater confidence in the safety and accuracy of their mammograms.

We should all be proud of the fact that mortality rates for breast cancer are falling – not nearly enough – but they are finally going down.

And we should all be proud that with this announcement today, we have replaced confusion with clarity and moved another step closer to the day when our grandchildren will have to turn to the history books to learn about a disease called breast cancer.

Working together, we can – and will – make it happen.

Thank you.

Questions and Answers: Mammography Screening for Women

Why is this decision important?

This year, over 180,000 American women will be newly diagnosed with breast cancer, and more than 40,000 will die of this disease. It is the second leading cause of death from cancer for women, and the most common cause of death from any cause in women aged 40-44.

Early detection of breast cancer is crucial for successful treatment, and regular mammography screening is our best tool now for early detection. But the question that has been difficult to resolve is when women should begin regular screening mammography. Until recently, in the judgment of the NCI, clinical studies did not satisfactorily support evidence of benefit for women in their 40s. Now, more recent evidence from clinical trials and current evidence that regular mammograms reduce the death rate from breast cancer by about 17 percent in the 40-49 age group, the National Cancer Advisory Board and the NCI are recommending that women in their 40s should be screened every one to two years with mammography.

The importance of this decision is that women now have a clear and consistent answer to the question of when they should begin regular mammogram screening – and we have improved our capacity to detect and treat this disease. Two leading cancer organizations, the American Cancer Society in the private sector and the National Cancer Institute, part of the National Institutes of Health, are delivering a common message about how women can help reduce the chance of breast cancer – and that message is based on the best scientific evidence currently available.

Now it's up to women and their health care providers to act on this recommendation, and it's up to all of us to help support that action by making these findings universally known and by providing access to these life-saving services.

Was the NCAB or NCI under pressure from the White House to recommend mammography for women in their 40s?

No. The National Cancer Advisory Board is a presidentially appointed committee that advises and consults with the director of the National Cancer Institute and the Secretary of Health and Human Services. It has advised NCI on the mammography issue for years, and planned its current review more than a year ago. In this review, the Board considered the updated findings from breast cancer screening studies. These new data showed that regular screening mammography of women in their 40s reduces deaths from breast cancer by about 17 percent.

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Doesn't the new recommendation support the contention that the only reason that NCI withdrew its recommendation in 1993 was to hold down the cost of the Health Security Act?

No. In December 1993, NCI announced that it would no longer recommend that screening for mammography begin at age 40 because of a lack of scientific evidence. The decision was based on a lack of clear scientific evidence for a reduction in deaths among women in that age group, and the realization of the risks of screening. Today's decision is based on new scientific evidence now available to NCI.

Women have been the focus of many of your recent events, are you "repaying" women for their votes in the 1996 election?

No. Over 180,000 American women will be newly diagnosed with breast cancer, ^{this year} and more than 40,000 will die of this disease. This is a terrifying disease for women and the Clinton Administration is working hard to provide women with the most effective tools in the fight against breast cancer.

Isn't mammography for all women in their 40s a very expensive proposition for the number of lives to be saved?

This is a terrifying disease for women. It is a leading killer, and it can have devastating effects even for those who do not die from it.

Mammography is a real and effective step that women can take to help detect this disease early. Early detection not only improves their chances for life, but also for effective treatment that is the least disfiguring.

If we can indeed reduce the death rate from breast cancer by 17 percent among women 40-49, we should do that. If we can help women get effective treatment at the earliest ~~women~~, we should do that. It's worth the cost.

Isn't the NCI recommendation still different from the ACS recommendation?

Both organizations are giving the same answer to the basic question: "When should women begin mammography screening?" Both organizations have now recommended mammography screening of women in their 40s. ^{regular}

As for the interval between screening mammograms, the NCI and ACS recommendations are compatible. While NCI recommends screening either every one or two years, and the ACS recommends annual mammograms, both recommendations allow annual screening if a woman wishes to have it and advise women to discuss the pros and cons with their doctor.

- 3 -

On what basis should a woman and her doctor decide the frequency of mammography? What factors should decide?

In deciding how frequently to be screened, a woman and her health care provider should consider her risk factors. Some factors a woman must consider include whether or not she has a personal or family history of breast cancer; whether she has signs or symptoms of menopause; and whether or not she has a personal history of benign breast disease, such as atypical hyperplasia. NCI will develop educational materials to help women and health professionals do this.

What is going to be done to educate the public about mammography screening?

NCI is developing a national public education program to provide women with understandable information on when women should begin regular mammography screening, and concerning an individual's risk of getting breast cancer. In addition to developing a wide variety of new information materials (print, radio and TV, and electronic) for women and for health professionals, NCI will work with the national media to develop coherent and accurate information.

NCI will also work with health professional organizations and associations, as well as other federal agencies, to communicate the latest and most accurate information. As always, this information will be available through the NCI's toll-free Cancer Information Service at 1-800-4-CANCER, and through other groups including the American Cancer Society and the National Alliance of Breast Cancer Organizations.

What portion of women in their 40s have regular mammography today?

Of women ages 40-49, 60 percent received a mammogram in the past two years, according to 1993 figures from the National Center for Health Statistics.

Do most private insurers cover mammography screening?

According to the Health Insurance Association of America, about 79 percent of all employer health plans covered mammography screening in 1991. Most states (40) have legislation concerning insurance reimbursement for routine screening mammograms for women in their 40s, according to the State Cancer Legislative Database. The provisions of the laws vary from state to state, but most require that health plans cover all or part of the costs for women in their 40s.

How much do Medicare and Medicaid spend on mammography now?

Estimated Medicare spending for mammography is about \$270 million this year; and for Medicaid, about \$10 million.

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How many women will benefit from the additional Medicare coverage, and how much will it cost?

There are about 380,000 women in their 40s who will have Medicare coverage in 1998, rising to over 400,000 in the next five years. The cost of the added annual mammography benefit for this group is estimated to be about \$2.7 million over five years.

How many women will benefit from additional coverage in Medicaid?

Since coverage policies are made by the states, we cannot estimate the extent of new benefits that will be provided. However, our letter to state Medicaid directors will urge states to make mammography screening available to women in their 40s on an annual basis.

In yesterday's Journal of the American Medical Association (JAMA), the Cancer Genetics Studies Consortium recommended annual mammograms for women between ages 25 and 35 who are born with mutations in the BRCA1 and BRCA2 genes -- two identified breast cancer susceptibility genes. What do you think about this recommendation and will you extend Medicare and Medicaid coverage for these women too?

No. At this time we do not know enough about the links between genetics and cancer to make this decision. We will continue the important research into the genetic basis of breast cancer, for which President Clinton recently announced \$30 million in new funding for a collaborative initiative between the Department of Defense and the National Institutes of Health.

As we have always recommended, in deciding when and how frequently to be screened, a woman and her health care provider should consider her risk factors and determine when to begin mammography screening.

You're challenging the private sector to provide expanded benefits to insurers and health plans across the country. How and when will you do this for federal government employees?

The President believes that there should be no double standard. He will ensure that the federal government complies with this challenge as quickly as possible. As such, the President is ensuring that Medicare, Medicaid and the health plans covering federal employees amend their policies to reflect today's NCAB recommendation.

How much will this cost to apply the NCAB recommendation to cover mammograms in their forties to the Federal Employees Health Benefit (FEHB) program?

The new policies for FEHB will become effective in January, 1998. At this time, we do not have the necessary information to know the final cost. Our projected cost of this change will be available soon. However, we do know that it will be extremely modest.

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Will this policy increase premiums for federal government employees?

We have no indication that this policy will notably increase premiums for federal government employees. This is an extremely low cost, high return benefit change.

Doesn't the new NCI recommendation conflict with the U.S. Preventive Services Task Force?

In its 1996 recommendation, the Task Force (an independent advisory group supported through HHS) found insufficient evidence to recommend for or against routine mammography for women in their 40s. This recommendation did not take into account recently announced results of important clinical studies, which have been considered by the National Cancer Advisory Board. It is expected that the Task Force will be reconvened later this year or early in 1998, and at that time they will begin reviewing the most recent evidence and if appropriate making any modifications to their recommendations accordingly.

What is the current status of the use of mammography, and what are the trends?

According to data collected in 1993, about 60 percent of women aged 40 and over had a mammogram in the previous two years. (60 percent for 40-49, 65 percent for 50-64, 54 percent for those 65 and over). The number of women over 40 who had a mammogram in the previous two years more than doubled between 1987 and 1993, from about 29 percent to 60 percent.
(Source: 1993 National Health Interview Survey, NCHS)

TO: Elena and Bruce
FR: Pauline and Christa

Attached please find the following Mammogram Announcement background documents:

- Event Memo
- 1 page fact sheet
- 1 page of breast cancer accomplishments
- Letter HCFA is sending to State Medicaid Directors
- NCI Press Release (to be released at 10:00 am tomorrow.)
- Draft of POTUS remarks
- Draft of Secretary Shalala's remarks
- Internal Q&A from HHS

Chris Jennings has reviewed these documents.

THE WHITE HOUSE
WASHINGTON

March 26, 1997

MAMMOGRAM ANNOUNCEMENT

DATE: March 27, 1997
LOCATION: Oval Office
BRIEFING TIME: 11:30 am - 12:00 pm
EVENT TIME: 12:00 pm - 12:30 pm
FROM: Bruce Reed

I. PURPOSE

You will be announcing several new steps to encourage women to undergo regular mammograms beginning at age 40 as recommended by the National Cancer Institute in a morning press conference. This will highlight your continued commitment to making mammograms more readily available to women of all ages and the Administration's ongoing efforts to prevent, detect and treat breast cancer more effectively.

II. BACKGROUND

At 10:30am on Thursday, the Presidentially appointed National Cancer Advisory Board will announce that they are now recommending mammograms every one or two years for women in their forties. At this event, Richard Klausner, the Director of the National Cancer Institute, will also announce that he is accepting their recommendations. Since 1993, the National Cancer Institute has not recommended regular mammograms for women in their forties; the decision had been left up to women and their doctors.

This decision by the National Cancer Institute means there is now consensus in the medical community on regular mammogram screening. However, the American Cancer Society recommends screening every year and the National Cancer Institute is recommending them every one or two years. In practice the National Cancer Institute informs us that there will be little to no difference between the recommendations.

You will be responding to these new recommendations by announcing the following steps that will expand coverage of mammograms to women in their forties and to provide clearer educational information to women on this issue:

- MEDICARE LEGISLATION - You will announce that as you forward the health portion of the balanced budget to Congress on Thursday, the Medicare provisions will be amended to include annual mammograms for women age 40 and over.

(This expansion will be added to reforms already in your budget that improve the mammography benefit by eliminating the copayment.)

- MEDICAID

You will be announcing that the Health Care Financing Administration (HCFA) is sending a letter to state Medicaid directors to urge states to provide annual mammography screening to Medicaid beneficiaries over age 40, and to assure them that HCFA will provide federal matching payments for these screenings.

- FEDERAL EMPLOYEES

You will announce that starting January 1, 1988, the Office of Personnel Management will require all federal health benefits plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings.

- PUBLIC INFORMATION CAMPAIGN

You will announce that the Administration is launching a public education campaign to provide information to women about breast cancer screening. Secretary Shalala will announce in her remarks that the 1-800-4-CANCER hotline will begin immediately to provide information consistent with the recommendations of the National Cancer Institute.

- CHALLENGE TO PRIVATE SECTOR HEALTH PLANS

You will call on the private sector health plans to follow the federal government lead to require federal health plans to provide coverage consistent with the National Cancer Institute's recommendations.

III. PARTICIPANTS

Briefing Participants:

Secretary Shalala
Erskine Bowles
Rahm Emanuel
Bruce Reed
Chris Jennings
Kitty Higgins
Betsy Myers
Terry Edmonds
Mike McCurry

Event Participants:

Secretary Shalala

There will be no invited guests to this event.

IV. PRESS PLAN

Pool Press.

V. SEQUENCE OF EVENTS

- You will enter the Oval Office, accompanied by Secretary Shalala, and walk directly to the podium.
- You will make remarks and then introduce Secretary Shalala.
- Secretary Shalala will make remarks.
- The Pool will ask questions, and then you will depart.

VI. REMARKS

Remarks Provided by Terry Edmonds in Speechwriting.

PRESIDENT CLINTON ANNOUNCES MAMMOGRAPHY ACTIONS

March 27, 1997

Today President Clinton announced actions to encourage women to begin receiving regular mammograms in their forties in response to the National Cancer Institute's (NCI) recommendation that women should begin undergoing regular mammography screening at forty. The President is taking action to bring Medicare, Medicaid, and federal employee health plans in line with the NCI's new recommendations, and is calling on private health plans to do the same.

With the NCI's recommendation, women now have clear and consistent science-based advice that they should begin regular mammography screening in their forties. The Clinton Administration has strived to make high quality mammograms more readily available to women of all ages and to improve efforts to prevent, detect, and treat breast cancer, which currently affects 1 in 8 American women in their lifetime.

The President announced the following actions today in response to the NCI's recommendation:

- **Medicare.** President Clinton is proposing that Medicare cover annual screening mammograms for women beginning at age forty without coinsurance and deductibles. Currently, Medicare does not cover annual screening mammograms for women in their forties, and covered mammograms can be subject to coinsurance and deductibles. The proposed changes are included in the President's overall Medicare and Medicaid budget proposals, which the Administration is sending to Congress today.
- **Medicaid.** The President announced that the Health Care Financing Administration at HHS is sending a letter today to every State Medicaid director to encourage them to cover annual mammography screening beginning at age 40 and to make clear that the federal government will provide federal matching payments for these services. States currently have the option of covering mammography screening, but not all States cover annual mammography screening beginning at age 40.
- **Federal Employee Health Plans.** President Clinton is directing the Office of Personnel Management to require all federal employee health plans to cover annual mammograms beginning at age 40. Current Federal Employee Health Benefits program policy only covers one mammogram screening every two years for women in their forties. The new policy will take effect in January 1998, the start of the FEHB's next contract year.
- **Challenge to Private-Sector Health Plans.** President Clinton called on private-sector health plans to follow his lead in making the federal health plans consistent with the NCI's recommendations by covering annual screening mammograms beginning at age 40.
- **Public Education Campaign.** The Administration announced that it will lead a national public education campaign to provide women with clear information about when they should begin regular mammography screening. The NCI will also work with health organizations and associations to communicate the latest and most accurate information. Information will be available through the NCI's toll-free Cancer Information Service at 1-800-4-CANCER and on the web at <http://rex.nci.nih.gov>.

5/25

A Strong Record on Breast Cancer

The Clinton Administration has worked hard to combat breast cancer, the second leading cause of death from cancer for women. This year over 180,000 women will be newly diagnosed with breast cancer and more than 40,000 will die of this disease. The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. The following are examples of new initiatives undertaken since 1993:

- **Nearly Doubling Breast Cancer Research, Prevention, and Treatment.** Since the Clinton Administration has taken office, funding for breast cancer research, prevention and treatment at HHS has nearly doubled, from about \$276 million in FY 1993 to an estimated \$513 million in FY 1997.
- **Signed the Kassebaum-Kennedy Legislation into Law, Ending Pre-existing Condition Exclusions.** As a result of this legislation, no American will live in fear of being denied coverage just because they have a pre-existing condition such as breast cancer. This legislation is particularly helpful for the millions of cancer victims who will no longer face the dilemma of hesitating to go to a new and better job for fear of losing their health insurance.
- **Medicare Mammography Campaign.** The Clinton Administration has made it a priority to educate older women about the importance of detecting breast cancer early and to inform them about Medicare coverage of mammography services. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings. Breast cancer is more prevalent in older age groups and the risk of breast cancer increases with age. About 80 percent of breast cancers occur in women age 50 or older. Yet, only 65 percent of women age 50-64 have had a mammogram in the past two years, and only 45 percent of women age 65 and older have a mammogram every two years.
- **Mammography Quality Standards.** In 1992, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA). The rules ensure that the roughly 10,000 mammography facilities nationwide accredited by the FDA meet high quality standards for equipment and personnel.
- **National Breast and Cervical Cancer Early Detection Program.** The Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, and minority women. Since the program's inception, it has provided screening tests to almost one million medically underserved women. In October 1996, the program went nationwide, with funding for all 50 states.
- **Research on Using Imaging Technologies from the Defense, Space, and Intelligence Communities to Detect Cancer Earlier and with Greater Accuracy.** 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.

DRAFT

Dear State Medicaid Director:

I am writing to encourage States to provide coverage for annual screening mammograms for women age 40 and older. We are sensitive to the fiscal effect this may have on States, and want to assure you that Federal financial participation (FFP) will continue to be available for this service.

Breast cancer is the second leading cause of cancer deaths in American women. While all States provide some coverage for screening mammography, coverage limitations for women in this age group may reduce early detection of breast cancer.

Recent announcements concerning the appropriate age and frequency at which women should receive screening mammograms have heightened public interest in this critical issue. There is a particular focus on women from age 40 to 49. The National Cancer Board, a presidentially-appointed committee that advises and consults with the Director of the National Cancer Institute (NCI) and the Secretary of Health and Human Services, recently considered an updated finding from breast cancer studies. The new data show that regular screening mammograms for women in their 40s reduces death from breast cancer by about 17 percent. Today, March 27, the Board recommended to the Director of the NCI that women over age 40 get screening mammograms every one to two years. The NCI adopted the Board's recommendations. (See attachment.)

As you know, all State Medicaid programs must cover diagnostic mammograms. These services are included under one of the mandated service categories and are determined to be medically necessary as a result of a sign, symptom, or complaint. However, States have flexibility in choosing whether, and on what basis, to cover screening mammograms as an optional service.

In light of the new recommendation, we urge you to consider providing annual coverage for screening mammograms for women over age 40. Regular screening mammograms for these women should lead to decreasing morbidity and mortality rates from breast cancer. Medicaid coverage of screening mammograms will eliminate financial impediments to this important service for Medicaid beneficiaries in this age category, and providing coverage for annual screens assures, consistent with the NCI recommendations, that women choosing to have annual mammograms will be able to obtain this service. Again, we ~~reassure you~~ that we will provide federal matching payments for service expansions in this area. *want to reiterate*

In recent years, State have made aggressive efforts to ensure that Medicaid beneficiaries have access to preventive health measures. As partners with the States in Medicaid, we appreciate your commitment to ensuring the best possible preventive health services for Medicaid beneficiaries.



Office of Cancer
Communications Building 31 Room 10A24
Bethesda, Maryland 20892

For Response to Inquiries

National Institutes of Health

March 27, 1997

NCI Press Office
(301) 496-6641

**Statement from the National Cancer Institute on the
National Cancer Advisory Board Recommendations on Mammography**

The National Cancer Institute (NCI) accepts the recommendations of the National Cancer Advisory Board on screening mammography.

As a result, NCI will recommend that:

- Women in their 40s 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 than average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and the frequency of screening.

The board also stated that because of mammography's limitations, it is important that a clinical breast examination by a health care provider be included as part of regular, routine health care. NCI will include that statement in its recommendations.

Richard Klausner, M.D., NCI director, expressed his gratitude to the board for coming to closure on the issue quickly and for helping to bring clarity to this important issue. He said the board also made important recommendations for future research on breast cancer screening and education, and that NCI would address those research recommendations.

Klausner said the institute will immediately begin to develop new educational materials to communicate the screening recommendations and to help women and health professionals determine an individual's breast cancer risk. He said that NCI also will work with the American Cancer Society, other government agencies, advocacy organizations, cancer centers, and other

(more)

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groups to educate the public and health professionals about the benefits, limitations, and risks of screening mammography.

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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 federal government'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://rex.nci.nih.gov>) and (<http://cancernet.nci.nih.gov>) servers.

PRESIDENT WILLIAM J. CLINTON
MAMMOGRAPHY ANNOUNCEMENT
THE WHITE HOUSE
MARCH 27, 1997

Good afternoon. Secretary Shalala has just briefed me on the National Cancer Institute's new recommendations on mammography. These recommendations, based on the latest and best medical evidence, give clear, consistent guidance to women in our national fight against breast cancer. Breast cancer is the most commonly diagnosed cancer among women. It affects one in eight women in their lifetimes. My own mother fell victim to this terrible disease. We may not yet have a cure -- but we do know that early detection and early treatment are our most potent weapons in this battle. And we know that mammography can save lives.

That is why it is so important to send a clear, consistent message to women and their families about when to start getting mammograms and how often to repeat them. Today, we are offering women and their families that clear guidance, based on solid science.

After careful study of the science, the National Cancer ^{Advisory Board} ~~Institute~~ has now concluded that women between the ages of 40 and 49 should get a mammogram examination for breast cancer every one or two years in consultation with their doctors. ~~These new recommendations should end the debate.~~ The medical community is now in agreement -- regular mammograms starting at age 40 are the best way women can protect themselves against breast cancer.

The National Cancer Institute has accepted that recommendation

confusion.

In addition to Secretary Shalala, I want to thank National Cancer Advisory Board chairperson, Dr. Barbara Rimer [RHYMER] and all the members of the Board, along with NCI Director, Dr. Richard Klausner for the fine and speedy job you did in producing these recommendations. I also want to thank the First Lady, who could not be here today because of her historic visit to Africa. Hillary has devoted countless hours to educating women about the importance of mammography. She has particularly tried to educate older women to take advantage of Medicare coverage of mammograms because we know that too few of them do. ~~She is a part of this achievement and~~ I want to thank her for all she has done in the fight against breast cancer.

Now that medical experts agree on the need for regular mammograms for women beginning at age 40, we have to take steps to see that they get them and that they and their doctors understand the benefits of the procedure. So today, I am taking action to bring Medicare, Medicaid and federal ~~health~~ ^{health} employee health plans in line with the National Cancer Institute's recommendations. First, in the Medicare budget I am sending to Congress today, I am making annual ^{screening} mammography exams, beginning at age 40, a covered expense, without ~~co-payments~~ ^{co-insurance} and deductibles. Second, Secretary Shalala is sending a letter to state Medicaid Directors urging them to also cover ~~a~~ annual mammogram and assuring them that the federal government will pay its matching share. And today, I am directing the Office of Personnel Management to require all

federal health benefits plans to comply with the National Cancer Advisory Board's recommendations on mammogram screenings beginning next year.

Finally, we all know that there has been much discussion on this issue and a lot of confusion. ~~But we should all remember that there is not one prescription for all women. That is why women should make this decision in consultation with their doctors. We want to make sure that every woman who decides to have a mammogram has both coverage and access to this potentially life saving test.~~ That is why we are launching a major public education campaign to make sure every woman and every health professional in America is aware of these new recommendations. We all should know that regular mammograms are a critical weapon in our fight against breast cancer.

Now, I'd like to turn it over to Secretary Shalala.

SHIALALA

Thank you Mr. President for your leadership – and for once again showing your deep and personal commitment to lifting the ugly shadow of breast cancer that hangs over every American woman.

One of the biggest fears women have about breast cancer is the fear of not knowing what to do, or when to do it.

But today years of confusion have been replaced by a clear and consistent scientific recommendation for women between 40 and 49.

We can now tell them talk to your doctor because regular mammograms can save your life.

To get the word out, we are developing written materials, and using our 1-800-4-CANCER number to reach out to insurance companies, medical associations, advocacy groups and women themselves.

The guidance we offer today to women in their forties is a step forward.

But it is only one piece of our overall strategy to fight breast cancer and win.

We know that around 80 percent of breast cancers occur in women over 50; and that regular mammography reduces their risk of death by at least one-third.

And we know that breast cancer is the second leading cause of cancer death among American women.

But, thanks to the President, behind this pain and loss lies hope and real progress.

Under the President's leadership, we have almost doubled funding for breast cancer research, treatment and prevention to more than \$500 million dollars since 1993.

And we're working hard to improve access to quality mammograms.

That's why we're reaching out to women in all 50 states – especially low income women and women of color – to make sure they know about and have access to mammograms.

That's why the First Lady has led a mammography awareness campaign aimed at women over 65 – those women most at risk.

And that's why under the Mammography Quality Standards Act, American women can now have greater confidence in the safety and accuracy of their mammograms.

We should all be proud of the fact that mortality rates for breast cancer are falling – not nearly enough – but they are finally going down.

And we should all be proud that with this announcement today, we have replaced confusion with clarity and moved another step closer to the day when our grandchildren will have to turn to the history books to learn about a disease called breast cancer.

Working together, we can – and will – make it happen.

Thank you.

Questions and Answers: Mammography Screening for Women

Why is this decision important?

This year, over 180,000 American women will be newly diagnosed with breast cancer, and more than 40,000 will die of this disease. It is the second leading cause of death from cancer for women, and the most common cause of death from any cause in women aged 40-44.

Early detection of breast cancer is crucial for successful treatment, and regular mammography screening is our best tool now for early detection. But the question that has been difficult to resolve is when women should begin regular screening mammography. Until recently, in the judgment of the NCI, clinical studies did not satisfactorily support evidence of benefit for women in their 40s. Now, more recent evidence from clinical trials and current evidence that regular mammograms reduce the death rate from breast cancer by about 17 percent in the 40-49 age group, the National Cancer Advisory Board and the NCI are recommending that women in their 40s should be screened every one to two years with mammography.

The importance of this decision is that women now have a clear and consistent answer to the question of when they should begin regular mammogram screening – and we have improved our capacity to detect and treat this disease. Two leading cancer organizations, the American Cancer Society in the private sector and the National Cancer Institute, part of the National Institutes of Health, are delivering a common message about how women can help reduce the chance of breast cancer – and that message is based on the best scientific evidence currently available.

Now it's up to women and their health care providers to act on this recommendation, and it's up to all of us to help support that action by making these findings universally known and by providing access to these life-saving services.

Was the NCAB or NCI under pressure from the White House to recommend mammography for women in their 40s?

No. The National Cancer Advisory Board is a presidentially appointed committee that advises and consults with the director of the National Cancer Institute and the Secretary of Health and Human Services. It has advised NCI on the mammography issue for years, and planned its current review more than a year ago. In this review, the Board considered the updated findings from breast cancer screening studies. These new data showed that regular screening mammography of women in their 40s reduces deaths from breast cancer by about 17 percent.

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Doesn't the new recommendation support the contention that the only reason that NCI withdrew its recommendation in 1993 was to hold down the cost of the Health Security Act?

No. In December 1993, NCI announced that it would no longer recommend that screening for mammography begin at age 40 because of a lack of scientific evidence. The decision was based on a lack of clear scientific evidence for a reduction in deaths among women in that age group, and the realization of the risks of screening. Today's decision is based on new scientific evidence now available to NCI.

Women have been the focus of many of your recent events, are you "repaying" women for their votes in the 1996 election?

No. Over 180,000 American women will be newly diagnosed with breast cancer, ^{this year} and more than 40,000 will die of this disease. This is a terrifying disease for women and the Clinton Administration is working hard to provide women with the most effective tools in the fight against breast cancer.

Isn't mammography for all women in their 40s a very expensive proposition for the number of lives to be saved?

This is a terrifying disease for women. It is a leading killer, and it can have devastating effects even for those who do not die from it.

Mammography is a real and effective step that women can take to help detect this disease early. Early detection not only improves their chances for life, but also for effective treatment that is the least disfiguring.

If we can indeed reduce the death rate from breast cancer by 17 percent among women 40-49, we should do that. If we can help women get effective treatment at the earliest ~~women~~, we should do that. It's worth the cost.

Isn't the NCI recommendation still different from the ACS recommendation?

Both organizations are giving the same answer to the basic question: "When should women begin mammography screening?" Both organizations have now recommended mammography screening of women in their 40s. ^{regular}

As for the interval between screening mammograms, the NCI and ACS recommendations are compatible. While NCI recommends screening either every one or two years, and the ACS recommends annual mammograms, both recommendations allow annual screening if a woman wishes to have it and advise women to discuss the pros and cons with their doctor.

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On what basis should a woman and her doctor decide the frequency of mammography? What factors should decide?

In deciding how frequently to be screened, a woman and her health care provider should consider her risk factors. Some factors a woman must consider include whether or not she has a personal or family history of breast cancer; whether she has signs or symptoms of menopause; and whether or not she has a personal history of benign breast disease, such as atypical hyperplasia. NCI will develop educational materials to help women and health professionals do this.

What is going to be done to educate the public about mammography screening?

NCI is developing a national public education program to provide women with understandable information on when women should begin regular mammography screening, and concerning an individual's risk of getting breast cancer. In addition to developing a wide variety of new information materials (print, radio and TV, and electronic) for women and for health professionals, NCI will work with the national media to develop coherent and accurate information.

NCI will also work with health professional organizations and associations, as well as other federal agencies, to communicate the latest and most accurate information. As always, this information will be available through the NCI's toll-free Cancer Information Service at 1-800-4-CANCER, and through other groups including the American Cancer Society and the National Alliance of Breast Cancer Organizations.

What portion of women in their 40s have regular mammography today?

Of women ages 40-49, 60 percent received a mammogram in the past two years, according to 1993 figures from the National Center for Health Statistics.

Do most private insurers cover mammography screening?

According to the Health Insurance Association of America, about 79 percent of all employer health plans covered mammography screening in 1991. Most states (40) have legislation concerning insurance reimbursement for routine screening mammograms for women in their 40s, according to the State Cancer Legislative Database. The provisions of the laws vary from state to state, but most require that health plans cover all or part of the costs for women in their 40s.

How much do Medicare and Medicaid spend on mammography now?

Estimated Medicare spending for mammography is about \$270 million this year; and for Medicaid, about \$10 million.

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How many women will benefit from the additional Medicare coverage, and how much will it cost?

There are about 380,000 women in their 40s who will have Medicare coverage in 1998, rising to over 400,000 in the next five years. The cost of the added annual mammography benefit for this group is estimated to be about \$2.7 million over five years.

How many women will benefit from additional coverage in Medicaid?

Since coverage policies are made by the states, we cannot estimate the extent of new benefits that will be provided. However, our letter to state Medicaid directors will urge states to make mammography screening available to women in their 40s on an annual basis.

In yesterday's Journal of the American Medical Association (JAMA), the Cancer Genetics Studies Consortium recommended annual mammograms for women between ages 25 and 35 who are born with mutations in the BRCA1 and BRCA2 genes -- two identified breast cancer susceptibility genes. What do you think about this recommendation and will you extend Medicare and Medicaid coverage for these women too?

No. At this time we do not know enough about the links between genetics and cancer to make this decision. We will continue the important research into the genetic basis of breast cancer, for which President Clinton recently announced \$30 million in new funding for a collaborative initiative between the Department of Defense and the National Institutes of Health.

As we have always recommended, in deciding when and how frequently to be screened, a woman and her health care provider should consider her risk factors and determine when to begin mammography screening.

You're challenging the private sector to provide expanded benefits to insurers and health plans across the country. How and when will you do this for federal government employees?

The President believes that there should be no double standard. He will ensure that the federal government complies with this challenge as quickly as possible. As such, the President is ensuring that Medicare, Medicaid and the health plans covering federal employees amend their policies to reflect today's NCAB recommendation.

How much will this cost to apply the NCAB recommendation to cover mammograms in their forties to the Federal Employees Health Benefit (FEHB) program?

The new policies for FEHB will become effective in January, 1998. At this time, we do not have the necessary information to know the final cost. Our projected cost of this change will be available soon. However, we do know that it will be extremely modest.

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Will this policy increase premiums for federal government employees?

We have no indication that this policy will notably increase premiums for federal government employees. This is an extremely low cost, high return benefit change.

Doesn't the new NCI recommendation conflict with the U.S. Preventive Services Task Force?

In its 1996 recommendation, the Task Force (an independent advisory group supported through HHS) found insufficient evidence to recommend for or against routine mammography for women in their 40s. This recommendation did not take into account recently announced results of important clinical studies, which have been considered by the National Cancer Advisory Board. It is expected that the Task Force will be reconvened later this year or early in 1998, and at that time they will begin reviewing the most recent evidence and if appropriate making any modifications to their recommendations accordingly.

What is the current status of the use of mammography, and what are the trends?

According to data collected in 1993, about 60 percent of women aged 40 and over had a mammogram in the previous two years. (60 percent for 40-49, 65 percent for 50-64, 54 percent for those 65 and over). The number of women over 40 who had a mammogram in the previous two years more than doubled between 1987 and 1993, from about 29 percent to 60 percent. (Source: 1993 National Health Interview Survey, NCHS)