Admin - 220 million

Sindh/Chip - 250

House — 425

NBCC

NATIONAL BREAST CANCER COALITION

« grassroots advocacy in action »

October 31, 2000

Ms. Heather Howard
Associate Director for Domestic Policy and Senior Policy Advisor to the First Lady
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20501

Dear Heather:

On behalf of the National Breast Cancer Coalition (NBCC) and the more than 2.6 million women living with breast cancer, I am writing to thank you for your leadership on passage of H.R. 4386, the Breast and Cervical Cancer Treatment Act. NBCC applauds the Administration for signing this lifesaving legislation into law last week.

As you know, enactment of this legislation means that states will now have the option of providing low-income women screened and diagnosed with breast and cervical cancer through the National Breast and Cervical Cancer Early Detection Program. NBCC and the women diagnosed through this program have waited ten long years for the treatment component to be added to complement the screening program.

I sincerely appreciate all the work you did with NBCC to move this legislation forward. Your help in ensuring that funding for treatment of these women was included in the Administration's fiscal year 2001 budget was critical in enacting this bill. Without the Administration's support, we would not be where we are today.

The National Breast Cancer Coalition is very proud of the collaboration we have had with this Administration over the past 8 years. We look forward to a continued partnership with you to move forward substantive breast cancer policy, and continue working towards eradicating this disease.

Thank you again for your outstanding work and support of our shared goals.

Sincerely,

Fran Visco

Fran Visco
President

1707 L Street, NW, Suite 1060, Washington, DC 20036 phone: (202) 296-7477 fax: (202) 265-6854 http://www.natlbcc.org

NBCC

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NBCC
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" grassroots advocacy in action "

October 31, 2000

First Lady Hillary Rodham Clinton
The White House
Washington, DC 20500

Dear Mrs. Clinton:

On behalf of the National Breast Cancer Coalition (NBCC) and for me personally, I want to thank you for your outstanding leadership in supporting passage of H.R. 4386, the Breast and Cervical Cancer Treatment Act. As you know, enactment of this legislation means that low-income women screened and diagnosed with breast cancer will now have access to the life-saving treatment they deserve.

NBCC and the women diagnosed thorough the National Breast and Cervical Cancer Early Detection Program have waited ten long years for the treatment component to be added to complement the screening program. You were a true leader on this issue in helping to ensure that funding for this critical legislation was included in the Administration's fiscal year 2001 budget. Since then, you have worked tirelessly with us publicly, and behind the scenes, to ensure that this bill became law.

The National Breast Cancer Coalition is very proud of the collaboration we have had with the Administration over the past 8 years. As First Lady, you have always been there for us, helping to make certain that a substantive agenda on breast cancer became and remained a national priority. Without you, we wouldn't be where we are today. We look forward to a continued partnership with you to move forward substantive breast cancer policy, and to ultimately eradicate this disease.

Thank you again for the extraordinary work that you have done, and the work that you continue to do.

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THE WHITE HOUSE

WASHINGTON

October 13, 2000

Warm greetings to everyone gathered in New York for the National Breast Cancer Coalition's annual gala. I am delighted to join you in congratulating this year's distinguished honorees for their commitment to the battle against breast cancer.

This year we have much to celebrate, and Hillary and I wish we could be with you in person. Final passage of the Breast and Cervical Cancer Treatment Act means new security for thousands of women with breast and cervical cancer. I was pleased to include this initiative in my budget this year, and I look forward to signing it into law.

As members and supporters of the National Breast Cancer Coalition, you can be proud of your role in this success story. Thanks in large part to your steadfast commitment and dedicated grassroots network, this legislation is finally becoming a reality. I also want to thank Hillary for her leadership on this initiative. She has been a champion for women with breast cancer and an inspiration for my Administration's unwavering commitment to this issue.

It has been my privilege and joy to serve the American people over the past eight years, and among my greatest satisfactions has been working with organizations like the NBCC to improve the quality of life for people battling cancer and to give them real hope for better treatment and ultimately a cure. I thank you for all you do each day to create a brighter future for women with breast cancer, and Hillary joins me in extending best wishes for every success in the years to come.

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Bill Clinton

To: Heather

The Coburn Amendment addresses a serious disease, HPV, but it distracts us from the purpose of this bill -- getting treatment services to women positively diagnosed with breast or cervical cancer and jeopardizes the passage of the bill.

We respect Dr. Coburn's concern about this disease but his amendment is the wrong approach. We know that HHS is willing work with the Congress on a variety of strategies for preventing HPV and those efforts are underway.

Regrettably, the Coburn amendment seems to require ALL relevant educational and prevention materials, used by all federal agencies, and All their grantees and all their subgrantees to speak to ALL issues related to condom effectiveness on virtually all STD diseases. This is overly prescriptive. Messages about condom use should be based on science and tailored to specific targeted populations in ways that optimally prevent disease and save lives.

There is also a risk of unintentionally confusing the public about when condoms do or do not work. Condoms are unquestionably effective in preventing the transmission of human immunodeficiency virus (HIV) and other sexually-transmitted diseases (STDs);but there is a danger that stressing a message about when condoms do not prevent the transmission of an STD may reduce their use in situations where they do.

Educating people about the dangers of HPV is important; but it needs to be done based on the best science both about the disease itself and about the most effective ways of delivering prevention messages.The last thing this Congress needs to do is get between doctors and patients and begin prescribing what can and can't be said to patients by their providers.

By delivering conflicting and confusing messages about condoms, we risk that they not be used at all when we know that they are effective in preventing HIV and other diseases.

At a time when the Institute of Medicine and others are reporting a growing sense of complacency about condom use, and a resulting upsurge in infections is occurring in some communities , we do not want to deliver unnecessarily equivocal messages ---as the amendment would require–

Finally, there is no provision for the substantial resources that would be necessary to carry out the research or surveillance provisions required in the amendment. HHS has in fact begun some preliminary research and surveillance activities and has indicated a willingness to expand those activities if resources are made available.

Margaret M. Suntum
10/05/2000 12:43:09 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: remarks of the President upon departure on education

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 5, 2000

REMARKS BY THE PRESIDENT
ON EDUCATION

The Rose Garden

11:27 A.M. EDT

THE PRESIDENT: Good morning. I want to thank Senator Daschle and Congressman Gephardt and the distinguished members of the House and Senate who have come here today for a meeting on education. And I want to direct my remarks toward that and then call on Senator Robb and Representative Berkley to talk. But before I do, I would like to say a few words about the Breast and Cervical Cancer Treatment Act, which passed the Senate unanimously yesterday.

This bill will help thousands of low-income women with cancer get the early, affordable treatment which can save their lives. I just spoke with Speaker Hastert and he said that he expected the bill to pass the House immediately, so that help can start flowing to women for whom it could be a matter of life and death.

I was glad to include this initiative in my budget, and I'll be proud to sign it into law. It is a good example of how we can work together for the good of the American people.

Unfortunately, so far we still don't have that same

Kara Hughes

From: Katie Allison
Sent: Thursday, October 05, 2000 4:48 PM
To: Cathie Levine; Peter Kauffmann; Ann Lewis; Josh Nanberg; Howard Wolfson; Karen Dunn; Karen Finney; Nina Blackwell; Ben Holzer; Chris Monte; Dan Burstein; Eric Schultz; Glen Weiner; Katie Allison; Megan Thompson; Michelle Jeung; Elizabeth Condon; Kara Hughes; Neera Tanden; Wendy Katz
Subject: FW: Clinton Breast Cancer Claim "The Biggest Whopper Yet"

<<...>>
FOR IMMEDIATE RELEASE
Contact: Press Office
Thuroday, October 5, 2000
646/227-9370

www.lazio.com

Clinton Breast Cancer Claim "The Biggest Whopper Yet"
Taking Credit for Lazio Bill Likened to Al Gore's Internet Gaffe; White House Initially Opposed Measure; President Himself Later Praised Lazio for
Bill

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today joked that President Clinton crediting his wife with passing the Breast and Cervical Cancer Treatment Act was the President's "biggest whopper yet."

The White House yesterday issued a statement from the President thanking Mrs. Clinton for her efforts on behalf of the legislation.

"Mrs. Clinton taking credit for this legislation is like Al Gore claiming to
have invented the Internet," Lazio Campaign Manager Bill Dal Col laughed.
"If she claims to have gone to Texas observing wildfire damage, we'll really
start to worry about her."

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prior to the current one. At that time, the two prime movers on the Senate
side were Senators Moynihan and D'Amato. This year, Lazio introduced and
was the prime sponsor of the legislation in the House. During hearings on
the matter, officials from the Clinton Administration's Centers for Disease
Control (CDC) actually testified against passage of the bill.

After the measure passed the House, Clinton himself praised Lazio for his
leadership on the issue during his weekly radio address.

###

6/14

Breast + Cervical Cancer Treatment

~~Jennifer~~ Jennifer Katz
973-0595

Graham - wanted to offer an amendment to cover legal immigrant pregnant ♀ - very controversial + not related to the bill

Nickles - argued against - "massive Medicaid expansion" saying Adm. was right, not putting enhanced match in

~~[illegible]~~

NBCC can live w/ the CHIP match ~~[illegible]~~ if it kicks in now

Graham also raised questions

Bob Kerrey -
Robb said weird things

CHIP match - 65-82

TB program
is precedent
for program

CHIP is precedent
for enhanced
match.

17 states would do better under Chip match

Finance cmte said diff btwn 75/25 + CHIP was ~ 100 million

Lisa Kountoupes
Joanne Stanley

NBCC - still pushing for 75

wondering what we're going to say

CBO - 200 over 5 - (House bill) starting 1 year late
360 million w/ start immediately

straight match - $140 million
(but president budget had 250)

Bob Graham spoke out against + Fran Visco asked to help + if anyone would like to help
↓
enhanced match

NBCC

cost esthmates

~~Cost estimates~~

per Jeanne Lambrew

Over 5 years — another 20 million

CBO - my math - 405

1707 L Street, NW, Suite 1060
Washington, DC 20036
(Phone) 202-296-7477 (Fax) 202-265-6854

National Breast Cancer Coalition

Fax

To: Heather Howard **From:** Jennifer Katz

Fax: 202-456-2878 **Pages:** 8

Phone: **Date:** October 6, 2000

Re: **CC:**

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

TESTIMONY OF

NANCY C. LEE, M.D.

DIRECTOR

DIVISION OF CANCER PREVENTION AND CONTROL

NATIONAL CENTER FOR CHRONIC DISEASE

PREVENTION AND HEALTH PROMOTION

CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

before the

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

July 21, 1999

Good Morning. I am Dr. Nancy Lee, Director of the Division of Cancer Prevention and Control of the National Centers for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC). I am pleased to be here this morning to discuss CDC's National Breast and Cervical Cancer Early Detection Program.

Recognizing the value of appropriate cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). CDC is in the ninth year of the National Breast and Cervical Cancer Early Detection Program, which brings critical breast and cervical cancer screening services to underserved women, including older women, women with low incomes, and women of racial and ethnic minorities. While successes and advances have been made with the help of this program, challenges still exist.

CDC supports early detection programs in all 50 states, five U.S. territories, the District of Columbia, and 15 American Indian and Alaska Native organizations. The program establishes, expands, and improves community-based screening services for women to reduce breast and cervical cancer mortality. The success of the breast and cervical cancer program depends on screening, education and outreach, partnership development, case management, and mechanisms to assure the quality of tests and procedures.

Through September of 1998, more than 2 million screening tests have been provided to over 1.3 million women. That number includes 1 million Pap tests and 950,000 mammograms. Almost half of these screenings were to minority women, who have traditionally had less access to these services. Over 5,000 women have been diagnosed with breast cancer, more than 30,000 women were diagnosed with precancerous cervical lesions, and 411 women had invasive cervical cancer.

CDC collects data from all funded programs to monitor and evaluate each program's provision of clinical services. For each woman enrolled in the program, information is collected on demographic characteristics, results from mammograms, breast exams, and Pap tests, diagnostic procedures and outcomes, cancer diagnoses, and for women diagnosed with cancer, whether treatment was initiated.

The program's success is due in part, from a large network of professionals, coalitions and national organizations dedicated to the early detection of breast and cervical cancer.

- An estimated 27,000 health professionals are involved in providing breast and cervical cancer screening services to underserved women.
- More than 18,000 health educators and outreach workers are educating women on the importance of early detection and helping them access critical screening and follow-up services.
- More than 7,000 individuals are now members of a national network of coalitions that have joined together with State health departments in support of this program.
- One of CDC's partners in the program, Avon, has raised more than $32 million in additional dollars to educate women about breast cancer and to provide underserved women with access to early detection services.

There has been a 20 percent increase in screening mammography rates among all women 50 years and older since 1991, when the program was formally established. For both mammograms and Pap tests, the disparity rates for most of the minority groups have either been eliminated or reduced. There has been a recent decline in the rate of breast cancer mortality. And while there remains much to be done, our most recent mortality data from 1996 indicates that we have met the Healthy People 2000 goal of reduced mortality from breast cancer.

Insuring that all women with abnormal screening results receive adequate follow-up and a definitive diagnosis is a crucial component of this program. Thus, breast diagnostic services funded by federal dollars include diagnostic mammography, breast ultrasound, fine needle aspiration and breast biopsy and for the cervix, colposcopy and colposcopy-directed biopsy.

The legislation that authorizes the National Program does not allow federal resources appropriated for the program to be used for treatment. However, States are required, under terms of the grants they receive, to assure that women who are screened and need cancer treatment, receive care.

Data through March 1998 show that 92 percent of the women diagnosed with breast cancer and invasive cervical cancer have initiated treatment. The rest refused treatment, have not yet initiated treatment, or are lost to follow-up. For women diagnosed with breast cancer, data show a median of 8 days between the cancer diagnosis and the initiation of treatment.

A detailed study of seven state screening programs conducted by Battelle Centers for Public Health Research and Evaluation and the University of Michigan, funded by the CDC, documents the innovative approaches that have been implemented to identify and secure resources for treatment services. The study confirmed what we see in our Program data that arrangements for treatment were made for almost all clients who received a diagnosis of breast or cervical cancer. States' efforts to secure treatment for women screened through the Program have been further documented in a separate study conducted by the Susan G. Komen Breast Cancer Foundation.

State programs and their partners have invested significant amounts of time and effort to develop systems of care for diagnostic follow-up and treatment; these systems appear to be working. However, tremendous effort is involved in developing, implementing, and maintaining strategies and systems for these services. Rarely is there a standardized way that a State, tribe or territory obtains treatment services women need that are not covered by the program. Efforts typically are tailored to an individual client's needs and resources.

State programs have developed sophisticated, creative and successful strategies to deal with the tremendous challenge of payment for cancer treatment. The following are some of the strategies that are employed by States to secure treatment services for women:

- Providers assist eligible clients in applying for Medicaid, Hill Burton funds, or other types of public assistance.
- Clients may be referred to public hospitals, or receive care though hospital community benefit programs, donated services, or other charitable care.
- Contracts with screening providers require that agreements with treatment providers be established before screening commences.
- The Program appeals to treatment providers, through state and county medical societies and professional associations, to offer free or reduced-cost services to program clients.

Both North Carolina and Arkansas have appropriated State resources to the Cancer Control Programs to provide for cancer diagnostic and treatment services for all state citizens who meet eligibility criteria. California utilized a one-time allocation of $12.8 million from the Blue Cross Foundation to create a Breast Cancer Treatment Fund, which paid for treatment during the first year after diagnosis for any uninsured California women who met eligibility requirements.

Although States are currently meeting their commitment to help women access treatment services, several of the programs reviewed in the Battelle study expressed concerns regarding their ability to expand screening services to more women in need because the systems in place for obtaining charitable treatment are becoming overburdened. These programs stated that as long as the numbers of cancers diagnosed through the program remain near the current level, the burden should not be too great or too threatening.

Case management was identified in the Battelle study as one strategy that could assist programs in their efforts to ensure the follow-up and treatment of clients. CDC has developed a comprehensive policy on case management for the program. Increases in CDC's FY 1999 appropriation will be used to expand critical case management services in States that strengthen the fragile system for securing treatment services. With these funds, each program will enhance case management activities to assist clients navigate through the system to obtain treatment services that are not covered by the program.

The overall goal of this program is to reduce mortality from breast and cervical cancers, and the success of this effort hinges on the identification and treatment of early stage cancers and precancers. As they have in the past, CDC and its state partners will continue to give priority to this critical aspect of the early detection effort.

Let me relay to you how one woman felt about the program:

I was forty years of age, a recently divorced women with no health insurance and working for peanuts when I discovered a lump in my breast. It was a very traumatic experience, to say the least. My fears that accompanied this finding were overwhelming. In my present financial position, I would have never received the medical attention I needed, if it wasn't for your

program. I am healthy, the lump was benign. Through this entire ordeal, I was able to focus all my energies on my medical problem, while your office proficiently attended the bills.

CDC's National Breast and Cervical Cancer Early Detection Program does not change whether or not a women has cancer. However, it can help women by improving their chances of detecting cancer earlier and getting treatment for it. And by finding and treating precancerous cervical lesions, the Program prevents thousands of women from ever developing cervical cancer.

Thank you, and I would be happy to answer any questions you may have.

Kara Hughes

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To: Cathie Levine; Peter Kauffmann; Ann Lewis; Josh Nanberg; Howard Wolfson; Karen Dunn; Karen Finney; Nina Blackwell; Ben Holzer; Chris Monte; Dan Burstein; Eric Schultz; Glen Weiner; Katie Allison; Megan Thompson; Michelle Jeung; Elizabeth Condon; Kara Hughes; Neera Tanden; Wendy Katz
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###

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 20, 2000

S. 662
Breast and Cervical Cancer Prevention and Treatment Act of 2000

As ordered reported by the Senate Committee on Finance on June 14, 2000

SUMMARY

S. 662 would allow states to receive federal Medicaid funds for providing medical care to low-income women who have been screened under a Centers for Disease Control and Prevention (CDC) screening program and found to have breast or cervical cancer. CBO estimates that S. 662 would increase direct spending by $250 million over the 2000-2005 period. Since this bill would affect direct spending, pay-as-you-go procedures would apply.

S. 662 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). A new coverage option in the bill would allow states to increase spending in their Medicaid programs for the treatment of breast and cervical cancer. CBO estimates that the state portion of Medicaid expenditures for this optional coverage would total $107 million over the 2000-2005 period.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 662 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2000	2001	2002	2003	2004	2005
CHANGES IN DIRECT SPENDING						
Estimated Budget Authority	0	15	35	50	65	85
Estimated Outlays	0	15	35	50	65	85

BASIS OF ESTIMATE

S. 662 would give states the option of providing Medicaid coverage to women who have been screened under the CDC's National Breast and Cervical Cancer Early Detection Program and found to have breast or cervical cancer. States would receive an enhanced federal Medicaid match rate for services provided to women who become eligible for Medicaid under the bill. (This enhanced federal match rate, which is already used for services provided under the State Children's Health Insurance Program, averages about 70 percent, compared to 57 percent for the regular match rate.) Federal Medicaid funds would be available beginning in fiscal year 2001.

Under current law, women with breast or cervical cancer are eligible for Medicaid only if they fall into an existing eligibility category. The principal eligibility categories for low-income women are pregnancy, and welfare-related or disability-related coverage (which is largely based on receipt of either Temporary Assistance for Needy Families or Supplemental Security Income). If a woman is found to have breast or cervical cancer, does not have health insurance, and does not qualify for Medicaid, she either pays for the treatment with her own funds, receives treatment through a state, local, or privately funded program, receives charity care, or goes without treatment.

The Congress created the National Breast and Cervical Cancer Early Detection Program in 1990 and appropriated $166 million for the program for fiscal year 2000. The funds support screening activities in all 50 states, in the District of Columbia and U.S. territories, and for several American Indian/Alaska Native organizations. States set their own income eligibility levels, at or below 250 percent of the federal poverty line. Most states have set eligibility criteria at about 200 percent of poverty. The CDC estimates that the program currently screens about 15 percent of the eligible population. Program funds are not available for treating breast and cervical cancer.

The bill's effect on federal Medicaid spending depends on the number of women who would receive Medicaid-funded treatment as a result of the bill, the cost of the treatment, and the number of states that would choose the option. The following discussion focuses on the estimate for breast cancer treatment, which accounts for over 90 percent of the estimated costs of the bill. A brief discussion of the cost of cervical cancer treatment can be found at the end of the section.

Number of beneficiaries. The states provided 224,000 mammograms with funds available under the CDC screening program in 1998. Some states currently supplement the CDC screening funds with their own funds for screening, diagnosis, and treatment. Under the bill, CBO expects that the number of mammograms under the CDC program would rise to 540,000 by 2005, as states that fund diagnosis and treatment services redirect their funds to supplement the screening funds in the CDC program. Because participation in that program would provide access to federal Medicaid funds for diagnosis and treatment of breast cancer, states would have an incentive to redirect their own funds into the CDC screening program.

Of women screened for breast cancer by the CDC program since its inception, about 0.5 percent, or 5 per 1,000, have been found to have breast cancer. Another 7 percent have had abnormal screens that required additional diagnosis and perhaps minor treatment. CBO assumes that the same incidence of cancer and other abnormal results would continue under the bill, resulting in the identification of about 2,700 new cancers and 36,000 abnormal mammograms each year by 2005.

In addition to these new cases, CDC reports that it has already diagnosed over 5,800 breast cancers. CBO anticipates that about 2,400 of these women would receive coverage under the bill if states adopt the option.

Cost of treatment. Based on data from a large health maintenance organization, CBO has estimated the average cost of breast cancer treatment by age and year since diagnosis. In the first year after diagnosis, CBO estimates that cancer treatment would cost about $20,000. In subsequent years, CBO estimates about $6,000 a year in ongoing care costs, until the last year of a patient's life, when costs total about $33,000. CBO used information from the National Cancer Institute's Surveillance, Epidemiology, and End Results Program to estimate age-specific mortality rates from the time of diagnosis.

For women who have an abnormal mammogram, but who are not ultimately diagnosed with cancer, CBO estimates average treatment costs of about $2,000 in the year after the mammogram for follow-up diagnostic and treatment services.

The costs discussed above are for cancer treatment only and are expressed in fiscal year 2001 dollars. Because the bill would extend full Medicaid coverage during the time the woman needs cancer treatment, CBO added about $1,000 a year to the costs of cancer treatment (one-third of the average per capita Medicaid costs for adults) to determine total Medicaid costs for women newly eligible because of the bill. CBO expects that the average annual cost of treatment would rise at the same rate as the Consumer Price Index for medical care (CPI-M).

State participation. In 2001, CBO anticipates that states with 25 percent of potential Medicaid costs would choose to cover breast cancer patients screened through the CDC program in their Medicaid programs. By 2005, CBO projects that proportion would rise to 50 percent.

Cervical cancer. The costs of cervical cancer treatment under the bill stem principally from treatment of pre-cancerous conditions since screening often results in an abnormal finding at an early stage of the disease. CBO anticipates that about 120 new cases of cervical cancer would be diagnosed each year under the screening program, with average annual treatment costs similar to the treatment costs for breast cancer. CBO expects about 10,000 abnormal pap smears each year, with treatment costs averaging $1,000 to $2,000. In total, CBO estimates that treatment of cervical cancer under the bill would cost $15 million over the 2000-2005 period.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays that are subject to pay-as-you-go procedures are shown in the following table. (S. 662 would not affect receipts.) For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

	By Fiscal Year, in Millions of Dollars										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Changes in outlays	0	15	35	50	65	85	105	120	145	165	190
Changes in receipts	Not applicable										

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 662 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act. The bill would allow states to increase spending in their Medicaid programs for the treatment of breast and cervical cancer. CBO estimates that the state portion of Medicaid expenditures for this optional coverage would total $107 million over the 2000-2005 period.

State spending for the treatment of breast and cervical cancer among certain women who would otherwise be ineligible for Medicaid would qualify for a 70 percent federal match on average. Some states may already be covering this type of treatment in state-funded public health programs. In those cases, the federal matching funds would allow states to increase their overall level of spending for existing programs or to redirect a portion of their current spending to screening or other state programs.

PREVIOUS CBO ESTIMATE

On November 10, 1999, CBO estimated that section 2 of H.R. 1070, as ordered reported by the House Committee on Commerce on October 28, 1999, would increase federal Medicaid spending by $205 million over the 2000-2004 period. The provisions of that section are almost identical to those in S. 662, except for the federal match rate that would apply to Medicaid services provided under the new state option. Under H.R. 1070, the federal match rate would be 75 percent or the state's regular rate, whichever is higher. Since the federal match rate under S. 662 would generally be lower (70 percent, on average), CBO assumed that state participation in the new Medicaid option would also be lower. CBO's estimate for S. 662 also incorporates more recent data on the CDC screening program, new projections for the CPI-M, and budgetary effects in 2005.

ESTIMATE PREPARED BY:

Federal Costs: Eric Rollins
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Rekha Ramesh

ESTIMATE APPROVED BY:

Robert A. Sunshine
Assistant Director for Budget Analysis

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

November 10, 1999

H.R. 1070
Breast and Cervical Cancer Prevention and Treatment Act of 1999

As ordered reported by the House Committee on Commerce on October 28, 1999

SUMMARY

H.R. 1070 would allow states to receive federal Medicaid funds for providing medical care to low-income women who have been screened under a Centers for Disease Control and Prevention (CDC) screening program and found to have breast or cervical cancer. The bill also would reduce Medicare expenditures on partial hospitalization services for mental health conditions; would require the CDC to undertake surveillance, prevention, and education activities with respect to the human papillomavirus (HPV); and would require manufacturers of condoms to change their labels to state that the product does not effectively prevent transmission of HPV.

CBO estimates that the bill would increase direct spending by $205 million over the 2000-2004 period. Assuming appropriation of authorized amounts for CDC's new responsibilities, CBO estimates increased discretionary spending of $43 million over the same five-year period.

H.R. 1070 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA), but CBO estimates that the costs associated with the mandate would fall well below the $100 million threshold established in UMRA. H.R. 1070 contains no intergovernmental mandates as defined in UMRA. CBO estimates that states would spend an additional $93 million on their Medicaid programs over the 2000-2004 period to implement the provision that would allow them to increase such spending for the treatment of breast and cervical cancer.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1070 is shown in the following table. The costs of this legislation fall within budget functions 550 (health) and 570 (Medicare).

	By Fiscal Year, in Millions of Dollars				
	2000	2001	2002	2003	2004
CHANGES IN DIRECT SPENDING					
Breast and Cervical Cancer Treatment					
Medicaid					
Estimated Budget Authority	0	25	60	85	110
Estimated Outlays	0	25	60	85	110
Mental Health Partial Hospitalization					
Medicare					
Estimated Budget Authority	-7	-16	-17	-17	-18
Estimated Outlays	-7	-16	-17	-17	-18
Medicaid					
Estimated Budget Authority	a	a	a	a	a
Estimated Outlays	a	a	a	a	a
Total Direct Spending					
Estimated Budget Authority	-7	9	43	68	92
Estimated Outlays	-7	9	43	68	92
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Centers for Disease Control and Prevention					
Estimated Authorization Level	12	10	10	10	11
Estimated Outlays	4	9	10	10	10

a. Savings of less than $500,000.

BASIS OF ESTIMATE

For the purpose of this estimate CBO assumes that H.R. 1070 will be enacted in November 1999 and that the authorized funds will be appropriated for each fiscal year.

Optional Medicaid Coverage of Certain Breast or Cervical Cancer Patients

H.R. 1070 would give states the option of providing Medicaid coverage to women who have been screened under the CDC's National Breast and Cervical Cancer Early Detection Program and found to have breast or

cervical cancer. States with a federal Medicaid match rate below 75 percent would receive a 75 percent match rate for services to women newly eligible for Medicaid under the provision. States with a higher match rate would receive their regular match rate. Federal Medicaid funds would be available beginning in fiscal year 2001. CBO estimates that the provision would increase federal Medicaid spending by $280 million over the 2000-2004 period.

Under current law, women with breast or cervical cancer are eligible for Medicaid only if they fall into an existing eligibility category. The principal eligibility categories for low-income women are pregnancy, and welfare-related or disability-related coverage (which is largely based on receipt of either Temporary Assistance for Needy Families or Supplemental Security Income). If a woman is found to have breast or cervical cancer, does not have health insurance, and does not qualify for Medicaid, she either pays for treatment with her own funds, receives treatment through a state, local, or privately funded program, receives charity care, or goes without treatment.

Congress created the National Breast and Cervical Cancer Early Detection Program in 1990 and appropriated $158 million for the program for fiscal year 1999. The funds support screening activities in all 50 states, in the District of Columbia and U.S. territories, and for several American Indian/Alaska Native organizations. States set their own income eligibility levels, at or below 250 percent of the federal poverty line. Most states have set eligibility criteria at about 200 percent of poverty. The CDC estimates that the program currently screens 12 to 15 percent of the eligible population. Program funds are not available for treating breast and cervical cancer.

The provision's effect on federal Medicaid spending depends on the number of women who would receive Medicaid-funded treatment as a result of the bill, the cost of the treatment, and the number of states that would choose the option. The following discussion focuses on the estimate for breast cancer treatment, which accounts for over 90 percent of the estimated costs of the bill. A brief discussion of the cost of cervical cancer treatment can be found at the end of the section.

Number of beneficiaries. The states provided 208,000 mammograms with funds available under the CDC screening program in 1997. Some states currently supplement the CDC screening funds with their own funds for screening, diagnosis, and treatment. Under the bill, CBO expects that the number of mammograms under the CDC program would rise to 500,000 by 2003, as states that fund diagnosis and treatment services redirect their funds to supplement the screening funds in the CDC program. Because participation in that program would provide access to federal Medicaid funds for diagnosis and treatment of breast cancer, states would have an incentive to redirect their own funds into the CDC screening program.

Of women screened for breast cancer by the CDC program since its inception, about 0.5 percent, or 5 per 1,000, have been found to have breast cancer. Another 7 percent have had abnormal screens that required additional diagnosis and perhaps minor treatment. CBO assumes that the same incidence of cancer and other abnormal results would continue under the bill, resulting in the identification of about 2,500 new cancers and 35,000 abnormal mammograms each year by 2003.

In addition to those new cases, CDC reports that it has already diagnosed over 3,600 breast cancers. CBO anticipates that about 1,500 of these women would receive coverage under the bill if their states adopt the option.

Cost of Treatment. Based on data from a large health maintenance organization, CBO has estimated the average cost of breast cancer treatment by age and year since diagnosis. In the first year after diagnosis, CBO estimates that cancer treatment would cost about $17,000. In subsequent years, CBO estimates about

$6,000 a year in ongoing care costs, until the last year of a patient's life, when costs total about $30,000. CBO used information from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program to estimate age-specific mortality rates from the time of diagnosis.

For women who have an abnormal mammogram, but who are not ultimately diagnosed with cancer, CBO estimates average treatment costs of about $2,000 in the year after the mammogram for follow-up diagnostic and treatment services.

The costs discussed above are for cancer treatment only and are expressed in fiscal year 2000 dollars. Because the bill would extend full Medicaid coverage during the time the woman needs cancer treatment, CBO added $1,000 a year to the costs of cancer treatment (one-third of the average per capita Medicaid cost for adults) to determine total Medicaid costs for women newly eligible because of the bill. CBO expects that the average annual cost of treatment would rise at the same rate as the Consumer Price Index for medical care.

State participation. In 2001, CBO anticipates that, states with 30 percent of potential Medicaid costs would choose to cover breast cancer patients screened through the CDC program in their Medicaid programs. By 2005, CBO projects that proportion would rise to two-thirds.

Cervical Cancer. The costs of cervical cancer treatment under the bill stem principally from treatment of pre-cancerous conditions since screening often results in an abnormal finding at an early stage of the disease. CBO anticipates about 100 new cases of cervical cancer would be diagnosed each year under the screening program, with average annual treatment costs similar to the treatment costs for breast cancer. CBO expects about 10,000 abnormal pap smears each year, with treatment costs averaging $1,000 to $2,000. In total, CBO estimates that treatment of cervical cancer under the bill would cost about $10 million a year by 2004.

Mental Health Partial Hospitalization

CBO estimates that the bill's provisions that deal with partial hospitalization for mental health conditions would lower federal expenditures by $7 million in 2000 and by $75 million over the 2000-2004 period. Under current law, Medicare provides qualified beneficiaries with certain partial hospitalization services. The bill would reduce Medicare fee-for-service expenditures by prohibiting the provision of those services in residential settings, authorizing the Secretary of Health and Human Services (HHS) to specify new conditions of participation for community mental health centers (CMHCs), requiring inpatient psychiatric hospital admissions by CMHCs to be certified by a state-licensed mental health professional, and requiring periodic recertification of CMHCs by the Secretary. The bill would result in lower payments to Medicare+Choice plans because, under current law, capitation payments are based on fee-for-service spending. It also would reduce receipts from Medicare Part B premiums. Because Medicaid pays the Medicare Part B premiums for low-income beneficiaries, the bill would result in a small reduction in Medicaid expenditures.

Surveillance of HPV

H.R. 1070 would require the CDC to study the prevalence of HPV, the impact of HPV on individuals, and awareness of HPV; develop and disseminate educational materials related to HPV; and report to the Congress on further steps needed to prevent future HPV infections. The bill also would require HHS, as well as its contractors and grantees, to state the effectiveness of condoms in preventing HPV and other sexually transmitted diseases in all informational materials related to condoms that are made available to the public. CBO estimates that implementing these provisions would cost $43 million over the 2000-2004

period. This estimate assumes that the necessary amounts would be appropriated for each fiscal year and that outlays would follow historical spending rates for similar activities.

Condom Labeling

H.R. 1070 also would require that manufacturers of condoms change the labeling of condoms to state that condoms do not effectively prevent transmission of HPV and that the virus can cause cervical cancer in women. The provision would apply to condoms manufactured after the expiration of a 180-day period following the date of enactment. If manufacturers fail to comply, their products would be deemed misbranded and subject to administrative actions by the Food and Drug Administration.

CBO expects that all manufacturers would comply with this requirement; therefore, there would be no additional cost to the federal government to enforce compliance. Assuming full compliance, CBO estimates that there would be no increase in revenues arising from civil penalties that could be assessed on noncompliant manufacturers.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the following table. For the purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

	By Fiscal Year, in Millions of Dollars									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Changes in outlays	-7	9	43	68	92	125	149	177	204	238
Changes in receipts	not applicable									

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 1070 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). A new coverage option in the bill would allow states to increase spending in their Medicaid programs for the treatment of breast and cervical cancer. CBO estimates that the state portion of Medicaid expenditures for this optional coverage would total $93 million over the 2000-2004 period.

State spending for the treatment of breast and cervical cancer among women who would otherwise be ineligible for Medicaid would qualify for at least a $3 federal match for every $4 in state spending. Some states may already be covering this type of treatment in state-funded public health programs. In those cases, the federal matching funds would allow states to increase their overall level of spending for existing programs or to redirect a portion of their current spending to screening or other state programs.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 1070 would impose a mandate upon condom manufacturers and distributors that operate in the U.S. market. The bill would require such companies to meet new labeling requirements that would state that condoms do not effectively prevent the transmission of HPV and that such a virus can cause cervical cancer. The mandate would require companies to incur a largely one-time cost for modifying their labels. CBO estimates that the costs associated with the mandate would fall well below the $100 million threshold established in UMRA.

ESTIMATE PREPARED BY:

Federal Costs: Dorothy Rosenbaum (Medicaid), Michael Birnbaum (Medicare and CDC), Julia Christensen (Food and Drug Administration)
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Rekha Ramesh

ESTIMATE APPROVED BY:

Robert A. Sunshine
Assistant Director for Budget Analysis

SENATE OKS BILL WIDENING COVERAGE FOR TREATMENT

Friday, October 6, 2000

By ANDY SOLTIS

Cancer-care advocates yesterday hailed the Senate's passage of a bill that would provide full treatment for thousands of women diagnosed with breast or cervical cancer who fall through the cracks of government medical coverage.

The bipartisan measure, which is also expected to pass the House and be signed by President Clinton later this year, would expand a 10-year-old cancer-detection program.

That program has provided free screenings for more than a million women and led to the diagnosis of nearly 3,500 cases of breast cancer and more than 300 cases of cervical cancer.

But once a woman was diagnosed, the old program afforded no medical coverage for treatment - a situation lawmakers called callous.

"In my view, diagnosing women with cancer [then] failing to treat them is cruel and tantamount to doing nothing at all," said Sen. Lincoln Chafee (R-R.I.).

About 100,000 women in the metropolitan area have been screened for cancer since 1998 under the program.

Health-care partnerships in the city even send out mammogram vans to community centers and retirement homes to make it easier for many women to be screened.

Supporters said expansion of the detection program is valuable because studies have shown a woman's chances of living five years after an early diagnosis of

cancer is 96 percent.

"Enactment of this proposal will help women focus their energies on fighting the disease instead of worrying about how to pay," said Gerald Woolam, president of the American Cancer Society board of directors.

Fully paid treatment would be available for women who earn too much to be eligible for Medicaid but not enough to afford private insurance, or work in jobs that do not provide health insurance.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **October 4, 2000**

STATEMENT BY THE PRESIDENT

I am extremely pleased that the Senate unanimously passed legislation today providing an important new health coverage option to low-income, uninsured women with breast cancer. With passage of the Breast and Cervical Cancer Act of 1999, the Senate has virtually assured that the Congress will present me with legislation that I was pleased to include in this year's budget and that I will be proud to sign into law. I would like to thank my wife Hillary for her constant advocacy on behalf of this legislation. Her longstanding advocacy for women with breast cancer is well known and has been the inspiration behind this Administration's unwavering commitment to this issue. I look forward to final passage of this important bill and the new security it will provide for thousands of women with breast cancer.

30-30-30

October 3, 2000

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
U.S. Capitol H-232
Washington, D.C. 20515

The Honorable Trent Lott
Senate Majority Leader
U.S. Capitol S-230
Washington, D.C. 20510

The Honorable Richard Gephardt
House Minority Leader
U.S. Capitol H-204
Washington, D.C. 20515

The Honorable Thomas A. Daschle
Senate Minority Leader
U.S. Capitol S-221
Washington, D.C. 20510

Dear House Speaker Hastert, Senate Majority Leader Lott, House Minority Leader Gephardt, and Senate Minority Leader Daschle:

The undersigned organizations are writing to urge your support for adoption of S. 662, the Breast and Cervical Cancer Treatment Act, which was approved by the Finance Committee unanimously in June. This bill would provide an opportunity to extend necessary care and treatment to those low-income women diagnosed with cancer under the CDC breast and cervical cancer screening program. For many of these women, such a bill will ensure that these women have access to affordable care. S. 662 is sound and necessary health policy and should be passed in this Congress.

In most important ways, the Senate bill mirrors legislation passed by the House in May (H.R. 4386). However, it is important to point out that the House and Senate bills are not identical. The major policy difference is that the House bill (H.R. 4386) contains a provision we are concerned with regarding the human papillomavirus (HPV), authored by Representative Tom Coburn and rolled into the final bill during Commerce Committee mark up.

The current HPV provisions require the Centers for Disease Control and Prevention to conduct surveillance research on HPV, a positive and necessary step. However, the provisions go further to mandate that the Department of Health and Human Services outline steps to make HPV a reportable disease – a premature and costly requirement that is a highly questionable public health policy. The provisions also outline a requirement for an unprecedented congressionally-drafted mandatory condom label as well as specific written language on all STD informational materials produced by HHS and its public health grantees. The American College of Obstetricians and Gynecologists, with the support of other organizations, is discussing these concerns with Representative Coburn's office, but has yet to reach a compromise.

There is strong bipartisan support for enactment of the Senate Breast and Cervical Cancer Treatment Act – S. 662. This bill currently has 73 cosponsors, and has received the endorsement of many governors and many medical and women's health care organizations.

As organizations concerned with improving and protecting the health of women and addressing breast and cervical cancer treatment, we urge you to adopt S. 662.

Sincerely,

American Academy of Pediatricians
American College of Obstetricians and Gynecologists
American Medical Women's Association
American Public Health Association
American Society of Clinical Pathologists
Association of Reproductive Health Professionals
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric, and Neonatal Nurses
College of American Pathology
National Coalition of STD Directors
Society of Gynecologic Oncologists

Breast Cancer Issues

New Option for Uninsured Women with Breast and Cervical Cancer

In February, the President announced a new initiative to help cover uninsured women who have breast and cervical cancer. The FY 2001 budget invests $200 million over five years in a new Medicaid option that allows states to provide low income, uninsured women who were diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program with the full Medicaid benefits package for the duration of their treatment. A fact sheet on this program is attached.

Funding Levels

Funding for breast cancer research, prevention and treatment has more than doubled from fiscal years 1993 to 2000 – from $283 million to $623 million.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release February 5, 2000

PRESIDENT CLINTON ANNOUNCES NEW INSURANCE OPTION FOR WOMEN WITH BREAST AND CERVICAL CANCER
February 5, 2000

Today, in his weekly radio address, President Clinton will announce a new health initiative to cover more uninsured women who have breast and cervical cancer. Specifically, his FY 2001 budget will include a new Medicaid option to provide insurance to the thousands of uninsured women whose breast and cervical cancer was detected through federally-supported screening programs. This investment of $220 million over 5 years will help bring down current and frequently overwhelming financial barriers to treatment. The Vice President and the First Lady, as well as national leaders in the prevention, diagnosis, and treatment of breast cancer, have been strong advocates for this initiative. Similar legislation has received broad bipartisan support under the leadership of the late Senator Chafee, Sen. Mikulski, Sen. Snowe, and Representatives Eshoo and Lazio, and the President today will call on Congress to act swiftly on his proposal.

FOR LOW-INCOME UNINSURED WOMEN DIAGNOSED WITH BREAST OR CERVICAL CANCER, TREATMENT OPTIONS ARE LIMITED. The National Breast and Cervical Cancer Early Detection Program provides breast and cervical cancer screening to over 360,000 women without access to these services annually. Typically, Federal government-sponsored screening programs make every effort to assist individuals diagnosed with disease to access treatment. However, thousands of women still face financial barriers to care, and those that receive some help frequently do not receive comprehensive coverage for services they need.

- Early detection saves lives. An estimated 2 million American women will be diagnosed with breast or cervical cancer in this decade, and half a million women will lose their lives to these diseases. According for the Centers for Disease Control, approximately 15 to 30 percent of all deaths from breast cancer among women over the age of 40 and virtually all deaths from cervical cancer could have been prevented with early screening. When breast cancer is diagnosed early, the 5-year survival rate is 97 percent; but when it is diagnosed after it has spread, the 5-year survival rate is only 21 percent.

- Uninsured women with breast and cervical cancer face barriers to receiving lifesaving treatment. Women who are uninsured are 40 percent more likely to die from breast cancer than those with insurance. Not only are these women less likely to be screened, but the scope of treatment they receive is often limited by their ability to pay.

- Finding treatment for women without other options diverts scarce resources from crucial screening activities. The time and effort required to ensure that low-income, uninsured women with cancer receive the lifesaving treatment they need diverts scarce resources from critical screening activities and reduces the number of women being screened. Because of changes in the health care market, identifying sources of free or low-cost care for these women is also becoming steadily more difficult.

PRESIDENT ANNOUNCES NEW OPTION FOR UNINSURED WOMEN WITH BREAST AND CERVICAL CANCER. Today, the President will announce that his FY 2001

budget will invest $220 million over 5 years in a new Medicaid option that allows states to provide low income, uninsured women with access to critical treatment services. It will:

- Provide comprehensive health insurance to low income, uninsured women diagnosed with breast and cervical cancer. States will have the option to provide the full Medicaid benefit package to those uninsured women who were diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program. Coverage would extend for the duration of their treatment, eliminating financial barriers to care for these women. These women will be able to receive critical services necessary to treat their cancer, including radiation treatment, chemotherapy, and basic laboratory and palliative care services.

- Allow women to access life saving treatment without delay. States would also have the option to allow health care providers and other qualified entities to provide critical health care services to women pending official enrollment in Medicaid. This will increase the chances of survival for these women.

- Result in increased state spending on breast and cervical cancer screening. Some states currently supplement the federal funds they receive for breast and cervical cancer with their own funds for diagnosis and treatment of these diseases. Estimates by the Congressional Budget Office indicate that, under a proposal like the President's, states would redirect funds to supplement their investment in screening for breast and cervical cancer, resulting in a substantial increase in the number of mammograms and pap smears.

BUILDS ON THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO FIGHTING BREAST AND CERVICAL CANCER. The Clinton-Gore Administration has responded to the significant threat posed by breast and cervical cancer with increased efforts in research, prevention and treatment. Fighting the spread of this disease has been a high priority for both Vice President Gore and First Lady Hillary Clinton.

The Vice President successfully fought for historic increases in funding for breast cancer research, prevention and treatment at the National Cancer Institutes during the Clinton-Gore Administration. He has also advocated for access to cancer clinical trials for new cancer drugs for Medicare beneficiaries as Medicare currently does not cover these cutting edge treatments. In 1997, the Vice President unveiled the Cancer Genome Anatomy Project, an effort to unravel the genetics of cancer and help develop new treatments that more effectively target cancer. He has also called for legislation to prevent employers and health insurers from discriminating on the basis of genetic information. Studies show that a leading reason that women choose not to take genetic tests for breast cancer is fear that this information will be used against them.

First Lady Hillary Clinton has championed budget increases for the National Cancer Institute and other agencies to support research on breast cancer detection, treatment, and cures; launched the Medicare Mammography Campaign to urge older women to get mammograms and to promote the use of Medicare coverage for mammography; helped develop and implement the National Action Plan on Breast Cancer, a public-private partnership coordinated at the Department of Health and Human Services; advocated for legislation pending before the Congress to ensure that women who have mastectomies are entitled to sufficient hospital stays from their HMOs.

During the Clinton Administration, funding for breast and cervical cancer research, prevention and treatment increased from approximately

$520 million in FY 1993 to $844 million in FY 2000. President Clinton enacted the Mammography Quality Standards Act to ensure the quality of mammograms. Finally, the President's Medicare reform plan would eliminate all cost sharing for mammograms and pap smears, which should increase the number of older women using these critical services.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release May 9, 2000

STATEMENT BY THE PRESIDENT

I am extremely pleased that today the House passed H.R. 4386, the Breast and Cervical Cancer Treatment Act, in an overwhelming bipartisan vote. Each year, thousands of women who have been diagnosed with breast or cervical cancer do not receive the comprehensive coverage they need, despite extraordinary efforts by Federal health programs to provide that care. This legislation, which I was proud to include in this year's budget, will provide states with the option to provide the full Medicaid benefit package without delay to uninsured women diagnosed with breast or cervical cancer through Federal screening programs.

I also want to commend the Congress for today's strong bipartisan vote in support of the Long Term Care Security Act. This legislation, which I have long advocated, provides authorization for the Federal Employee Health Benefit Program to offer long term care insurance to current and retired Federal employees. I hope that the legislation serves as a model for all private employers and encourages them to provide this type of coverage to their employees. While this is an important step, it is only one step. We must also continue to work to pass a broad range of long term care initiatives, including a $3,000 tax credit for people with long-term care needs or their caregivers; new funding for services which support family caregivers of older persons; and efforts to enable states to improve equity in Medicaid eligibility for people in home- and community-based settings.

I am encouraged by the news of Congress acting on these significant policy initiatives. We need to build on these achievements and act now to pass a range of policies of importance to the American people, including the creation of a strong, enforceable, Patients' Bill of Rights and a new voluntary prescription drug benefit option as we take steps to modernize and strengthen the Medicare program. And finally, we must redouble our efforts to expand high quality, affordable coverage for all Americans. I urge the Congress to work towards passing the Administration's health coverage proposals that would expand coverage to at least 5 million uninsured Americans and provide health services to millions more by providing new, affordable health insurance options for parents, 19 to 20 year olds, legal immigrants, workers between jobs, and the near elderly.

30-30-30

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release February 5, 2000

RADIO ADDRESS BY THE PRESIDENT
TO THE NATION

The Oval Office

THE PRESIDENT: Good morning. Today, I want to talk about what we can and must do to help more women get the lifesaving treatment they need to fight breast and cervical cancer. More than 180,000 American women will be diagnosed with these diseases this year. Each of us has a sister, a daughter, a friend, or in my case a mother, who has struggled against them.

These cancers can be treated and cured -- if we catch them early and fight them aggressively. But more than 40,000 women will die from breast and cervical cancer this year. Many are women whose cancer was detected or treated too late because they had no health insurance and no hope of paying for treatment.

In fact, older women with breast cancer are 40 percent more likely to die from the disease if they're uninsured. With strong leadership from the First Lady, we've worked hard over the past seven years to increase free and low-cost cancer screenings, and to help women catch these diseases in time.

We've expanded the National Breast and Cervical Cancer Early Detection Program to serve hundreds of thousands of women a year in all 50 states. And Vice President Gore has led us to make a dramatic increase in our commitment to cancer research and treatment. But, still, it's true that every year, thousands of women are told they have cancer and must cope without insurance.

This is especially troubling, given the stunning progress scientists are making in the fight against cancer. Researchers now can identify genes that predict several kinds of cancers. They're experimenting with therapies that will shut down defective genes so that they can never multiply and grow. New drugs and new combinations of drugs will bring hope to those whose cancer has spread, or who suffer from the side effects of chemotherapy.

These breakthroughs will make a big difference for some of our most prevalent cancers, like breast cancer, which strikes one in eight American women over a lifetime. But these lifesaving new therapies can only help if patients have insurance or other resources that enable them to afford state-of-the-art treatment or any treatment at all.

At a time when we know more about cancer than ever and can fight it better than ever, we must not leave women to face cancer alone. That's why today I'm announcing a proposal to help states eliminate the barriers low-income women face to getting treatment for breast or cervical cancer. The budget I'm sending to Congress on Monday will allow states to provide full Medicaid benefits to uninsured women whose cancers are detected through federally funded screening programs. Too often, uninsured women face a patchwork of care, inadequate care, or no care at all. Many are denied new or better forms of treatment, or wait months to see a doctor.

Judy Lewis was one of the lucky ones. When a screening program

detected her breast cancer, she had no health insurance and no money to spare. Fortunately, she found doctors who would treat her, and 17 months later she's cancer-free. But she and her husband are also $28,000 in debt, with nothing left for their retirement. That is wrong, and it doesn't have to happen.

This initiative will help women get comprehensive treatment, and get it right away. It will make state-of-the-art therapies available to women who need them, not just those who can afford them. And it will free state and federal dollars to be spent on cancer screening and outreach to women at risk.

This proposal has strong bipartisan support in Congress, led by Senators Barbara Mikulski and Olympia Snowe, and Representatives Anna Eshoo and Rick Lazio. It was also strongly supported by the late Senator John Chafee of Rhode Island.

These Senators and Representatives from both parties have put forward legislation to meet our goal, and my budget includes the funds to make it happen. This is an issue that transcends political boundaries, because it touches all of us. Together, we can save lives and bring medical miracles of our time within the reach of every American. We can do it this year, and we ought to do it soon.

Thanks for listening.

END

Legislative Priority #2:

PASSAGE OF S. 662/H.R. 1070, THE BREAST AND CERVICAL CANCER TREATMENT ACT

History

In 1990, Congress passed the Breast and Cervical Cancer Mortality Prevention Act (PL 101-354), which authorized the Centers for Disease Control and Prevention (CDC) to provide screening services through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) for low-income women with no health insurance. While this program was enacted with the intention of reducing breast and cervical cancer mortality, it lacks a critical aspect - funding for treatment for women diagnosed with breast or cervical cancer. As a result, many women diagnosed with breast cancer under this program find themselves scrambling to find ways to pay for their treatment.

The women this program serves must be under or up to 250% of the federal poverty level. That means that make too much money to qualify for Medicaid, but not enough to afford health insurance. These women - often working women in jobs that do not offer health insurance - are falling through the cracks. They deserve assurance that if they are screened and diagnosed with breast and cervical cancer through a federally funded screening program, then they will have access to federally funded treatment.

HIGHLIGHTS OF THE BREAST AND CERVICAL CANCER TREATMENT ACT

Pending legislation, S. 662/H.R. 1070, would provide states the option of providing Medicaid coverage for low-income women who are screened and diagnosed with breast cancer through the NBCCEDP.

Importance of a federally funded treatment component - Screening must be coupled with treatment to reduce mortality. Providing federal funding for treatment of these low-income women would not constitute a new benefit based on a specific disease; rather, it would complement an existing federal program that is currently incomplete.

A treatment component is needed now - Health agencies currently work to find creative ways to help women screened in NBCCEDP find charity care. However, these networks are overloaded and the system of charity care they rely on is fragile and deteriorating. Thousands of women are left scrambling to find ways to pay for treatment. Often, they are forced to make medical decisions based on what they can afford, rather than what is medically necessary. Other women avoid the screening program, afraid they will be diagnosed with a terrible disease that they cannot afford to treat.

Bipartisan support in Congress and the Administration for S. 662/H.R. 1070 is strong - The late Sen. Chafee (R-RI) and Sens. Mikulski

(D-MD), Snowe (R-ME) and Moynihan (D-NY), and Reps. Lazio (R-NY), Eshoo (D-CA), Ros-Lehtinen (R-FL) and Capps (D-CA) are the lead sponsors of the Breast and Cervical Cancer Treatment Act. Recently, President Clinton included this legislation in his FY 01 budget. The GOP Leadership in the House has also pledged to pass this bill this year.

ACTION REQUESTED

This year, NBCC asks that you ask your Representatives and Senators to cosponsor S. 662/H.R. 1070, the Breast and Cervical Cancer Treatment Act. This legislation would ensure that women screened and diagnosed with cancer in the NBCCEDP have access to the lifesaving care they need. Under S. 662/H.R. 1070, states would have the option to enroll these women in Medicaid to receive the treatment and services they need. States that choose to provide breast and cervical cancer treatment as an optional benefit would receive an enhanced match to encourage participation in establishing this benefit.

ADDITIONAL INFORMATION ABOUT THE NEED FOR THE BREAST AND CERVICAL CANCER TREATMENT ACT

NBCCEDP serves women forty and over, low-income uninsured women, and minority women. The program has screened more than a million women for breast cancer since its inception in 1990 and has diagnosed almost 6,000 cases of breast cancer in women who are uninsured and under 65 (therefore ineligible for Medicare coverage). It has also provided over a million Pap smears and diagnosed over 500 cases of cervical cancer and over 31,000 cases of pre-cancerous cervical lesions in uninsured women. Nearly half the women screened in NBCCEDP are minority women, who are traditionally underserved. Now it is time to allow for Medicaid expansion to give women screened in NBCCEDP the treatment they need.

Why is a treatment component needed specifically for breast cancer?
Breast cancer is different from many other diseases in that it requires a number of steps for its treatment. It is very difficult to get these treatment services donated. Health care providers have testified before Congress that some low-income women screened under NBCCEDP have had to share medicine and that reconstructive surgery is almost never donated. Some low-income women found to have breast cancer in the NBCCEDP are making medical decisions based on cost rather than science. For instance, some women will decide to have a more radical mastectomy rather than a lumpectomy, which is less invasive, because a lumpectomy also requires radiation, and radiation requires additional money.

Importance of a federally funded treatment component for breast cancer patients
According to a 1998 CDC study, the single largest problem with the NBCCEDP is that women diagnosed with cancer under the program are struggling to find resources for treatment. State programs that run the NBCCEDP have identified the lack of treatment dollars as one of the biggest problems with the program - and they expect the problem to get worse. They report increasing barriers to recruiting health care providers for charity care. Funding for women found to have cancer under the NBCCEDP are now forced to rely on an ad hoc system of charity care that is deteriorating in our evolving healthcare system. This system relies on volunteers and state workers to help these women find charity care, which requires tremendous time and effort.

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

May 9, 2000 **(SENT)**
(House)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 4386 - Breast and Cervical Cancer Treatment Act
(Reps. Myrick (R) NC, Danner (D) MO, and Lazio (R) NY)

The Administration strongly supports the provisions of H.R. 4386 that would allow States to provide full Medicaid benefits to uninsured women whose cancers are detected through a certain federally funded screening program. This proposal, which was included in the President's FY 2001 Budget, would help States eliminate the barriers low-income women face to getting treatment for breast or cervical cancer.

The Administration has no objection to House passage of H.R. 4386, but will work with the Senate to address a number of concerns with provisions of the bill relating to condom labeling and human papillomavirus (HPV) screening programs.

Many of the provisions of H.R. 4386 concerning HPV will strengthen public health efforts to prevent HPV infection. Unfortunately, the provisions of the bill requiring labeling of condoms and providing information on condom effectiveness in all informational materials related to condoms or sexually transmitted diseases (STDs) will be problematic and potentially counterproductive to prevention efforts.

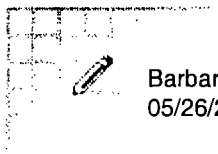
The Administration supports the goal of better informing the public about HPV and the fact that the use of condoms may not fully prevent HPV transmission. Public education, however, should be conducted in a manner to increase awareness about the issue while not confusing the public about when condoms are effective. It is well-documented that condoms are an effective method of preventing transmission of HIV and other STDs. In addition, requiring that information on condom effectiveness be provided on all STD informational materials could be confusing and contrary to the intent of the materials (e.g., materials related to "abstinence only" education).

The goal of HPV prevention efforts should be educating Americans about enhancing their ability to protect and preserve their health in a way that does not confuse them about means of protecting themselves from other STDs such as HIV.

Pay-As-You-Go Scoring

H.R. 4386 would increase direct spending; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget and Reconciliation Act of 1990. The bill's provisions allowing Medicaid treatment for breast or cervical cancer would increase direct spending by $15 million in FY 2001 and a total of $220 million during FYs 2001-2005. The bill does not contain provisions to offset the increased direct spending. Therefore, if the bill were enacted, its net budget costs could contribute to a sequester of mandatory programs. The Administration supports the Medicaid benefit provisions of the bill and will work with the Congress to avoid a sequester.

* * * * * * * * * *



Barbara D. Woolley
05/26/2000 12:32:10 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP

cc:
Subject: Weekend TV Update

devorah, I assume chris will handle Varmus issue. You know, Fran may bring up the "enhanced match." According to Joanne Howes, she talked to Chris about where the Administration is on the "enhanced match."

---------- Forwarded by Barbara D. Woolley/WHO/EOP on 05/26/2000 12:30 PM ----------

Karen Tramontano 05/26/2000

Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Devorah R. Adler/OPD/EOP@EOP, Barbara D. Woolley/WHO/EOP@EOP

cc:
Subject: Weekend TV Update

please see below --- war on cancer on this week --- does NIH know that we are supporting the breast cancer coaltion's bill -- if not -- someone needs to get to varmus -- i just don't want to have a fight over something we are for -- thank you

---------- Forwarded by Karen Tramontano/WHO/EOP on 05/26/2000 12:27 PM ----------

From: Julia M. Payne on 05/26/2000 12:20:17 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Weekend TV Update

MEMORANDUM

TO: **JOE LOCKHART**
FROM: **JULIA PAYNE**
RE: **WEEKEND TELEVISION**

Please check weekend Washington Post for listing changes

FRIDAY, MAY 26, 2000
WASHINGTON WEEK IN REVIEW

Topics: Israel withdrawal from Lebanon; Campaign 2000; PNTR; Africa and AIDS

Guests: Doyle McManus, LATimes; Michael Duffy, TIME; David Sanger, NYTimes; and Charlayne Hunter Gault, CNN

SATURDAY, MAY 27, 2000
EVANS, NOVAK, SHIELDS & HUNT (CNN)

Topic: Campaign 2000
Guest: Senator John McCain

CAPTIAL GANG (CNN)

Topic: Campaign 2000
Guest: Rep. Tom Davis

SUNDAY, MAY 28, 2000
FOX NEWS SUNDAY (FOX)

Topic: Campaign 2000
Guest: Mayor Ed Rendell

Topic: Napster Lawsuit
Guest: ex-Bishop John Shelby Phong and Metallica drummer, Lars Ulrich

Roundtable: Brit Hume, Mara Liasson, and Juan Williams

FACE THE NATION(CBS)

Topic: Campaign 2000 – Gore Campaign
Guest: Senators Breaux and Wellstone, Pollster John Zogby

Topic: Disbarment
Guest: Rep. Asa Hutchinson and Jack Quinn

THIS WEEK (ABC)

Topic: War on Cancer
Guest: Dr. Kim Johnson; Dr. Steven Rosenberg, NIH; Dr. Richard Clausner, NCI; Fran Visco, National Breast Cancer Coalition; Dr. Harold Varmus, fmr. NIH Director; Senator Connie Mack; and Michael Milken

MEET THE PRESS (NBC)

Topic: Arms Control, Preparedness, and Memorial Day
Guest: Secretary William Cohen

Topic: Campaign 2000
Guest: James Carville and Mary Maitlin

LATE EDITION (CNN)

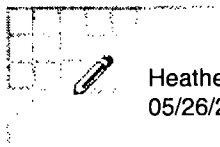
Topic: President's trip to Europe and Russia/Arms Control/other foreign policy developments
Guest: National Security Advisor Sandy Berger

Topic: NY Senate Race
Guest: Senator Daniel Patrick Moynihan

Topic: Disbarment
Guest: Lanny Davis and Dick Thornburgh

Roundtable: Susan Page, Steve Roberts, and Tucker Carlson

Message Sent To: _____



Heather H. Howard
05/26/2000 11:21:02 AM

Record Type: Record

To: Ruby Shamir/WHO/EOP@EOP

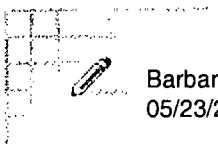
cc:
Subject: breast and cervical cancer treatment act

a few facts to remember:

- the Administration included the new Medicaid option for Breast and Cervical Cancer Treatment in its FY 2001 budget.

- On May 9, the House passed the legislation overwhelmingly. The Administration issued a SAP strongly supporting the legislation (and expressing concerns about unrelated HPV language that was added at the last minute). That same day, the President issued a statement praising the vote. (Neither mentioned the match.)

- The bill is bogged down in the Senate Finance Committee. (Roth has said he wants to do prescription drugs first and does not appear too interested in the bill). Karen Tramontano has called over to the Committee to urge them to move the bill and to express Administration support for the bill.



Barbara D. Woolley
05/23/2000 10:46:40 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Molly O'Malley/OMB/EOP@EOP
Subject: Breast and Cervical Cancer Act - Enhanced Match

As you know, Joanne Howes is anxious to know where the Administration is on the enhanced match issue. Any word on where we are?

Message Sent To:

Jeanne Lambrew/OMB/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Devorah R. Adler/OPD/EOP@EOP
Karen Tramontano/WHO/EOP@EOP
Heather H. Howard/OPD/EOP@EOP

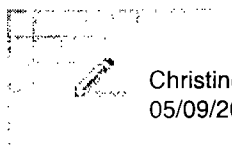
Anna Richter
05/09/2000 06:01:36 PM

Record Type: Record

To: Ann O'Leary/OPD/EOP@EOP, Heather H. Howard/OPD/EOP@EOP

cc:
Subject: Statement by the President: House Passes H.R. 4386, Breast and Cervical Cancer Treatment Act

fyi -- (unless y'all drafted this and I didn't know)
---------- Forwarded by Anna Richter/OPD/EOP on 05/09/2000 06:01 PM ----------



Christine L. Anderson
05/09/2000 05:56:41 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Statement by the President: House Passes H.R. 4386, Breast and Cervical Cancer Treatment Act

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **May 9, 2000**

STATEMENT BY THE PRESIDENT

I am extremely pleased that today the House passed H.R. 4386, the Breast and Cervical Cancer Treatment Act, in an overwhelming bipartisan vote. Each year, thousands of women who have been diagnosed with breast or cervical cancer do not receive the comprehensive coverage they need, despite extraordinary efforts by Federal health programs to provide that care. This legislation, which I was proud to include in this year's budget, will provide states with the option to provide the full Medicaid benefit package without delay to uninsured women diagnosed with breast or cervical cancer through Federal screening programs.

I also want to commend the Congress for today's strong bipartisan vote in support of the Long Term Care Security Act. This legislation, which I have long advocated, provides authorization for the Federal Employee Health Benefit Program to offer long term care insurance to current and retired Federal employees. I hope that the legislation serves as a model for all private employers and encourages them to provide this type of coverage to their employees. While this

is an important step, it is only one step. We must also continue to work to pass a broad range of long term care initiatives, including a $3,000 tax credit for people with long-term care needs or their caregivers; new funding for services which support family caregivers of older persons; and efforts to enable states to improve equity in Medicaid eligibility for people in home- and community-based settings.

I am encouraged by the news of Congress acting on these significant policy initiatives. We need to build on these achievements and act now to pass a range of policies of importance to the American people, including the creation of a strong, enforceable, Patients' Bill of Rights and a new voluntary prescription drug benefit option as we take steps to modernize and strengthen the Medicare program. And finally, we must redouble our efforts to expand high quality, affordable coverage for all Americans. I urge the Congress to work towards passing the Administration's health coverage proposals that would expand coverage to at least 5 million uninsured Americans and provide health services to millions more by providing new, affordable health insurance options for parents, 19 to 20 year olds, legal immigrants, workers between jobs, and the near elderly.

30-30-30

Message Sent To: _____

5/17 NBCC

Jennifer Katz

$175 million - DoD

Breast + Cervical cancer screening
- 75/25 Fed - State match
regardless
state option - hope to encourage states

completing screening program - uninsured, low income ♀
which is 75/25

Budget - can get - but not enhanced match

250 million in Cong Budget

took out enhanced match - Myrick/Dannen /Lazio
took off Eshoo
Threatened to not support +

Lazio has said the enhanced match is essential - Radio + press conference

found $ date of enacted postponed 1 year
committed to fix in Conference

will Pataki's name have enhanced match

(2)

220

We only have ~~250~~ in our budget -
no enhanced match

Note - Centers of Excellence - NIEHS
cuts reporting.

- find a way - expand view - to answer back R's on HiT
we understand the enhanced match is imp.
it's doable

- it will remain a mandated benefit - about how is enhanced benefit

Examples of enhanced: Family planning - 90/10
CHIP - 75/25 in some cases

Secretary - Rob - will do after prescription drug!
(philosophical problem - re: expanding Medicaid
coming along.

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

May 9, 2000 **(SENT)**
(House)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 4386 - Breast and Cervical Cancer Treatment Act
(Reps. Myrick (R) NC, Danner (D) MO, and Lazio (R) NY)

The Administration strongly supports the provisions of H.R. 4386 that would allow States to provide full Medicaid benefits to uninsured women whose cancers are detected through a certain federally funded screening program. This proposal, which was included in the President's FY 2001 Budget, would help States eliminate the barriers low-income women face to getting treatment for breast or cervical cancer.

The Administration has no objection to House passage of H.R. 4386, but will work with the Senate to address a number of concerns with provisions of the bill relating to condom labeling and human papillomavirus (HPV) screening programs.

Many of the provisions of H.R. 4386 concerning HPV will strengthen public health efforts to prevent HPV infection. Unfortunately, the provisions of the bill requiring labeling of condoms and providing information on condom effectiveness in all informational materials related to condoms or sexually transmitted diseases (STDs) will be problematic and potentially counterproductive to prevention efforts.

The Administration supports the goal of better informing the public about HPV and the fact that the use of condoms may not fully prevent HPV transmission. Public education, however, should be conducted in a manner to increase awareness about the issue while not confusing the public about when condoms are effective. It is well-documented that condoms are an effective method of preventing transmission of HIV and other STDs. In addition, requiring that information on condom effectiveness be provided on all STD informational materials could be confusing and contrary to the intent of the materials (e.g., materials related to "abstinence only" education).

The goal of HPV prevention efforts should be educating Americans about enhancing their ability to protect and preserve their health in a way that does not confuse them about means of protecting themselves from other STDs such as HIV.

Pay-As-You-Go Scoring

H.R. 4386 would increase direct spending; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget and Reconciliation Act of 1990. The bill's provisions allowing Medicaid treatment for breast or cervical cancer would increase direct spending by $15 million in FY 2001 and a total of $220 million during FYs 2001-2005. The bill does not contain provisions to offset the increased direct spending. Therefore, if the bill were enacted, its net budget costs could contribute to a sequester of mandatory programs. The Administration supports the Medicaid benefit provisions of the bill and will work with the Congress to avoid a sequester.

FAX

THE ALAN GUTTMACHER INSTITUTE
NEW YORK & WASHINGTON
1120 Connecticut Avenue, NW
Suite 460
Washington, DC 20036
Phone: 202 296-4012
Fax: 202 223-5756
E-mail: policyinfo@usa.org
Web site: www.agi-usa.org

Date: 5/8

Number of pages including cover sheet: 9

To: Heather Howard

@ 456-2878

From: Cynthia

____ Original will not follow
____ Original will follow, via _____

MESSAGE:

HPV

May 5, 2000

The Honorable Anna Eshoo
305 Cannon House Office Building
Washington, DC 20115

Dear Representative Eshoo:

We are writing to bring to your attention an important medical issue that must be addressed prior to floor consideration of the Breast and Cervical Treatment Act legislation (HR 1070). Our concern lies with the human papillomavirus (HPV) language added to the bill during the Commerce Committee mark-up by Representative Tom Coburn, MD.

HPV is a serious public health issue that deserves attention, as do all other sexually transmitted diseases, including HIV/AIDS. However, we believe that the HPV language included in HR 1070 is not medically appropriate. Indeed, we feel the language, if passed, would discourage condom use although condoms are effective in preventing other serious STDs such as HIV/AIDS.

ACOG is working with members of Congress before HR 1070 is brought to the House floor to encourage the adoption of an HPV research and sentinel surveillance provision that would deliver the most up-to-date and medically accurate message to the American public on HPV and all other STDs.

We urge you to work with us to make necessary improvements to ensure that your bill contains the strongest public health message on HPV and other STDs. To discuss this further, please contact Julie Scott with ACOG at 202-863-2566 or Tara Federici with HIMA at 202-434-7208.

Sincerely,

Ralph W. Hale MD

Ralph W. Hale, MD
American College of Obstetricians and Gynecologists

James S. Benson
Health Industry Manufacturers Association
Executive Vice President
Technology and Regulatory Affairs

cc: Commerce Committee

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS • WOMEN'S HEALTH CARE PHYSICIANS
409 12TH STREET SW WASHINGTON DC 20024-2188
MAILING ADDRESS: PO BOX 96920 WASHINGTON DC 20090-6920
202/638-5577

ACOG RECOMMENDED CHANGES TO HPV LANGUAGE (bold type):

"(2) REPORT; FINAL PROPOSAL. -- The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section, and shall develop a final proposal not later than two years after such effective date, including a detailed summary of the significant findings and problems. The report shall outline the ~~further steps needed to make HPV a reportable disease and the~~ best strategies to prevent future infections.

~~"(c) CONDOM EFFECTIVENESS; EDUCATION. — The Secretary shall require that the Department of Health and Human Services and all contractors, grantees, and subgrantees of such Department specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public. The Secretary shall assure that such information is made available to relevant operating divisions and offices of the Department of Health and Human Services. This subsection shall be effective within 6 months of the date of its enactment.".~~

~~SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS.~~

[insert] SEC. 4. LABELING INFORMATION WITH RESPECT TO SEXUALLY TRANSMITTED DISEASES.

(a) IN GENERAL. – Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

~~"(u) If it is a condom, unless its label and labeling bear information providing that condoms do not effectively prevent the transmission of the human papillomavirus and that such virus can cause cervical cancer.".~~

~~(b) APPLICABILITY. — The amendment made by subsection (a) applies to condoms manufactured on or after the expiration of the 180 day period beginning on the date of the enactment of this Act.~~

[insert] "The Secretary shall develop labeling information for devices used to prevent the transmission of sexually transmitted diseases, including human papillomavirus (HPV) and HIV. Such labeling is intended to inform consumers on the effectiveness of such devices against disease transmission and shall be based on the most up-to-date biomedical, health services, and disease prevention research."

Washington, DC-based Office on Women's Health in the Department of Health and Human Services (HHS), the Web site provides a gateway to a wide array of federal and other women's health information resources. Site visitors can link to, read, and download material developed by HHS, other federal agencies, and private sector resources.

4. Healthtouch Online: www.healthtouch.com. A resource developed by Medical Strategies in Dublin, OH, Healthtouch Online offers information from national health organizations, including the CDC's Division of HIV/AIDS Prevention and the National Institute of Allergy and Infectious Diseases, on a comprehensive list of health conditions. The site carries a disclaimer that information may be downloaded and/or reprinted for personal use only.

5. Office of Disease Prevention and Health Promotion's The Year 2000 National Health Observances Web page. nhic-nt.health.org/Pubs/2000healthobserv/nho.htm. When is the Great American Smokeout? How about National Osteoporosis Prevention Month? This calendar from the Washington, DC-based Office of Disease Prevention and Health Promotion can help plan sponsorship of health promotion events, stimulate awareness of health risks, or focus on disease prevention. The site lists events by month, with names, contact information, e-mail addresses, and Web sites (if available), and denotes availability of educational materials.

The February 2000 *CTU* **(p. 25)** listed a number of Web sites that carry responsible reproductive health information for teens. Take a look at the following site, suggested by **Susan Wilson**, executive coordinator of the Network for Family Life Education, a component of Rutgers University School of Social Work in Piscataway, NJ:

6. The Network for Family Life Education Sex, Etc. newsletter: www.sxetc.org. The Network for Family Life Education established this sexuality and health newsletter "written by teens for teens" in 1994, with the help of two health educators and a professional journalist. Each year, the network recruits a new editorial board of high school students from New Jersey, New York, and Philadelphia. The editors develop story ideas and interview teens and adults for story information. A professional journalist helps teens turn interviews into stories; national correspondents from around the country also contribute stories. The Web site features an "Ask the Experts" section and offers information for adults to help them discuss sexual health issues with teens. ■

The politics of HPV: Legislation at issue

Conservatives using disease to further cause

By **Cynthia Dailard**
Senior Public Policy Associate
Alan Guttmacher Institute
Washington, DC

Conservative policy-makers on Capitol Hill have seized upon human papillomavirus (HPV) to advance their abstinence-only agenda. Genital HPV is an extremely common sexually transmitted disease (STD) that cannot be entirely prevented through condom use and is linked to cervical cancer. Based on this information, they believe HPV provides them with a silver bullet to discredit the notion of safe sex.

Conservatives also are using HPV to attack the family planning community — with its ongoing call for safer sex practices designed to reduce the risk for STDs and unintended pregnancy — for turning its back on this disease. However, the family planning community is teaming up with other public health advocates to educate policymakers about the facts of HPV to achieve a more balanced public policy response to both HPV and cervical cancer.

(*Editor's note:* To help answer questions surrounding HPV, a national hotline has been established as the first project of the new National HPV & Cervical Cancer Prevention Resource Center. The center has been launched by the Research Triangle Park, NC-based American Social Health Association, a nonprofit organization dedicated solely to the prevention and control of all STDs. **Read more about the Center in the April 2000 issue of *Contraceptive Technology Update*, p. 46.**)

Congress first encountered HPV as a political issue in the context of the Breast and Cervical Cancer Prevention and Treatment Act of 1999 (HR 1070). That legislation is designed to help low-income, uninsured women with breast or cervical cancer obtain treatment. During

committee consideration of the bill, Rep. Tom Coburn (R-OK), a conservative physician and long-standing opponent of government-funded family planning programs, threatened to hold up consideration of the bill unless the committee accepted his amendments targeting HPV.

To ensure smooth passage of the bill, which is cosponsored by 280 members of the House of Representatives, the sponsors agreed to accept Coburn's amendments. Some of those proposals, however, are problematic from a public health perspective, not just from the standpoint of family planning advocates.

Condom warning labels proposed

One of Coburn's proposals requires the Atlanta-based Centers for Disease Control and Prevention (CDC) to enter into cooperative agreements with the states and other entities to conduct sentinel surveillance surveys to determine the prevalence of specific types of HPV. However, another proposal mandates that condom labels contain a cigarette-type warning stating that condoms do not protect against HPV and that HPV can cause cervical cancer.

In response to that provision, Rep. Henry Waxman (D-CA), a congressional leader on health care issues for more than 20 years, voiced the concerns of the public health community during committee consideration of the bill.

Waxman stated, "There is also a risk of unintentionally confusing the public about when condoms do or do not work. Condoms are unquestionably an important means of preventing the transmission of human immunodeficiency virus and other sexually transmitted diseases. But there is a danger that stressing a message about when condoms do not prevent the transmission of an STD may reduce their use in situations where they do, thereby increasing the transmission of STDs other than HPV.

"I also am concerned that mandating HPV information on condom labels, labeling, and advertising can result in so much information on such a small package that it ultimately reduces the effectiveness of any warnings or other information."[1]

The proposed warning label would not make clear that there are many HPV types and not all lead to cervical cancer.[2] The label also would not help educate women that cervical cancer can be eliminated before it starts by receiving regular Pap tests to detect HPV infection and precancers.[2]

Groups such as the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) and the Chicago-based Society of Gynecologic Oncologists have expressed serious concern about the health message that might be received by the public if Coburn's proposal is enacted.[2] ACOG argued that HPV should not be singled out among all STDs and asked that information presented to consumers be based on accurate, medically based research.[2]

Public health advocates also take issue with Coburn's proposal to establish a process to lead to the required reporting of all cases of HPV to the CDC. Coburn suggests that such a measure would provide public health officials with vital information about the prevalence of HPV. His critics, however, contend that reporting all cases of HPV would not be worthwhile because many of those cases resolve on their own and only a small proportion leads to cervical cancer.

Bill in consideration

Having passed through the full committee, HR 1070 is awaiting consideration by the full House of Representatives. While the future of this bill is ultimately unclear, public health advocates hope to alter the more problematic HPV-related language as the bill moves through the legislative process. To cover his bases, however, Coburn has introduced his initiatives as a freestanding bill (HR 3248) as well.

Clearly, the politics of HPV have just begun, and HPV is likely to provide ample fodder for other debates surrounding publicly funded family planning programs, abstinence-only education, and other matters of public health.

(For additional information, see the article on HPV DNA testing research in *STD Quarterly* and the HPV consumer/patient fact sheet from the National HPV and Cervical Cancer Prevention Resource Center, both inserted in this issue.)

References

1. U.S. Congress, 106th Session. House of Representatives, Commerce Committee. Committee Report — House Rpt. 106-486 Part 1. Breast and Cervical Cancer Prevention and Treatment Act of 1999. Associated Bill H.R. 1070. Additional Views.

2. American College of Obstetricians and Gynecologists. ACOG takes stand against proposed HPV legislation. *ACOG Today* 2000; 44:5. ■

Make Decisions about Human Papillomavirus Based on Sound Medicine, Rather than Politics

Human papillomavirus (HPV) is a complex public health issue that deserves attention. While the vast majority of HPV infections do not lead to serious problems, a very small percentage can lead to cervical cancer. In order to respond to this linkage between HPV and cervical cancer, legislation addressing this complex public health issue was put forward by members of Congress last fall. However, before enacting policies that may be quite costly, yet have a limited impact on improving the overall health of American women, a review of what is known about cervical cancer and HPV, and what further research scientists need to conduct before establishing global policies needs to take place.

What is human papillomavirus?

Human papillomavirus (HPV) is the name of a group of viruses with more than 100 different strains, of which approximately 30 are sexually transmitted. HPV is usually spread through skin-to-skin contact during vaginal, anal, or oral sex with a carrier of the virus. Currently, HPV is the most common sexually transmitted disease in America. An estimated 80 percent of sexually active people contract it at some point in their lives. However, most cases resolve on their own.

Only a small fraction of women with HPV are at high risk for cervical cancer

Most types of HPV are quite specific in the sites they can invade and the pathology they can cause. Certain types of HPV cause warts on the hands or feet, while some genital strains cause visible genital warts. Some, however, are high risk and lead to cervical cancer. In fact, one out of a thousand women with HPV ends up with invasive cervical. Some genital strains of HPV most strongly associated with cervical cancer are types 16, 18, 31, and 45. These are known as "high-risk" types, not because they usually or frequently cause cancer – in fact, cervical cancer is a rare disease in the United States today, but because, in the infrequent event that cancer does develop, it can almost always be traced back to one of those types. In other words, infection with high-risk types appears to be "necessary" for the development of cervical cancer, it is not "sufficient" in that the cancer does not develop in the vast majority of

infected women. It is important to keep in mind that cervical cancer is preventable, treatable and curable when detected in a timely way.

In 1999, it was estimated that 12,800 cases of invasive cervical cancer would be diagnosed in the U.S. and that 4,800 women would die from cervical cancer. According to the National Cancer Institute, about half of women with newly diagnosed cervical cancer have never had a Pap smear, and another 10 percent have not had a smear in the past five years.

What is the appropriate public health response to HPV?

All women who are sexually active should continue to get yearly Pap smears. Efforts to increase access to and insurance coverage of Pap tests should be supported. They remain the most cost-effective safeguard against cervical cancer. Pap smears detect abnormal cells present on the surface of the cervix. Because cervical cancer most commonly takes 10 years to 20 years or more to develop, it can almost always be prevented through the early detection and treatment of abnormal cervical cells.

Recently, the federal Food and Drug Administration approved a test manufactured by the Digene Corporation that used DNA to test for HPV. However, it was approved as a secondary screening tool, meaning that it should be used only after a woman has had an ambiguous or abnormal Pap test in order to detect whether or not a woman has a "high-risk" strain of HPV that could potentially lead to cervical cancer. This test was not approved as a substitute for a Pap test. Currently, HPV testing has not been endorsed by the American College of Obstetricians and Gynecologists (ACOG) as a primary screening tool for women in the United States. ACOG *does* recommend, however, that sexually active women and women age 18 and older have an annual Pap test and pelvic examination.

Along these lines, the Centers for Disease Control and Prevention (CDC) acknowledged the usefulness of HPV testing as an option for use with women with the lowest level of abnormal Paps – referred to as ASCUS (atypical squamous cells of undermined significance.) The CDC has also suggested more research be conducted to determine the usefulness of HPV testing as a primary screen in targeted high-risk groups and for use as a primary screen in developing countries.

What does the HPV language in the Breast and Cervical Cancer Prevention and Treatment Act seek to achieve, and is it good public health policy?

The legislative language related to HPV that was authored by Representative Tom Coburn (R-OK) and included in the Breast and Cervical Cancer Treatment Act (H.R. 1070) during the House Commerce Committee's mark-up last fall has generated some concern in the public health community.

The Coburn amendment calls for the CDC to conduct sentinel surveillance of the prevalence of specific types of HPV. Given the many unanswered questions about the virus, such research may shed important light on the disease. However, public health experts take issue with the amendment's directive to the Department of Health and Human Services (HHS) to outline further steps toward making HPV a reportable disease. Such action may not be warranted given that most cases resolve on their own and only a very small proportion lead to cervical cancer. In fact, the CDC concluded in a December 1999 report, "Prevention of Genital HPV Infection and Sequelae," that "routine disease reporting of all genital HPV infections or for any specific types is not recommended at this time."

The Coburn amendment's further directive to HHS "contractors, grantees, and subgrantees" to specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases" is problematic and wasteful. Of greatest concern is Coburn's condom labeling provision, which would amend the federal Food, Drug, and Cosmetic Act to require condom labels to state that "they do not effectively prevent the transmission of the human papillomavirus and that such virus can cause cervical cancer."

These two provisions could easily be misinterpreted by the general public, which remains largely unaware of HPV. First, it could deter the use of condoms, despite their effectiveness against a range of STDs, including HIV. In addition, the warning label would not make clear that there are a number of types of HPV, of which only a small number can lead to cervical cancer.Furthermore, the label would not help educate women about cervical cancer and that it can be avoided through regular Pap smear examinations.

What <u>does</u> make sense as a public health response to HPV?

Since HPV has been causally linked to cervical cancer, it is being debated whether HPV testing should be used more routinely or even instead of a Pap test. However, at this time, primarily because the large majority of cervical lesions disappear on their own, HPV tests as a primary screen for

young women is unlikely to become the standard of care in this country. However, whether routine HPV testing is beneficial to high-risk populations, women who do not get routine Pap tests regularly, older women, and women in developing countries who do not have access to Pap tests, should be investigated.

Research that may prove useful to policymakers would answer some of the following questions:

- **What are the factors that activate the virus and which other factors (genetics, smoking, oral contraceptive use, environmental exposures), increase risk?**
- **Is the "cleared" virus suppressed or eliminated?**
- **To what degree do condoms decrease risk of the transmission or acquisition?**
- **Can HPV be transmitted asexually?**
- **What is the natural history of the disease?**
- **Is it possible or desirable to test men for the disease?**
- **How useful is HPV testing prior to Pap smear examination?**
- **What are the benefits/drawbacks of knowing HPV status?**
- **What are the legal issues regarding partner disclosure?**

Other research that may prove useful could focus on primary prevention methods, including vaccines, condoms, and microbicides. Increased funding for programs to increase patient and provider awareness and to assess and improve the effectiveness of behavioral interventions may also be worthwhile.

NFPRHA, 5/00

FAX

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Date: 5/8

Number of pages including cover sheet: 9

To: Heather Howard

@ 456-2878

From: Cynthia

____Original will not follow
____Original will follow, via _____

MESSAGE:

HPV

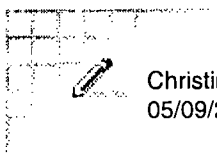
Anna Richter
05/09/2000 06:01:36 PM

Record Type: Record

To: Ann O'Leary/OPD/EOP@EOP, Heather H. Howard/OPD/EOP@EOP

cc:
Subject: Statement by the President: House Passes H.R. 4386, Breast and Cervical Cancer Treatment Act

fyi -- (unless y'all drafted this and I didn't know)
---------- Forwarded by Anna Richter/OPD/EOP on 05/09/2000 06:01 PM ----------



Christine L. Anderson
05/09/2000 05:56:41 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Statement by the President: House Passes H.R. 4386, Breast and Cervical Cancer Treatment Act

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **May 9, 2000**

STATEMENT BY THE PRESIDENT

I am extremely pleased that today the House passed H.R. 4386, the Breast and Cervical Cancer Treatment Act, in an overwhelming bipartisan vote. Each year, thousands of women who have been diagnosed with breast or cervical cancer do not receive the comprehensive coverage they need, despite extraordinary efforts by Federal health programs to provide that care. This legislation, which I was proud to include in this year's budget, will provide states with the option to provide the full Medicaid benefit package without delay to uninsured women diagnosed with breast or cervical cancer through Federal screening programs.

I also want to commend the Congress for today's strong bipartisan vote in support of the Long Term Care Security Act. This legislation, which I have long advocated, provides authorization for the Federal Employee Health Benefit Program to offer long term care insurance to current and retired Federal employees. I hope that the legislation serves as a model for all private employers and encourages them to provide this type of coverage to their employees. While this

is an important step, it is only one step. We must also continue to work to pass a broad range of long term care initiatives, including a $3,000 tax credit for people with long-term care needs or their caregivers; new funding for services which support family caregivers of older persons; and efforts to enable states to improve equity in Medicaid eligibility for people in home- and community-based settings.

I am encouraged by the news of Congress acting on these significant policy initiatives. We need to build on these achievements and act now to pass a range of policies of importance to the American people, including the creation of a strong, enforceable, Patients' Bill of Rights and a new voluntary prescription drug benefit option as we take steps to modernize and strengthen the Medicare program. And finally, we must redouble our efforts to expand high quality, affordable coverage for all Americans. I urge the Congress to work towards passing the Administration's health coverage proposals that would expand coverage to at least 5 million uninsured Americans and provide health services to millions more by providing new, affordable health insurance options for parents, 19 to 20 year olds, legal immigrants, workers between jobs, and the near elderly.

30-30-30

Message Sent To: _____

Bill Summary & Status for the 106th Congress

NEW SEARCH | HOME | HELP

S.662
Sponsor: Sen Chafee, John H. (introduced 3/18/1999)
Related Bills: H.R.1070
Latest Major Action: 7/27/1999 Senate committee/subcommittee actions
Title: A bill to amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program.

Jump to: Titles, Status, Committees, Related Bill Details, Amendments, Cosponsors, Summary

TITLE(S): (*italics indicate a title for a portion of a bill*)

- OFFICIAL TITLE AS INTRODUCED:
  A bill to amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program.

STATUS: (*color indicates Senate actions*) (Floor Actions/Congressional Record Page References)

3/18/1999:
Read twice and referred to the Committee on Finance.
7/27/1999:
Subcommittee on Health Care. Hearings held.
4/14/1999:
Star Print ordered on the bill.

COMMITTEE(S):

Committee/Subcommittee:	Activity:
Senate Finance	Referral

RELATED BILL DETAILS: (additional related bills may be indentified in Status)

Bill:	Relationship:
H.R.1070	Identical bill identified by CRS

AMENDMENT(S):

NONE

COSPONSORS(62), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date)

Sen Abraham, Spencer - 4/25/2000
Sen Akaka, Daniel K. - 4/22/1999
Sen Ashcroft, John - 2/23/2000
Sen Baucus, Max - 6/8/1999
Sen Bayh, Evan - 3/25/1999
Sen Bennett, Robert F. - 4/27/2000
Sen Biden, Joseph R., Jr. - 5/26/1999
Sen Bingaman, Jeff - 3/18/1999
Sen Bond, Christopher S. - 4/30/1999
Sen Boxer, Barbara - 3/18/1999
Sen Breaux, John B. - 8/5/1999
Sen Bryan, Richard H. - 7/27/1999
Sen Byrd, Robert C. - 7/27/1999
Sen Chafee, Lincoln D. - 2/29/2000
Sen Cleland, Max - 3/18/1999
Sen Cochran, Thad - 3/18/1999
Sen Collins, Susan M. - 3/23/1999
Sen Conrad, Kent - 3/25/1999
Sen Daschle, Thomas A. - 7/26/1999
Sen Dodd, Christopher J. - 4/14/1999
Sen Dorgan, Byron L. - 4/28/1999
Sen Durbin, Richard J. - 3/18/1999
Sen Edwards, John - 7/12/1999
Sen Feinstein, Dianne - 3/18/1999
Sen Graham, Bob - 4/30/1999
Sen Grams, Rod - 3/29/2000
Sen Grassley, Charles E. - 5/27/1999
Sen Hagel, Chuck - 9/10/1999
Sen Harkin, Tom - 3/18/1999
Sen Hatch, Orrin G. - 4/7/2000
Sen Hollings, Ernest F. - 3/18/1999
Sen Hutchison, Kay Bailey - 4/27/2000
Sen Inouye, Daniel K. - 4/13/1999
Sen Jeffords, James M. - 6/7/1999
Sen Johnson, Tim - 3/18/1999
Sen Kennedy, Edward M. - 3/18/1999
Sen Kerrey, J. Robert - 3/18/1999
Sen Kerry, John F. - 4/22/1999
Sen Kohl, Herb - 10/13/1999
Sen Landrieu, Mary L. - 6/22/1999
Sen Lautenberg, Frank R. - 3/18/1999
Sen Leahy, Patrick J. - 3/18/1999
Sen Levin, Carl - 9/15/1999
Sen Lieberman, Joseph I. - 3/18/1999
Sen Lincoln, Blanche - 4/28/1999
Sen Mikulski, Barbara A. - 3/18/1999
Sen Moynihan, Daniel Patrick - 3/18/1999
Sen Murkowski, Frank H. - 4/28/1999
Sen Murray, Patty - 3/18/1999
Sen Reed, Jack - 4/14/1999
Sen Reid, Harry M. - 3/18/1999
Sen Robb, Charles S. - 3/18/1999
Sen Rockefeller, John D., IV - 3/18/1999
Sen Sarbanes, Paul S. - 3/18/1999
Sen Schumer, Charles E. - 4/28/1999
Sen Smith, Gordon - 3/18/1999
Sen Snowe, Olympia J. - 3/18/1999
Sen Specter, Arlen - 10/14/1999
Sen Torricelli, Robert G. - 4/13/1999
Sen Warner, John W. - 4/7/2000
Sen Wellstone, Paul D. - 3/18/1999
Sen Wyden, Ron - 1/24/2000

Sen Dorgan, Byron L. - 3/23/1999(withdrawn - 3/25/1999)

MOST RECENT SUMMARY:
3/18/1999--Introduced.

Amends title XIX (Medicaid) of the Social Security Act to give States the option of making medical assistance for breast and cervical cancer-related treatment services available during a presumptive eligibility period to certain low-income women without creditable coverage who have already been

screened for such cancers under the Centers for Disease Control and Prevention breast and cervical cancer early detection program and need treatment. Provides for an enhanced match with regard to such Medicaid treatment services.

provisions to offset the increased direct spending. Therefore, if the bill were enacted, its net budget costs could contribute to a sequester of mandatory programs. The Administration supports the Medicaid benefit provisions of the bill and will work with the Congress to avoid a sequester.

* * * * * * * * * *

(Do Not Distribute Outside Executive Office of the President)

This Statement of Administration Policy was developed by the Legislative Reference Division (Pellicci) in consultation with the Department of Health and Human Services (Horvath) and HD (Morley/Vaeth/Nakagiri).

OMB/LA Clearance:_____

H.R. 4386 was introduced on May 4th by Rep. Sue Myrick. It is cosponsored by Reps Pat Danner (D) MO, and Rick Lazio (R) NY. There were no hearings or Committee action on this version of the bill.

Summary of H.R. 4386

As introduced, H.R. 4386 would give the States the option of providing Medicaid coverage to women who have been screened under the Centers for Disease Control and Prevention's national breast and cervical cancer early detection program for low-income women and found to have breast or cervical cancer.

The CDC screening program only provides for screening; it does not provide treatment. Under current law, low-income women with breast or cervical cancer are eligible for Medicaid coverage of their cancer treatment only if they meet one of the existing eligibility standards – such as if they are pregnant, they are receiving assistance under the Temporary Assistance for Needy Families program, or they are receiving Supplemental Security Income payments for a disability.

H.R. 4386 would also require CDC to study the prevalence of the human papillomavirus (HPV), its impact on individuals, and awareness of HPV. In addition, the bill would require CDC to develop and distribute educational materials related to HPV and report to Congress on further steps needed to prevent future infections.

Furthermore, H.R. 4386 would require condom manufacturers to change the labeling of condoms to state that condoms do not effectively prevent the transmission of HPV and that the virus can cause cervical cancer in women.

Pay-As-You-Go Scoring

BREAST AND CERVICAL CANCER TREATMENT ACT
PROBLEMS WITH HPV PROVISION

fm AGP

SUGGESTED STATEMENT:

While I strongly support the overall bill, I am deeply concerned about the provision included on Human Papillomavirus (HPV) and believe it is misguided from a public health perspective. The condom labeling requirement may have the unintended effect of discouraging condom use, which, as we all know, is effective in preventing other serious STDs, including HIV/AIDS.

Taking steps to make HPV a reportable disease also does not make sense, since most cases of HPV resolve on their own and only a very small percentage lead to cervical cancer. Our goal should not be to instill panic, but rather to educate Americans about how to best prevent all STDs, to inform them about the real risks associated with cervical cancer, and to instruct them how to protect themselves against cervical cancer through regular Pap smear examinations.

TALKING POINTS:

- Both women and men should be educated and informed about HPV and all other STD's including HIV/AIDS. A condom label will not adequately provide education on this disease.

- By stating that condoms do not effectively prevent the transmission of HPV, the language included in this bill belies the fact that condoms are highly effective in reducing the risk of contracting HPV and other STDs, including HIV/AIDS.

- The proposed language on condom labeling has the strong potential of discouraging condom use, thereby exposing men and women to the risks of HPV and other STDs, including HIV/AIDS.

- There are over 100 strains of the HPV virus, and very few of these have the potential to lead to cervical cancer. It is misleading to have a label that does not clarify this point.

- Only a small fraction of women with HPV are at high risk for cervical cancer. We should be advocating for public health policy that encourages women to be screened through Pap smear examinations to prevent the potential for cervical cancer.

- The provision in the bill also suggests working to make HPV a reportable disease. Over 80% of the population has been found to carry one of the 100's of HPV strains. Reporting 80% of the population is costly, unnecessary, and ineffective in providing good information to use to help address HPV.

- There is no current consistent method of screening men for HPV or other STD's, unlike women who are encouraged to seek an annual Pap smear examination. The process for reporting advocated in the bill is therefore, discriminatory and would not provide accurate information.

AMERICAN COLLEGE OF OBSTETRICIANS
& GYNECOLOGISTS
WOMENS HEALTH CARE PHYSICIANS

DEPARTMENT OF GOVERNMENT RELATIONS AND OUTREACH
409 12th Street, SW
Washington, DC 20024-2188
(202) 863-2509
FAX (202) 488-3985

DATE:

TO: Heather

FROM: Laura Hessburg 863-2534

RE:

NUMBER OF PAGES (including this page): 7

RECIPIENT'S FAX NUMBER:

COMMENTS:

As per Cynthia Dailard - attached is the HPV language that was sent to us this morning - Kennedy's office as well as Commerce committee staff asked for changes to the condom labeling section - Cynthia said you had the changes we wanted.

IF THERE IS A TRANSMISSION PROBLEM, OR IF YOU WOULD LIKE TO SPEAK WITH SOMEONE AT ACOG, PLEASE CALL (202) 863-2509

pls call if you need anything -
LH

SEC. 515. Section 410(b) of The Ticket to Work and Work Incentives Improvement Act of 1999 (Public Law 106–170) is amended by striking "2009" both places it appears and inserting "2001".

[SEC. 516. Part B of title III of the Public Health Services Act (42 U.S.C. 243 et seq.) is amended by inserting before section 318 the following section:

"HUMAN PAPILLOMAVIRUS

"SEC. 317P. (a) SURVEILLANCE.—

"(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall—

"(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as 'HPV') in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

"(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

"(2) REPORT.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) no later than one year after the effective date of this section.

"(b) PREVENTION ACTIVITIES; EDUCATION PROGRAM.—

"(1) IN GENERAL.—The Secretary, acting through the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

"(A) behavioral and other research on the impact of HPV-related diagnosis on individuals;

"(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

"(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

"(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

"(2) REPORT; FINAL PROPOSAL.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section, and shall develop a final report not later than three years after such effective date, including a detailed summary of the significant findings and problems and the best strategies to prevent future infections, based on available science.

"(c) HPV EDUCATION AND PREVENTION.—

"(1) IN GENERAL.—The Secretary shall prepare and distribute educational materials for health care providers and the public that include information on HPV. Such materials shall address—

"(A) modes of transmission;

"(B) consequences of infection, including the link between HPV and cervical cancer;

"(C) the effectiveness of condoms in preventing infection with HPV; and

"(D) the importance of regular pap smears, and other diagnostics in preventing cervical cancer.

"(2) MEDICALLY ACCURATE INFORMATION.—Educational material under paragraph (1), and all other relevant educational and prevention materials

prepared for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address HPV shall contain medically accurate information regarding the effectiveness of condoms in preventing ~~HPV infection.~~ Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.".

~~For the purpose of carrying out the activities described in the previous sections, there are authorized such sums as may be needed for fiscal years 2001–2006.~~]

SEC. 517. Section 403(o) of the Food, Drug, and Cosmetic Act (21 U.S.C. 343(o)) is repealed. Subsections (c) and (d) of section 4 of the Saccharin Study and Labeling Act are repealed.

SEC. 518. (a) Title VIII of the Social Security Act is amended by inserting after section 810 (42 U.S.C. 1010) the following new section:

☆ just in case you don't have the edits handy, Following are the changes we would like.

SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS AND OTHER SEXUALLY TRANSMITTED DISEASES.

The Secretary of Health and Human Services shall ~~examine~~ evaluate existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to ~~ensure that the labels are medically accurate and not misleading regarding the overall effectiveness and lack of~~ determine whether such labeling adequately informs consumers about the effectiveness of condoms ~~in preventing sexually transmitted diseases, including HPV infection and infection with the human papillomavirus~~. against disease transmission, including HPV infection.

429A

THE WHITE HOUSE
WASHINGTON

Date: 12/13

To: JEANNE

Telephone: Fax: 55631

From: Heather Howard

Telephone: 456-7263 Fax: 456-2878

Subject: HPV

Pages: 7 (Including this cover sheet)

Comments:

Please find attached:

- Latest version of the HPV language that I had in my files. It's from October 24 – what the family planning groups were proposing.

- FYI – The groups believe that they basically got these changes to all the sections (study, report, medically accurate educational materials), except for condom labeling. They are not thrilled with the condom labeling language, but have heard that CDC thinks it's ok. (This is based on language they've seen from Harkin's office.) I'd be happy to look at language if you have any.

SECOND FLOOR WEST WING ❖ WASHINGTON, DC 20502
TELEPHONE (202) 456-7263 ❖ FACSIMILE 456-2878

FAX

THE ALAN GUTTMACHER INSTITUTE
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Web site: www.agi-usa.org

Date: 10/24

Number of pages including cover sheet: 6

To: Heather

@ 456-2878

From: Cynthia

____Original will not follow
____Original will follow, via _____

MESSAGE:

This reflects changes proposed by WO + CDC.

Refaxed - 6:45 pm

study
report
medically accurate info
evaluate adequacy of
condom labeling

detergent labelling changes –

F:\M6\COBURN\COBURN.098

PROPOSED PROVISIONS FOR HOUSE AMENDMENT TO SENATE AMENDMENT TO H.R. 4386

Add at the end of the Senate amendment the following section:

SEC. 3. HUMAN PAPILLOMAVIRUS; ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting before section 318 the following section:

"HUMAN PAPILLOMAVIRUS

"SEC. 317P. (a) SURVEILLANCE.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as 'HPV') in ~~different sites~~ in various regions of the United States, through collection of special specimens for HPV using a variety of

laboratory-based testing and diagnostic tools; and

"(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

"(2) REPORT.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section.

"(b) PREVENTION ACTIVITIES; EDUCATION PROGRAM.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

"(A) behavioral and other research on the impact of HPV-related diagnoses on individuals;

"(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

"(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

"(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

"(2) REPORT; FINAL ~~PROPOSAL~~ Report.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section, and shall develop a final ~~proposal~~ report not later than ~~two~~ three years after such effective date, including a detailed summary of the significant findings and problems and the best strategies (based on available science) to prevent future infections.

"(o) HPV EDUCATION AND PREVENTION.—

"(1) IN GENERAL.—The Secretary shall prepare and distribute educational materials for health care providers and the public ~~that include information on all sexually transmitted diseases, including~~ on HPV ~~and HIV infection~~. Such materials shall address—

"(A) modes of HPV transmission;

"(B) consequences of infection, including the link between HPV and cervical cancer;

"(C) the effectiveness ~~or lack of effectiveness~~ of both condoms and abstinence in pre-

venting infection with ~~sexually transmitted diseases, including~~ HPV, and

"(D) the importance of regular pap smears, ~~HPV testing, and sexually transmitted disease screening for early intervention purposes~~ and other screening tests in preventing cervical cancer.

"(2) MEDICALLY ACCURATE INFORMATION.—Educational materials under paragraph (1), and all other relevant educational and prevention materials prepared for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by other Federal departments or agencies, or by contractors, grantees, or subgrantees thereof, that are specifically designed to address sexually transmitted diseases or ~~condoms~~ shall contain medically accurate information regarding the effectiveness ~~or lack of effectiveness~~ of condoms in preventing ~~HPV infection, HIV infection, and other sexually transmitted~~ diseases. Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.".

the effectiveness of condom use in preventing HPV infection, HIV infection, or other those

(d) Authorization of Appropriations - For the purposes of carrying out the activities under subsections (b) and (c), there are authorized to be appropriated [redacted] to OD such sums as may be necessary for fiscal years 2001-2006.

SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS AND OTHER SEXUALLY TRANSMITTED DISEASES.

The Secretary of Health and Human Services shall evaluate ~~determine~~ existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to determine whether such labeling ~~ensure that the labels are medically accurate and not misleading regarding the overall effectiveness and lack of~~ adequately informs consumers about the effectiveness of condoms in ~~preventing sexually transmitted diseases, including HIV infection and infection with the human papillomavirus and other~~ disease transmission, including HPV infection.

SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS AND OTHER SEXUALLY TRANSMITTED DISEASES.

The Secretary of Health and Human Services shall reexamine existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to ensure that the labels are medically accurate and not misleading regarding the overall effectiveness and lack of effectiveness of condoms in preventing sexually transmitted diseases, including HIV infection and infection with the human papillomavirus.

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Heather H. Howard
12/14/2000 02:43:15 PM

Record Type: Record

To: Jeanne Lambrew/OMB/EOP@EOP

cc:
Subject: Latest on Condom Labeling

Jeanne -- I wanted to make sure you knew that some of the family planning groups are apparently still trying to get changes to the condom labeling language. They are working through Cybele (sp?) in Kennedy's office, who is negotiating with Christina Hamilton. Apparently 3 of the 4 authorizers have been making a stink about the language(Dingell, Jeffords and Kennedy). The changes that the groups have settled on and that Kennedy's staffer is proposing are noted below:

Labeling of Condoms . . .

The Secretary of Health and Human Services shall reexamine existing condom labels that are authorized pursuant to the Food, Drug and Cosmetic Act to ~~ensure that~~ **determine whether** the labels are medically accurate ~~and not misleading~~ regarding the overall effectiveness ~~and~~ **or**lack of effecitveness of condoms in preventing sexually transmitted diseases~~, including HIV infection and infection with the human papillomavirus~~.