Devorch—
What does OMB/HHS think of this?
Thanks

October 27, 1999

President William Jefferson Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C., 20500

Dear President Clinton,

As our nation observes Breast Cancer Awareness this month, we are encouraged by the government's commitment to developing new treatments and possible cures for the disease. A different kind of research is needed now, however, to uncover why women are getting breast cancer in the first place, so we can prevent new cases.

We are writing to urge your support in forging a bold new path in breast cancer research — one that examines the potential pathways for prevention, including the link between the disease and the chemicals in the air we breathe, the water we drink, the food we eat, and the products we buy.

This year, an estimated 43,300 women nationwide will die of breast cancer. In the past 50 years, since World War II, the rate of breast cancer among women has more than doubled. Yet, in as many years, cancer research has yielded only two known causes of the disease: radiation and genetic defects. And while scientists have identified a handful of factors associated with increased risk, these factors, taken all together, account for less than half of breast cancer incidence. Today, we remain unable to explain the causes behind the majority of all breast cancer cases or the reasons for increasing risk over the past several decades.

But here's what we do know: If cancer is the crime, among the suspects are toxicants in our environment. Laboratory research shows that approximately 100 chemicals in current use give rise to mammary gland cancer in animals. There are 75,000 chemicals in commerce today. We know a little about the toxic nature of less than 3,000 of them. However, some of these chemicals can cause cancer. Others can interfere with hormone systems that affect cancer growth.

We have a right to know what toxic chemicals are in our bodies and the impact these agents may have on our health. Toward that end, we urge your commitment and action on the following:

- Increase funding for research that examines the environmental links to breast cancer. Currently, funding for environmental research represents only a tiny fraction of the government's budget for disease research. Of the National Institutes of Health's $15 billion budget this year, just $382 million, or 2.4 percent,

went to the National Institute of Environmental Health Sciences, the primary agency that conducts research on environmental health.

- Establish a national registry and inventory of the chemicals in our bodies. Researchers at the Centers for Disease Control's Environmental Health Lab are currently studying human blood samples to identify what chemicals are present in our bodies and at what levels. Their findings will inform future efforts to reduce or eliminate exposure to harmful chemicals. This "biomonitoring" research deserves more funding and should be expanded to include a wider range of chemicals, as well as testing of breast milk, which often contains high levels of carcinogenic and hormone-disrupting chemicals.

- Fully fund the Environmental Protection Agency's program to screen and test "hormone disrupters," environmental toxicants that mimic estrogen and can cause the rapid growth of cancer cells.

- Establish a cross-agency committee to oversee government funding for environmental health research. Recently, a $15 million appropriation earmarked for a study that would have explored environmental factors in regions with high breast cancer incidence was diverted to unrelated projects on genetics and air pollution. A cross-agency oversight committee that includes consumer participation would help insure the correct and wisest placement of new funding.

We welcome the opportunity to discuss the above in greater detail with you and your staff. Time is of the essence. Women at risk for breast cancer - which is all women - are engaged in a battle to save our bodies and our lives. Until we arm ourselves with new intelligence about the causes of the disease, we will continue to fight blindfolded. On behalf of our mothers, sisters and daughters, we call on you to vigorously support policy and research that will empower us to fight with both eyes open.

Sincerely,

(see attached list of endorsers)

cc: Bill Bradley
Vice President Al Gore
Governor George W. Bush

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- California Breast Cancer Treatment Fund
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- Central CA Breast Cancer Partnership of the California Health Collaborative
- California Women's Law Center
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- Sisters Advocating Against Cancer
- Vital Options
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- Women's Cancer Resource Center
- Women CARE
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- Brentwood/Bay Shore Breast Cancer Coalition
- Cancer Awareness Coalition
- Group for the South Fork
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For more information, contact Kasia Grisso or Lisa Chen at (415)255-1946

Am Can

Devorah Adler

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Exposure to organochlorine pesticides and risk of breast cancer

Some organochlorine pesticides have estrogen-like activity in the body, raising concern that they may cause or increase risk for breast cancer. In a collaborative study with investigators from Denmark, CDC's Environmental Health Laboratory measured exposure of Danish women to organochlorine pesticides to see if levels were related to breast cancer. These women were not occupationally exposed to organochlorine pesticides and their serum levels were similar to women in the United States.

In this study of 268 women with breast cancer, exposure to the pesticide dieldrin in the upper quartile was associated with a 2.1 fold increased risk of developing breast cancer compared to the lowest quartile. The upper quartile represented the highest quartile of exposure to dieldrin by women in the general population. In addition, women with breast cancer in the upper quartile were more than 2.5 times likely to die of breast cancer than women with breast cancer in the lowest quartile of dieldrin levels. Dieldrin exposure appeared to not only increase risk of breast cancer but also to decrease life expectancy in persons with breast cancer. The laboratory is collaborating in several additional studies of organochlorine pesticides to further investigate this finding.

Exposure to polychlorinated biphenyls (PCBs) and risk of non-Hodgkins lymphoma

The incidence of non-Hodgkins lymphoma has been increasing in the United States since the 1940's. In collaboration with investigators from the National Cancer Institute, Johns Hopkins University and Georgetown University, CDC's Environmental Health laboratory measured the exposure of 74 cases of non-Hodgkins lymphoma and 147 controls to organochlorine pesticides including PCBs. Persons in the study were from Washington County, Maryland and had exposure to PCBs typical of the general population.

There was a strong dose-response relationship between quartiles of PCB concentrations and risk of non-Hodgkin's lymphoma, with persons in the highest quartile at 4.5 times increased risk when compared to the lowest quartile. In addition, persons in the upper half of PCB concentrations and seropositive for Epstein-Barr virus had more than a 22 fold increased risk for non-Hodgkins lymphoma compared to persons seropositive for Epstein-Barr virus and in the lower half of PCB concentrations. The laboratory is collaborating in a followup study to further investigate these findings.

Illegal indoor spraying of methyl parathion

Methyl parathion is a powerful pesticide that can kill people by paralyzing muscles necessary to breathe, like a "junior strength" nerve agent. It is approved only for use outdoors, principally for pests attacking cotton. Previously, two children in Mississippi have died from indoor spraying of methyl parathion. In the mid 90's, methyl parathion was illegally sprayed in thousands of homes in Illinois, Mississippi, Louisiana, Texas, Tennessee, Arkansas and Alabama as a pest control agent. Believing the chemical to be safe, people had sometimes requested extra spraying on cribs or carpets in front of the TV to be sure pests did not bother their children.

Since homeowners rarely verified what pest control agents were being sprayed in their homes, health officials were faced with thousands of homes potentially contaminated with no method of determining which families were exposed and which were safe. CDC's Environmental Health Laboratory developed a urine test for methyl parathion that was used by state and federal health officials to decide who had been exposed and how much exposure each

person has had. Based on the urine measurement of methyl parathion, health officials prioritized medical treatment of exposed children and adults and determined which homes should be evacuated and remediated. From November 1996 through February 1999, the laboratory performed urine tests on more than 15,000 persons. The urine measurements provided unique individual assessments of exposure that otherwise would not have been available. In addition to identifying persons with elevated levels requiring prompt attention, the measurements also reassured thousands of persons, who did not know what had been sprayed in their homes, that they had no exposure.

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No. of pages (including this one): 2

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Per request for information on breast cancer and the environment.

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Acknowledgments
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Organochlorine exposure and risk of breast cancer

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Summary

Background Some organochlorine compounds may have weak oestrogenic effects and are, therefore, suspected of increasing the risk of breast cancer. We assessed prospectively the risk of breast cancer in relation to serum concentrations of several organochlorine compounds.

Methods In 1976, serum samples from 7712 women were obtained from participants in the Copenhagen City Heart Study as part of physical examinations and interviews about lifestyle factors. During 17 years of follow-up, 268 women developed invasive breast cancer. Each woman with breast cancer was matched with two breast-cancer-free women from the remaining cohort. We analysed in 1996–97 the serum samples from 240 women with breast cancer and 477 controls.

Findings Dieldrin was associated with a significantly increased dose-related risk of breast cancer (adjusted odds ratio 2·05 [95% CI 1·17–3·57], p for trend 0·01). β-hexachlorocyclohexane increased risk slightly but not significantly (p for trend 0·24). There was no overall association between risk of breast cancer and *p,p'*-dichlorodiphenyltrichloroethane or metabolites or for polychlorinated biphenyls. Exclusion of women with breast cancer diagnosed within 5 years of blood sampling strengthened the result for dieldrin, but did not affect the other results.

Interpretation These findings support the hypothesis that exposure to xeno-oestrogens may increase the risk of breast cancer.

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Introduction

Breast cancer is the most common cancer among women in many western countries. In Denmark, about 14% of all women develop breast cancer, and the incidence has more than doubled in the past 30 years.[1] This trend is seen also in some developing countries with lower incidences.[2] Recognised risk factors for breast cancer and improved diagnostic methods such as mammography can account for only a small part of this trend.[1] Most of the risk factors for breast cancer, such as early menarche, late menopause, nulliparity, late conception of the firstborn, and hormone-replacement treatment after menopause suggest that oestrogen has a prominent role in the pathogenesis of breast cancer.[3] The substantial international differences and changes in incidence of breast cancer seen among migrants highlight environmental factors.[2,4] Certain organochlorine compounds, including agricultural pesticides, such as *p,p'*-dichlorodiphenyltrichloroethane (DDT), chlordane, lindane, dieldrin, and industrial chemicals such as polychlorinated biphenyls, may disrupt the endocrine system.[5–7] More than 15 000 organic chlorinated compounds have been or are currently used. Biological half-lives of several years have been reported in human beings for some substances, which leads to accumulation in lipid-rich tissue.[8,9] The xeno-oestrogens known so far have a much lower oestrogenic potency than oestradiol. Human beings can, however, be exposed to several compounds at the same time, and there is evidence of synergistic effects.[7,10]

We investigated whether women with high serum concentrations of potentially oestrogenic compounds (kepone, dieldrin, *o,p'*-DDT, *p,p'*-DDT, and low chlorinated PCB congeners) are at increased risk of breast cancer.

Methods

Participants

We used information on women enrolled in the Copenhagen City Heart Study (CCHS).[11–13] The study population was selected randomly through the Civil Registration System in ten electoral constituencies around Rigshospitalet, Copenhagen,

Denmark. In 1976, 49 128 women aged 20 years or older lived in these constituencies, and 21% (10 317) of these were invited to participate in the CCHS. 7712 women provided baseline information. Each participant filled in a standard questionnaire about lifestyle and underwent a physical examination, including anthropometric measurements, blood pressure, and electrocardiography. We took blood samples from non-fasting participants from cubital veins into test-tubes containing edetic acid, and placed them immediately in ice water. Within 2 h the samples were centrifuged. Enzymatic serum lipid analysis was done and the remaining serum was stored in a freezer.[10,11]

We identified women who developed breast cancer between the start of the study and end of follow-up in 1993 by linkage to the Danish Cancer Registry.[12] All women were traced by the unique ten-digit identification number issued to each person living in and entering Denmark. Women were excluded who had breast cancer before the start of the study. 268 women developed breast cancer during the 17 years of follow-up, and we included these women as cases in our case-control study nested within the CCHS cohort. From the rest of the cohort, for each woman with cancer, we randomly chose two women who were free of breast cancer matched for age, date of examination, and vital status at time of diagnosis to act as controls. We obtained information on vital status, cause, and date of death through linkage to the Civil Registration System and the Causes of Death Registry, Danish National Board of Health.

From CCHS we obtained information on socioeconomic status, school education, age at menopause, number of full-term pregnancies, height, weight, smoking and alcohol consumption, physical activity, and total serum concentration of cholesterol, HDL cholesterol, and triglycerides. We calculated the total serum lipid concentration as recommended by Phillips and colleagues:[13]

Total serum lipid (mg/dL)=2·27×serum cholesterol (mg/dL)+serum triglycerides (mg/dL)+0·623.

From 240 (89%) women with breast cancer and 477 controls, at least 0·5 mL of the original serum sample was available in 1995. The samples were coded before transfer to the laboratory.

Laboratory analysis

The Centers for Disease Control and Prevention laboratory, Atlanta, USA, analysed the serum samples for 18 organochlorine pesticides or metabolites, and 28 PCB congeners: mirex, dieldrin, aldrin, endrin, α-chlordane, γ-chlordane, heptachlor, heptachlor epoxide, oxychlordane, transnanochlor, γ-hexachlorocyclohexane, β-hexachlorocyclohexane (β-HCH), hexachlorobenzene (HCB), *o,p'*-DDT, *o,p'*-DDE, *p,p'*-DDT, *p,p'*-DDE, *p,p'*-DDD, and PCB congeners (IUPAC numbers) 28, 52, 56, 66, 74, 99, 101, 105, 110, 118, 138, 146, 153, 156, 170, 172, 177, 178, 180, 183, 187, 189, 193, 194, 195, 201, 203, and 206. We calculated total PCB and total DDT concentrations by adding all concentrations of PCB congeners and all DDT isomers. The samples were separated into three series of 200 samples and one of 117.

The analytical technique has been described previously.[14] A two-stage solid-phase extraction for C18 extraction was used with florisil clean-up of pesticides and PCBs in serum. After extraction, samples were evaporated to 0·5–0·9 mL, and 0·1 mL dichloronaphalene (125 parts per billion) was added as an internal standard for gas chromatography analysis.

To test for quality, bovine serum was used to which three concentrations of nine commercially available analytes were added. With every batch of ten human samples one quality control sample and one reagent-blank sample was analysed. All quality control results were compared with limits established in the laboratory. If the quality sample was not within control limits or showed no trend, the human samples in that batch were discarded. 2 μL of each sample was injected into two separate gas chromatographs containing two different columns, DB5 and DB1701. Elution times were determined by injection of a standard of each commercially obtained analyte separately. Only completely resolved peaks for each analyte were used for quantification, in which peak area ratios were compared (analyte/internal standard) with a linear calibration curve. This curve was generated by analysis of standards at six different concentrations at least three times.

The quantitative results were adjusted for total serum lipid content, and reported as ng/g lipid. The detection limit for all analytes was based on three SD of the results from the lowest quality control samples over the course of the analyses. Limits of detection varied from 0·08 ng/mL to 0·66 ng/mL for HCB and *p,p'*-DDT, respectively. Results for eight serum samples could not be obtained because of inadequate volume or sample quality. The analytes *o,p'*-DDT, and PCB–56 (series 1); endrin (series 2); mirex; PCB–99 and PCB–189 (series 3); and PCB–56 and PCB–189 (series 4) did not meet quality control standards.

Factor	Number of cases/controls*	Odds ratio (95% CI)†	p for trend in odds ratio
Number of full-term pregnancies			
0	65/108	1·00‡	
1	67/102	1·08 (0·69–1·68)	
>2	108/264	0·67 (0·45–0·99)	0·02
Menopausal status			
Premenopausal	72/150	1·00‡	
Postmenopausal	169/327	1·24 (0·75–2·09)	
Hormone-replacement therapy			
Never	176/367	1·00‡	
Ever	63/106	1·24 (0·84–1·82)	
Weight (kg) by quartile			
I <56·2	39/119	1·00‡	
II 56·2–63·1	65/120	1·89 (1·11–3·22)	
III 63·2–70·5	68/122	1·96 (1·18–3·24)	
IV >70·5	68/116	1·89 (1·13–3·15)	0·04
Height (m) by quartile			
I <1·57	49/130	1·00‡	
II 1·57–1·61	63/116	1·30 (0·81–2·08)	
III 1·62–1·65	57/118	1·31 (0·82–2·09)	
IV >1·65	70/111	1·65 (1·03–2·65)	0·05
Physical activity			
Passive	71/116	1·00‡	
Light	87/184	0·86 (0·57–1·29)	
Heavy	40/93	0·72 (0·44–1·19)	0·20
Drinking habits			
Never or hardly ever	92/198	1·00‡	
Sometimes each month	87/181	1·07 (0·75–1·54)	
Sometimes each week	41/73	1·23 (0·77–1·98)	
Every day	17/24	1·60 (0·82–3·11)	0·16
Smoking			
Never	114/218	1·00‡	
Ever	126/259	0·92 (0·68–1·26)	
Marital status			
Married	139/282	1·00‡	
Unmarried	34/41	1·89 (1·12–3·20)	
Separated/divorced	24/56	0·91 (0·54–1·54)	
Widowed	28/60	1·01 (0·57–1·77)	
School education (years)			
<7	113/238	1·00‡	
7–10	103/192	1·12 (0·80–1·57)	
>10	23/47	1·02 (0·58–1·79)	0·69
Household income per month before taxes (DKK)			
<4000	73/143	1·00‡	
4000–10 000	124/219	1·07 (0·72–1·57)	
>10 000	33/86	0·74 (0·43–1·25)	0·35

*Women with missing data excluded. †Univariate analysis. ‡Reference group.

Table 1: Risk of breast cancer associated with reproductive characteristics, life-style factors, and demographic variables

Statistical analysis

Our main analysis was done for organochlorine compounds that are suspected to have oestrogenic properties. We also included all PCBs, all DDTs, and *p,p'*-DDE since these compounds may be indicators of previous exposure to less persistent compounds that may be oestrogenic. Explorative analysis was done for β-HCH, lindane, and chlordane metabolites. Relative risks were

Organochlorine	Proportion blood samples with detectable concentrations*	Median (IQR) blood concentrations in (ng/g)†
Total PCB	98·5%	1099·89 (547·99)
Total DDT	100%	1325·95 (1047·77)
p,p'-DDT	91·8%	141·35 (123·49)
p,p'-DDE	98·5%	1182·98 (953·62)
β-HCH	97·2%	118·94 (68·06)
Dieldrin	78·0%	24·42 (42·40)

*Irrespective of breast-cancer status. †Concentrations of lipid-adjusted organochlorine compounds.

Table 2: **Concentrations of organochlorine compounds in blood samples**

calculated from odds ratios estimated by conditional multiple logistic regression with pesticide and PCB exposure separated into four groups with quartiles as the cut-off points.[16] The quartiles were based on the frequency distribution of controls, and the SAS software (version 6) was used to obtain the odds ratios.

Adjustment was made for potential confounders, except age, which was the main matching variable. Potential confounders included weight, height, number of full-term pregnancies, alcohol consumption, smoking, physical activity, menopausal status, household income, marital status, and education. We investigated the modifying effect of the potential confounders with a backwards stepwise procedure, and only variables that reached significance ($p<0·05$) remained in the model. Number of full-term pregnancies and weight were confounders. Since bodyweight and parity seem to be related to the body burden of organochlorines, the significance of interactions between these and serum organochlorine concentrations were assessed. No interaction reached significance and, therefore, were not included in the final model. 95% CIs for odds ratios were calculated from the SEs of the regression coefficients. We also tested for trend in risk with concentrations of organochlorine pesticides and PCBs.[16]

Results

The risk of breast cancer decreased with increasing number of full-term pregnancies, and increased with increasing bodyweight and height. Unmarried women had an 89% higher risk of breast cancer than married women. Non-significant risks were associated with physical activity and alcohol consumption, whereas there was no association with smoking, school education, and household income (table 1).

All women had measurable concentrations of at least one of the DDTs, more than 90% had detectable PCBs and β-HCH, and about 78% had detectable dieldrin (table 2).

The risk of breast cancer was twice as high in women with the highest serum concentrations of dieldrin as that in women with the lowest concentrations, and a significant dose-response relation was apparent (odds ratio 2·25 [95% CI 1·32–3·84], p for trend 0·003; table 3). We found also a slight increase in risk of breast cancer with increasing concentrations of β-HCH. No association was apparent for total DDT, *p,p'*-DDE, *p,p'*-DDT, total PCB or any specific congeners, kepone, lindane, or chlordane metabolites (data not shown). After mutual adjustment for organochlorine compounds and potential confounders the odds ratios remained unchanged (table 3).

Exclusion of women who developed breast cancer within 5 years of serum sampling strengthened the results for dieldrin and β-HCH, but did not alter the other results when adjusted for parity and weight (dieldrin 2·65 [1·36–5·17], p for trend 0·002; β-HCH 1·53 [0·83–2·81], p for trend 0·15).

To assess possible synergism between organochlorine compounds, we compared women in the highest quartile with those in the lowest quartiles for the folowing pairs of compounds: total PCB and total DDT, total PCB and *p,p'*-DDE, total PCB and dieldrin, and dieldrin and β-HCH. We found no synergistic effect.

Organochlorines	Number of cases/controls	Unadjusted odds ratio (95% CI)*	Adjusted odds ratio (95% CI)†	p for trend in odds ratio	
				Unadjusted	Adjusted
Total PCB					
I	68/117	1·00‡	1·00‡		
II	61/118	0·89 (0·57–1·39)	0·92 (0·58–1·45)		
III	46/117	0·68 (0·43–1·08)	0·78 (0·48–1·26)		
IV	63/117	0·95 (0·61–1·47)	1·11 (0·70–1·77)	0·60	0·77
Total DDT					
I	43/81	1·00‡	1·00‡		
II	37/82	0·82 (0·48–1·41)	0·79 (0·45–1·39)		
III	46/82	1·01 (0·60–1·69)	0·92 (0·54–1·58)		
IV	40/81	0·92 (0·54–1·56)	0·84 (0·49–1·45)	0·93	0·65
***p,p'*-DDT**					
I	55/115	1·00‡	1·00‡		
II	59/117	1·09 (0·70–1·70)	1·07 (0·68–1·68)		
III	51/119	0·92 (0·57–1·48)	0·91 (0·56–1·47)		
IV	72/119	1·31 (0·84–2·02)	1·19 (0·76–1·87)	0·32	0·57
***p,p'*-DDE**					
I	65/115	1·00‡	1·00‡		
II	55/116	0·85 (0·54–1·33)	0·83 (0·53–1·31)		
III	55/119	0·79 (0·50–1·24)	0·77 (0·49–1·22)		
IV	62/119	0·94 (0·61–1·45)	0·88 (0·56–1·37)	0·72	0·52
β-HCH					
I	52/117	1·00‡	1·00‡		
II	56/118	1·14 (0·70–1·87)	1·13 (0·69–1·86)		
III	66/118	1·43 (0·85–2·41)	1·35 (0·79–2·30)		
IV	63/117	1·36 (0·80–2·31)	1·26 (0·79–2·33)	0·21	0·24
Dieldrin					
I	41/117	1·00‡	1·00‡		
II	57/118	1·62 (0·98–2·73)	1·58 (0·93–2·67)		
III	66/117	2·04 (1·19–3·47)	1·96 (1·14–3·39)		
IV	73/117	2·25 (1·32–3·84)	2·05 (1·17–3·57)	0·003	0·01

*Univariate analysis. †Adjusted analysis. ‡Reference group.

Table 3: **Risk of breast cancer in relation to lipid-adjusted serum concentrations of organochlorines in quartiles**

Discussion

Organochlorines such as dieldrin, which has oestrogenic effects, might increase the risk of breast cancer. Previous prospective studies have given ambiguous results. In a cohort of 14 290 women from New York diagnosed with breast cancer 1–6 months after blood sampling, women with the highest serum concentrations of total PCB and DDE had a four-fold increase in the risk of breast cancer.[17] Another study that followed up 57 040 women in California, USA, for about 20 years showed a similar trend, but only in black women.[18] The largest study tested serum from 240 women with breast cancer and an equal number of controls taken from a cohort of 32 826 US nurses. The results of that study could not confirm the results of the other two studies.[19] The blood samples were, however, collected between 1989 and 1990, and follow-up for breast cancer was done only until mid-1992.

Organochlorine compounds generally distribute evenly in the lipid phase of the body, and the concentrations are proportional to the lipid content of the tissue.[1] Food consumption increases the serum lipid concentration and can, therefore, affect the organochlorine concentrations. To compare serum organochlorine concentrations between individuals, blood samples should be taken under fasting conditions or the concentrations adjusted for serum lipid content.[14] Only one previous study has made any adjustment, but only for cholesterol. That approach is, however, only partially successful in correction for non-fasting variations.[14,19] Measurements of serum cholesterol and triglycerides at the start of our study, which made it possible to estimate total serum lipid content and make a full adjustment.

Previous studies have focused solely on DDE and total PCB. Experimental evidence suggests that *o,p'*-DDT is oestrogenic, and a slight oestrogenic effect in some animal studies has been noted for *p,p'*-DDT.[5,6,20] The major effect of *p,p'*-DDE may rather be the ability to block the effect of testosterone.[21,22]

The situation is even more complex for PCBs. Some congeners seem to have oestrogenic effects, especially those that contain less than 48% chlorine, in particular after hydroxylation.[5] Other congeners bear structural similarities to dioxins, which exhibit antioestrogenic activity in vitro.[23,24] The overall effect of a mixture of PCBs will, therefore, depend on the concentrations of relevant congeners. Therefore, when looking at total PCBs and DDE alone an association between these substances and risk of breast cancer would not be expected unless the serum concentrations of these compounds reflects hydroxylated or low chlorinated PCB congeners, and *o,p'*-DDT or *p,p'*-DDT. The lack of association between total PCB, total DDT, or *p,p'*-DDE and risk of breast cancer seen in our study seems to be meaningful. Information on *o,p'*-DDT was insufficient because only 20% of the serum samples contained this compound in detectable amounts.

There may be a threshold above which organochlorine compounds exert their effect on risk of breast cancer. Our initial mean unadjusted lipid concentrations of total PCB and DDE were within the range of those found in the New York cohort 10 years later[17] (CCHS—total PCB cases 8·6 ng/mL, controls 8·7 ng/mL; DDE cases 10·2 ng/mL, controls 10·5 ng/mL; New York—total PCB cases 8·0 ng/mL, controls 6·7 ng/mL; DDE 11·0 ng/mL, controls 7·7 ng/mL). A threshold effect cannot explain the differences in these findings.

In our study, the risk of breast cancer increased slightly with increasing serum concentrations of β-HCH. This result should be taken to be hypothesis generating. Before a causal relation can be identified for exposure to β-HCH, our findings require replication, and the biological plausibility of an association with breast cancer needs further investigation. We did, however, see a significant dose-related association between dieldrin and risk of breast cancer. This relation is biologically supported by the oestrogenic properties of dieldrin in the E-screen test with oestrogen-receptor-positive breast cancer cells, and in a modified yeast strain containing the human oestrogen receptor.[7,10]

Organochlorine concentrations in serum have not been measured previously in Denmark, but human breastmilk was analysed in 1982. The average lipid-based concentrations of DDE, total PCB, dieldrin, and β-HCH in breastmilk from 57 Danish women were lower than the serum concentrations that we found.[25] With the temporal span between our study and the breastmilk survey, a secular decline would be expected. The CCHS cohort seems, therefore, to be representative of Danish women for organochlorine concentrations.

The quality of serum samples stored frozen for several years may be questionable.[26] We addressed this issue by measuring serum cholesterol again. The mean concentrations in 1996 were the same as those in 1976 (6·1 [1·5] mmol/L; 6·4 [SD 1·3] mmol/L).

Even though our study includes more women with breast cancer than most previous studies, it still has limited statistical power, which makes firm conclusions difficult. Risk estimates for established breast cancer risk factors are, however, in accordance with other studies.[3]

There was a possibility of mass significance because we assessed the association of several organochlorine compounds with risk of breast cancer. To avoid the difficulty of multiple comparisons, we focused on organochlorine compounds known to have or suspected of having oestrogenic activity.[5–7]

The strengths of this study are the prospective design, long follow-up, and well-characterised participants. Study participants were selected independently of risk of developing breast cancer from a well-defined homogeneous population that represented a fifth of the background population in the study area. Measurement of organochlorine concentrations for most women was based on blood samples taken several years before the diagnosis of breast cancer, which has been done in only one previous study.[18] The influence of metabolic effects in preclinical breast cancer stages on the results was, therefore, limited. Furthermore, exclusion of all women who developed breast cancer within 5 years of sampling strengthened the result for dieldrin and β-HCH, but did not alter the results for total PCB, total DDT and its isomers.

The sustainable amount of information contained in the CCHS assures the ability to adjust sufficiently for potential confounding. There is a lack of information about lactation, which is the major route by which women excrete organochlorine compounds and has an effect on the association between DDE and risk of breast cancer.[17,26–28] Lactation may not, however, be a likely confounder, since it is not an established risk factor for breast cancer.[29] We adjusted for number of full-term pregnancies, which to a certain extent would account for history of lactation. Furthermore, we found no

interaction between parity and serum organochlorine concentrations. There is, therefore, no substantial difference in risk of breast cancer in relation to exposure to organochlorines between women who have never given birth and parous women.

Although several organochlorine compounds have oestrogenic properties in bioassays, the low potencies of these compounds suggest that they would have little effect on risk of breast cancer. There is, nevertheless, evidence of a synergistic effect of weak xeno-oestrogens.[7,10] As in the cohort of US nurses, however, we identified no evidence of synergism.[10]

Our results support the hypothesis that organochlorine compounds such as dieldrin, which have oestrogenic properties, may increase the risk of breast cancer. They do not, however, suggest that exposure to total PCB, total DDT, and *p,p'*-DDE have any influence on risk of breast cancer.

Contributors

Annette Pernille Høyer initiated the study. The design was done in collaboration with Torben Jørgensen and Philippe Grandjean. Annette Pernille Høyer organised the data, discussed the core ideas, participated in the data analysis, interpreted the results, was the main writer of the paper, and acts as guarantor. Helle Boggild Hartvig did the statistical analysis and John W Brock the pesticide analyses. Both participated together with Torben Jørgensen and Philippe Grandjean in discussion about core ideas, interpretation of results, and edited the paper.

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The National Biomonitoring Program: Better exposure assessment to prevent cancer, birth defects and other diseases caused by exposure to toxic substances ($15 million)

This initiative expands CDC's biomonitoring program to accurately assess ***individual human exposure*** by measuring toxic substances ***directly in blood or urine***. Biomonitoring identifies exposures that cause cancer, birth defects and other diseases; improves exposure assessment; reduces uncertainty in risk assessment; evaluates the effectiveness of interventions to reduce human exposure; provides individual exposure information for children and persons at high risk of dangerous exposures; saves money and needless anxiety by recognizing exposures of negligible health consequence; and provides essential exposure data needed for medical management of persons exposed to toxic substances. CDC is nationally and internationally recognized for its expertise in biomonitoring and performs many biomonitoring measurements that are ***unique in the world.*** This initiative expands the National Biomonitoring Program to markedly improve our ability to prevent disease caused by exposure to toxic substances.

National Exposure Report Card ($6 million)

Current funding: CDC measures the exposure of the U.S. population to 50 toxic substances known or suspected to cause cancer, birth defects, or other diseases. Blood and urine samples from approximately 1500 participants (that collectively represent the U.S. population) are measured for these 50 toxic substances each year. Examples of toxic substances measured include lead, cadmium, arsenic, mercury, uranium, DDT, dieldrin, chlordane, benzene, MTBE, and methylene chloride. In late FY2000, the first year's National Exposure Report Card will be available on the internet and updated each year.

New funding: Additional funding of $6 million dollars will allow the National Exposure Report Card to assess exposure of the U.S. population to 75 *additional* toxic substances that are known or reasonably expected to cause cancer. These include substances that may cause breast cancer through their similarity to estrogen. A list of these 75 substances is attached. This data would provide the first ever assessment of the exposure of the population to these dangerous substances and each year would show whether exposure levels are going up or down for each individual carcinogen. The information would also include exposure information for population subgroups such as women of childbearing age, children, minorities and the elderly. This human exposure information is *absolutely critical* for public health decisions on what interventions need to be implemented to reduce exposure to carcinogens and to assess whether those interventions are effective.

Development of methods to measure toxic substances in people ($5 million)

Current funding: CDC can currently measure about 200 toxic substances in human blood and urine. People in the U.S. are regularly exposed to tens of thousands of chemical compounds and we are currently unable to measure these in people to determine if exposures are safe or dangerous. With current funding, CDC develops methods to measure 10 new toxic substances per year in people and to improve methods (make them more accurate, faster, less costly) for an additional 10 toxic substances per year.

New funding: With $5 million additional funding, CDC would increase research and develop methods to measure 15 additional toxic substances per year in people (a total of 25) and improve methods for an additional 10 toxic substances per year (a total of 20). Compounds known or suspected of causing cancer, birth defects, respiratory, and other diseases will receive highest priority.

Health studies to determine what toxic substances and what exposure levels cause cancer, birth defects, and other diseases ($4 million)

Current funding: CDC's special capabilities to measure human exposure to toxic substances using biomonitoring is essential for studies that determine what levels of exposure are safe and what levels cause disease. Without CDC's individual exposure assessment, people cannot know if they are exposed to a trivially low level that is of no health concern, to an intermediate level of moderate health concern, or a high level that will cause serious disease or death. CDC collaborates with academic institutions, health organizations, foreign governments, states, and communities in planned studies of risk of cancer, birth defects, and other disease that result from differing levels of exposure to toxic substances. Currently, CDC collaborates in 20-25 such studies per year.

New funding: With additional funding of $4 million, CDC would increase the number of health studies to 50-60 per year. Priority would be given to studies designed to evaluate cancer risk from exposure to potential carcinogens and to risk of birth defects from exposure to chemicals that may cause birth defects.

Additional 75 carcinogens to be added to the National Exposure Report Card

4-Aminobiphenyl
Azathioprine
Benzidine
Bis(chloromethly)ether and Technical-Grade Chloromethyl Methyl Ether
1,4-Butanediol Dimethylslfonate (Myleran)
Melphalan
2-Naphthylamine
Vinyl Chloride
2-Acetylaminofluorene
Acrylonitrile
2-Aminoanthraquinone
o-Aminoazotoluene
1-Amino-2-methlyanthraquinone
o-Anisidine Hydrochloride
Benxotrichloride
Bromodichloromethane
1,3-Butadiene
Butylated hydroxyanisole
3-Chloro-2-methylpropene
4-Chloro-o-phenylenediamine
2,4-Diaminotoluene
1,2-Dibromo-3-chloropropane
1,2-Dibromoethane (EDB)
3,3-Dichlorobenzidine and 3,3'-Dichlorobenzidine Dihydrochloride
Di(2-ethylhexyl)phthalate
3,3'-Dimethoxybenzidine and 3,3'-Dimethoxybenzidine
4-Dimethylaminoazobenzene
3,3'-Dimethylbenzidine
1,1-Dimethylhydrazine
Dimethyl Sulfate
Dimethylvinyl Chloride
1,4-Dioxane
Estradiol-17
Estrone
Ethinylestradiol
Mestranol
Ethyl Methanesulfonate
Hexamethylphosphoramide
Hydrazine and Hydrazine Sulfate
Hydrazobenzene
Kepone® (Chlordecone)
2-Methylaziridine (Propyleneimine)
4-4'-Methylenebis (N,N-dimethyl) benzenamine
4,4'-Methylenedianiline and its Dihydrochloride
Methyl Methanesulfonate
N-Methyl-N'-nitro-N-nitrosoguanidine
Metronidazole
Mirex
N-Nitrosodi-n-butylamine
N-Nitrosodiethanolamine
N-Nitrosodiethylamine
N-Nitrosodimethylamine
N-Nitrosodi-n-propylamine
N-Nitroso-N-ethylurea
4-(N-Nitroso methylamine)-1-(3-pryidyl)-1-butanone
N-Nitroso-N-methylurea
N-Nitrosomethylvinylamine
N-Nitrosomorpholine
N-Nitrosonornicotine
N-Nitrosopiperidine
N-Nitrosopyrrolidine
Norethisterone
Phenoxybenzamine Hydrochloride
Polycyclic Aromatic Hydrocarbons
- Benz[a]anthracene
- Benzo[b]fluoranthene
- Benzo[j]fluoranthene
- Benzo[k]fluoranthene
- Benzo[a]pyrene
- Dibenz[a,h]acridine
- Dibenz{a,j]acridine
- Dibenz[a,h]anthracene
- 7H-Dibenzo[c,g]carbazole
- Dibenzo[a,e]pyrene

Dibenzo[a,h]pyrene
Dibenzo[a,j]pyrene
Dibenzo[a,l]pyrene
Indeno[1,2,3-cd]pyrene
5-Methylchrysene

2,3,7,8-Tetrachlorodibenzo-p-dioxin
(TCDD) and 17 related dioxin congeners
Thioacetamide
Toluene Diisocyanate
o-Toluidine and o-Toluidine Hydrochloride
2,4,6-Trichlorophenol

Steve Reynolds

October 27, 1999

President William Jefferson Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C., 20500

Dear President Clinton,

As our nation observes Breast Cancer Awareness this month, we are encouraged by the government's commitment to developing new treatments and possible cures for the disease. A different kind of research is needed now, however, to uncover why women are getting breast cancer in the first place, so we can prevent new cases.

We are writing to urge your support in forging a bold new path in breast cancer research — one that examines the potential pathways for prevention, including the link between the disease and the chemicals in the air we breathe, the water we drink, the food we eat, and the products we buy.

This year, an estimated 43,300 women nationwide will die of breast cancer. In the past 50 years, since World War II, the rate of breast cancer among women has more than doubled. Yet, in as many years, cancer research has yielded only two known causes of the disease: radiation and genetic defects. And while scientists have identified a handful of factors associated with increased risk, these factors, taken all together, account for less than half of breast cancer incidence. Today, we remain unable to explain the causes behind the majority of all breast cancer cases or the reasons for increasing risk over the past several decades.

But here's what we do know: If cancer is the crime, among the suspects are toxicants in our environment. Laboratory research shows that approximately 100 chemicals in current use give rise to mammary gland cancer in animals. There are 75,000 chemicals in commerce today. We know a little about the toxic nature of less than 3,000 of them. However, some of these chemicals can cause cancer. Others can interfere with hormone systems that affect cancer growth.

We have a right to know what toxic chemicals are in our bodies and the impact these agents may have on our health. Toward that end, we urge your commitment and action on the following:

- Increase funding for research that examines the environmental links to breast cancer. Currently, funding for environmental research represents only a tiny fraction of the government's budget for disease research. Of the National Institutes of Health's $15 billion budget this year, just $382 million, or 2.4 percent,

this is a #1 priority for CDC Environmental Health Lab. 2001 they could do a lot more with $15 million

went to the National Institute of Environmental Health Sciences, the primary agency that conducts research on environmental health.

epidemiologic side to that

- Establish a national registry and inventory of the chemicals in our bodies. Researchers at the Centers for Disease Control's Environmental Health Lab are currently studying human blood samples to identify what chemicals are present in our bodies and at what levels. Their findings will inform future efforts to reduce or eliminate exposure to harmful chemicals. This "biomonitoring" research deserves more funding and should be expanded to include a wider range of chemicals, as well as testing of breast milk, which often contains high levels of carcinogenic and hormone-disrupting chemicals.

data for

good ideas

report card

ATSDR; Nat Centers for Envir

- Fully fund the Environmental Protection Agency's program to screen and test "hormone disrupters," environmental toxicants that mimic estrogen and can cause the rapid growth of cancer cells.

endocrine disrupters

- Establish a cross-agency committee to oversee government funding for environmental health research. Recently, a $15 million appropriation earmarked for a study that would have explored environmental factors in regions with high breast cancer incidence was diverted to unrelated projects on genetics and air pollution. A cross-agency oversight committee that includes consumer participation would help insure the correct and wisest placement of new funding.

no redund.

enough momentum for this — interest & awareness

there was a commission that looked into this to see if there is any redundancy (Nat Env. Institute idea that died

We welcome the opportunity to discuss the above in greater detail with you and your staff. Time is of the essence. Women at risk for breast cancer - which is all women - are engaged in a battle to save our bodies and our lives. Until we arm ourselves with new intelligence about the causes of the disease, we will continue to fight blindfolded. On behalf of our mothers, sisters and daughters, we call on you to vigorously support policy and research that will empower us to fight with both eyes open.

Sincerely,

Claudia Prorata 404 639 7281

(see attached list of endorsers)

Dr. Tim Tinker (ATSDR) 404 639 5018

cc: Bill Bradley
Vice President Al Gore
Governor George W. Bush

Marilyn Bisirio 770 488 7020 Nat Center for Environ Health

Tom Sinks 770 488 7007

Alison Kelly 770 488 7250

what's our overall strategy?

Call for Research into the Possible Environmental Causes of Breast Cancer: List of Endorsers

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Minneapolis, MN

Gwendolyn Barker, Teacher
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Gwen Reed, Member
African American Breast Cancer Alliance, Inc.
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Anne S. Pruitt-Logan, President
Black Women's Agenda, Inc.
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Clarita Herrera, M.D., President
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Elsa Ford

Elsa Ford, President
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Lorraine Pace
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Founder, Breast Cancer Mapping Project
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Meryl Streep & Wendy Gordon, Co-Founders
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Linda Blachman, Founder & Director
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Marj Plumb
Marj Plumb & Associates
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Gloria Steinem
Writer, Lecturer, Consulting Editor, *Ms. Magazine
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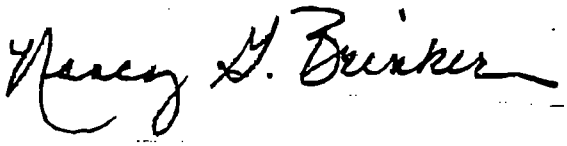

Nancy Brinker, Founding Chair
Susan Braun, President & CEO
The Susan G. Komen Foundation
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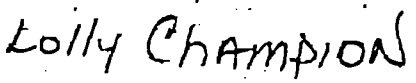
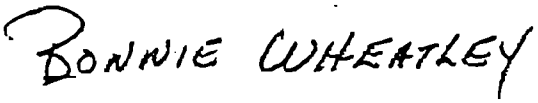
Carmen Austin, Director/Facilitator
African American Breast Cancer Support
Walnut Ave. Women's Center
Santa Cruz, CA



Lolly Champion
Education & Outreach for Central and Eastern Oregon
The Susan G. Komen Foundation,
Oregon, SW Washington Affiliate
Benet, OR



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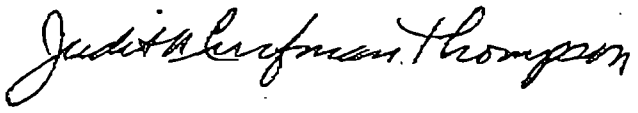
Oakland, CA

Patricia M. Years, President
The Susan G. Komen Foundation, San Diego Affiliate
El Canon, CA

Terry Tempest Williams, Writer
Castle Valley, UT



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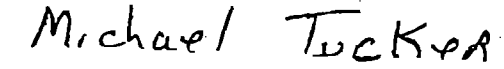
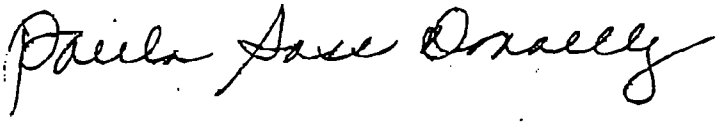
*South Carolina Nurses Association
Columbia, SC

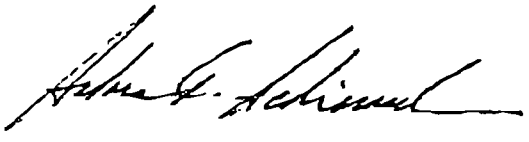
Connie Batten, Director
WomenCARE
Santa Cruz, CA



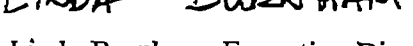
Michael Tucker, Actor
Mill Valley, CA



Paula Sass Donnelly, Chair
Women In Search of Health
Santa Fe, NM



Selma R. Schimmel, President & CEO
Vital Options
Sherman Oaks, CA



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Women of Color Resource Center
Berkeley, CA

Diane Estrin

Diane Estrin, Executive Director
Women's Cancer Resource Center
Berkeley, CA

Ceci Shapland

Ceci Shapland, Executive Director
Women's Cancer Resource Center
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Vera Spohr Cohen

Vera Spohr Cohen
Women's Community Cancer Project
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Pamela Ransom PhD

Pamela Ransom, Ph.D.
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* Organization included for identification purposes only.

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Mrs. G. Landry Humphrey, Founder
Women's Network for Cancer Prevention
Los Angeles, CA

Susan N. Nathanson

Susan N. Nathanson, Ph.D., Executive Director
Y-ME National Breast Cancer Organization
Chicago, IL

Prema Mathai-Davis

Prema Mathai-Davis, CEO
YWCA of the U.S.A.
Washington, D.C.

Olivia Newton John, Actress
Los Angeles, CA

Call for Research into the Possible Environmental Causes of Breast Cancer:
List of Endorsers

PROMINENT INDIVIDUALS

- Gloria Steinem, Writer, Lecturer, Consulting Editor, *Ms. Magazine
  New York, NY
- Angela Davis, Professor
  *University of California, Santa Cruz
  Oakland, CA
- Kate Millet, Writer
  New York, NY
- Terry Tempest Williams, Writer
  Castle Valley, UT
- Meryl Streep & Wendy Gordon
  Co-Founders, Mothers & Others
  New York, NY

NATIONAL ORGANIZATIONS

- Patricia Ireland, President
  National Organization for Women
  Washington, D.C.
- Dr. Clarita Herrera, M.D., President
  American Medical Women's Association
  Alexandria, VA
- Marie Wilson, President
  Ms. Foundation for Women
  New York, NY
- Jane E. Smith, President & CEO
  National Council of Negro Women, Inc.
  Washington, D.C.
- Prema Mathai-Davis, CEO
  YWCA of the U.S.A.
  Washington, D.C.
- Gloria T. Johnson, National President
  Coalition of Labor Union Women
  Washington, D.C.
- Andrea Martin, Founder & Executive Director
  The Breast Cancer Fund
  San Francisco, CA
- Nancy Brinker, Founding Chair,
  Susan Braun, President & CEO
  Susan G. Komen Breast Cancer Foundation
  Dallas, TX
- Susan Biachi-Sand, Chair
  National Council of Women's Organizations
  Washington, D.C.
- Bonnie Lipton, President
  Hadassah
  New York, NY
- Anne S. Pruitt-Logan, President
  Black Women's Agenda, Inc.
  Washington, D.C.
- Barbara Ferris, President
  International Women's Democracy Center
  Washington, D.C.
- Eileen Meier, Health Policy Associate
  Oncology Nursing Society
  Washington, D.C.
- Carol Kerry, Co-Chair
  DES Cancer Network,
  Washington, D.C.

CALIFORNIA

- African American Breast Cancer Alliance
- Asian and Pacific Island National Cancer Survivors Network
- Asian and Pacific Islander American Health Forum
- Breast Cancer Action
- Breast Cancer Alliance of California
- Breast Cancer Coalition of California
- California Breast Cancer Treatment Fund
- California Health Collaborative
- Central CA Breast Cancer Partnership of the California Health Collaborative
- California Women's Law Center
- Charlotte Maxwell Complementary Clinic
- Community Health Partnership
- Community Breast Health Project
- Healing Journeys, Inc.
- Humboldt Community Breast Health Project
- Link to Life
- Margaret Cruz Latina Breast Cancer Foundation
- Margery Tabankin & Associates
- Marj Plumb & Associates
- Marin Breast Cancer Committee
- Marin Breast Cancer Watch
- Mendocino Cancer Resource Center

* Organization included for identification purposes only

CALIFORNIA, continued

- Mothers' Living Stories Project
- The Pacific Institute For Women's Health
- Partnered for Progress
- Planned Parenthood Golden Gate
- Sisters Advocating Against Cancer
- Vital Options
- Walnut Ave. Women's Center
- Women's Information Network (WIN) Against Breast Cancer
- Women's Cancer Resource Center
- Women CARE
- Women of Color Resource Center
- Women's Network for Cancer Prevention

COLORADO

- Colorado Breast Cancer Coalition

ILLINOIS

- Y-ME National Breast Cancer Organization

KENTUCKY

- Kentucky Breast Cancer Coalition

LOUISIANA

- Louisiana Breast Cancer Task Force

MASSACHUSETTS

- Massachusetts Breast Cancer Coalition
- Marblehead Cancer Prevention Project
- Pioneer Valley Breast Cancer Network
- Silent Spring Institute
- Women's Community Cancer Project

MINNESOTA

- African American Breast Cancer Alliance, Inc.
- Women's Cancer Resource Center

NEW JERSEY

- Center for Women's Global Leadership

NEW MEXICO

- People Living through Cancer
- Women In Search of Health
- Action for Women's Health

NEW YORK

- 1 in 9 The Long Island Breast Cancer Action Coalition
- Breast Cancer Help
- Breast Cancer Network of WNY, Inc.
- Breast Cancer Coalition of Rochester
- Brentwood/Bay Shore Breast Cancer Coalition
- Cancer Awareness Coalition
- Group for the South Fork
- Huntington Breast Cancer Action Coalition
- Informed Decisions
- Ithaca Breast Cancer Alliance
- Women's Environment and Development Organization

TEXAS

- Breast Cancer Resource Center of Austin
- Intercultural Cancer Council

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- Lisa Bailey, M.D.
- Gwendolyn Barker
- Terri G. Cowger
- Devra Lee Davis
- Jill Eikenberry
- Nancy Evans
- Donna G. Horne, M.D.
- Olivia Newton John
- Kate Monico Klein
- Lisa R. Lambiase
- Cynthia M. Lewis
- Jill Sheinberg
- Gina Solomon, M.D., M.P.H.
- Judith Curfman Thompson
- Michael Tucker
- Bonnie Wheatley

For more information, contact Kasia Grisso or Lisa Chen at (415)255-1946

how to deal with this within the FY 01 budget process

Devorah Adler

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Phone: 202-456-5707

Exposure to organochlorine pesticides and risk of breast cancer

Some organochlorine pesticides have estrogen-like activity in the body, raising concern that they may cause or increase risk for breast cancer. In a collaborative study with investigators from Denmark, CDC's Environmental Health Laboratory measured exposure of Danish women to organochlorine pesticides to see if levels were related to breast cancer. These women were not occupationally exposed to organochlorine pesticides and their serum levels were similar to women in the United States.

In this study of 268 women with breast cancer, exposure to the pesticide dieldrin in the upper quartile was associated with a 2.1 fold increased risk of developing breast cancer compared to the lowest quartile. The upper quartile represented the highest quartile of exposure to dieldrin by women in the general population. In addition, women with breast cancer in the upper quartile were more than 2.5 times likely to die of breast cancer than women with breast cancer in the lowest quartile of dieldrin levels. Dieldrin exposure appeared to not only increase risk of breast cancer but also to decrease life expectancy in persons with breast cancer. The laboratory is collaborating in several additional studies of organochlorine pesticides to further investigate this finding.

Exposure to polychlorinated biphenyls (PCBs) and risk of non-Hodgkins lymphoma

The incidence of non-Hodgkins lymphoma has been increasing in the United States since the 1940's. In collaboration with investigators from the National Cancer Institute, Johns Hopkins University and Georgetown University, CDC's Environmental Health laboratory measured the exposure of 74 cases of non-Hodgkins lymphoma and 147 controls to organochlorine pesticides including PCBs. Persons in the study were from Washington County, Maryland and had exposure to PCBs typical of the general population.

There was a strong dose-response relationship between quartiles of PCB concentrations and risk of non-Hodgkin's lymphoma, with persons in the highest quartile at 4.5 times increased risk when compared to the lowest quartile. In addition, persons in the upper half of PCB concentrations and seropositive for Epstein-Barr virus had more than a 22 fold increased risk for non-Hodgkins lymphoma compared to persons seropositive for Epstein-Barr virus and in the lower half of PCB concentrations. The laboratory is collaborating in a followup study to further investigate these findings.

Illegal indoor spraying of methyl parathion

Methyl parathion is a powerful pesticide that can kill people by paralyzing muscles necessary to breathe, like a "junior strength" nerve agent. It is approved only for use outdoors, principally for pests attacking cotton. Previously, two children in Mississippi have died from indoor spraying of methyl parathion. In the mid 90's, methyl parathion was illegally sprayed in thousands of homes in Illinois, Mississippi, Louisiana, Texas, Tennessee, Arkansas and Alabama as a pest control agent. Believing the chemical to be safe, people had sometimes requested extra spraying on cribs or carpets in front of the TV to be sure pests did not bother their children.

Since homeowners rarely verified what pest control agents were being sprayed in their homes, health officials were faced with thousands of homes potentially contaminated with no method of determining which families were exposed and which were safe. CDC's Environmental Health Laboratory developed a urine test for methyl parathion that was used by state and federal health officials to decide who had been exposed and how much exposure each

person has had. Based on the urine measurement of methyl parathion, health officials prioritized medical treatment of exposed children and adults and determined which homes should be evacuated and remediated. From November 1996 through February 1999, the laboratory performed urine tests on more than 15,000 persons. The urine measurements provided unique individual assessments of exposure that otherwise would not have been available. In addition to identifying persons with elevated levels requiring prompt attention, the measurements also reassured thousands of persons, who did not know what had been sprayed in their homes, that they had no exposure.

Date: 2/2/00

FAX

Health Division

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

To: Devorah Adler

Fax: ~~[redacted]~~ x65557

From: Gretchen Morley x57827

Number of Pages (excluding cover):

Subject: Breast Cancer info

Voice Numbers:

Health Division (Front Office)	202/395-4922
Health & Human Services Unit	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7840
Health Division (Room 7002)	202/395-5648

202 395 4922

Mr. KLECZKA, Mr. PAYNE, Mr. WYNN, Mr. JEFFERSON, Mr. SMITH of New Jersey, Mr. MASCARA, Mr. LOBIONDO, Mr. OBERSTAR, Mr. LEACH, Mr. RUSH, Mr. MATSUI, Mr. DINGELL, Mrs. EMERSON, Mr. FILNER, Mrs. MYRICK, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Commerce

---

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. OPTIONAL MEDICAID COVERAGE OF CERTAIN BREAST OR CERVICAL CANCER PATIENTS.

(a) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP-

(1) IN GENERAL- Section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended--

(A) in subclause (XIII), by striking `or' at the end;

(B) in subclause (XIV), by adding `or' at the end; and

(C) by adding at the end the following:

`(XV) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);'.

(2) GROUP DESCRIBED- Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following:

`(aa) Individuals described in this paragraph are individuals who--

`(1) are not described in subsection (a)(10)(A)(i);

`(2) have not attained age 65;

`(3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and

`(4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (45 U.S.C. 300gg(c)).'.

(3) LIMITATION ON BENEFITS- Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (F)--

(A) by striking `and (XIII)' and inserting `(XIII)'; and

(B) by inserting `, and (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XV) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer' before the semicolon.

(4) CONFORMING AMENDMENTS- Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended in the matter preceding paragraph (1)--

(A) in clause (x), by striking `or' at the end;

(B) in clause (xi), by adding `or' at the end; and

(C) by inserting after clause (xi) the following:

`(xii) individuals described in section 1902(aa),'.

(b) PRESUMPTIVE ELIGIBILITY-

(1) IN GENERAL- Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1920A the following:

`PRESUMPTIVE ELIGIBILITY FOR CERTAIN BREAST OR CERVICAL CANCER PATIENTS

`SEC. 1920B. (a) STATE OPTION- A State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(aa) (relating to certain breast or cervical cancer patients) during a presumptive eligibility period.

`(b) DEFINITIONS- For purposes of this section:

`(1) PRESUMPTIVE ELIGIBILITY PERIOD- The term `presumptive eligibility period' means, with respect to an individual described in subsection (a), the period that--

`(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(aa); and

`(B) ends with (and includes) the earlier of--

`(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

`(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

`(2) QUALIFIED ENTITY-

`(A) IN GENERAL- Subject to subparagraph (B), the term `qualified entity' means any entity that--

`(i) is eligible for payments under a State plan approved under this title; and

`(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

`(B) REGULATIONS- The Secretary may issue regulations further limiting those entities that may become qualified entities in order to prevent fraud and abuse and for other reasons.

`(C) RULE OF CONSTRUCTION- Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities, consistent with any limitations imposed under subparagraph (B).

`(c) ADMINISTRATION-

`(1) IN GENERAL- The State agency shall provide qualified entities with--

`(A) such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and

`(B) information on how to assist such individuals in completing and filing such forms.

`(2) NOTIFICATION REQUIREMENTS- A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall--

`(A) notify the State agency of the determination within 5 working days after the date on which determination is made; and

`(B) inform such individual at the time the determination is made that an application for medical assistance under the State plan is required to be made by not later than the last day of the month following the month during which the determination is made.

`(3) APPLICATION FOR MEDICAL ASSISTANCE- In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively

eligible for medical assistance under a State plan, the individual shall apply for medical assistance under such plan by not later than the last day of the month following the month during which the determination is made.

`(d) PAYMENT- Notwithstanding any other provision of this title, medical assistance that--

`(1) is furnished to an individual described in subsection (a)--

`(A) during a presumptive eligibility period;

`(B) by a entity that is eligible for payments under the State plan; and

`(2) is included in the care and services covered by the State plan;

shall be treated as medical assistance provided by such plan for purposes of section 1903(a)(5)(B).'.

(2) CONFORMING AMENDMENTS-

(A) Section 1902(a)(47) of the Social Security Act (42 U.S.C. 1396a(a)(47)) is amended by inserting before the semicolon at the end the following: `and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section'.

(B) Section 1903(u)(1)(D)(v) of such Act (42 U.S.C. 1396b(u)(1)(D)(v)) is amended--

(i) by striking `or for' and inserting `, for'; and

(ii) by inserting before the period the following: `, or for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section'.

(c) ENHANCED MATCH- Section 1903(a)(5) of the Social Security Act (42 U.S.C. 1396b(a)(5)) is amended--

(1) by striking `an' and inserting `(A) an';

(2) by adding `plus' after the semicolon; and

(3) by adding at the end the following:

`(B) an amount equal to 75 percent of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of breast or cervical cancer-related treatment services; plus'.

(d) EFFECTIVE DATE- The amendments made by this section apply to medical assistance furnished on or after October 1, 1999, without regard to whether final regulations to carry out such amendments have been promulgated by such date.

END

CONGRESSIONAL BUDGET OFFICE
U.S. CONGRESS
WASHINGTON, DC 20515

Dan L. Crippen
Director

November 10, 1999

Honorable Tom Bliley
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1070, the Breast and Cervical Cancer Prevention and Treatment Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Dorothy Rosenbaum who can be reached at 226-9010.

Sincerely,

Dan L. Crippen

Enclosure

cc: Honorable John D. Dingell
Ranking Minority Member

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 Bimbaum (Medicare and CDC), Julia Christensen (Food and Drug Administration) (226-9010)
Impact on State, Local, and Tribal Governments: Leo Lex (225-3220)
Impact on the Private Sector: Rekha Ramesh (225-2613)

ESTIMATE APPROVED BY:

Robert A. Sunshine
Assistant Director for Budget Analysis

National Breast and Cervical Cancer Early Detection Program

From 1991 through March 31, 1999, the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provided more than 2.2 million screenings. A total of 676,474 women received 1,049,752 mammograms and 761,822 women received 1,192,346 Pap tests. African-American women received 17.2 percent of the mammograms provided and 15 percent of the Pap tests. Hispanic women received 19.3 percent of the mammograms and 20 percent of the Pap tests. Nearly 50 percent of all tests combined were provided to minority women.

Of the mammograms provided to women aged 40 years and older, 77,229 (7.5 percent) were abnormal, and 5,830 breast cancers were diagnosed. There were also an additional 435 women diagnosed with breast cancer that were referred to the program for a diagnostic evaluation after receiving an abnormal mammogram from providers outside the program. Of the Pap tests provided, 29,946 (3 percent) were abnormal, and 16,168 cases of cervical intraepithelial neoplasia (CIN) I, II, or III and 436 cases of invasive cervical cancer were diagnosed. An additional 17,899 CIN I, II, or III and 125 invasive cervical cancers were identified when women were referred to the program for a diagnostic evaluation after receiving an abnormal screening result from providers outside the program.

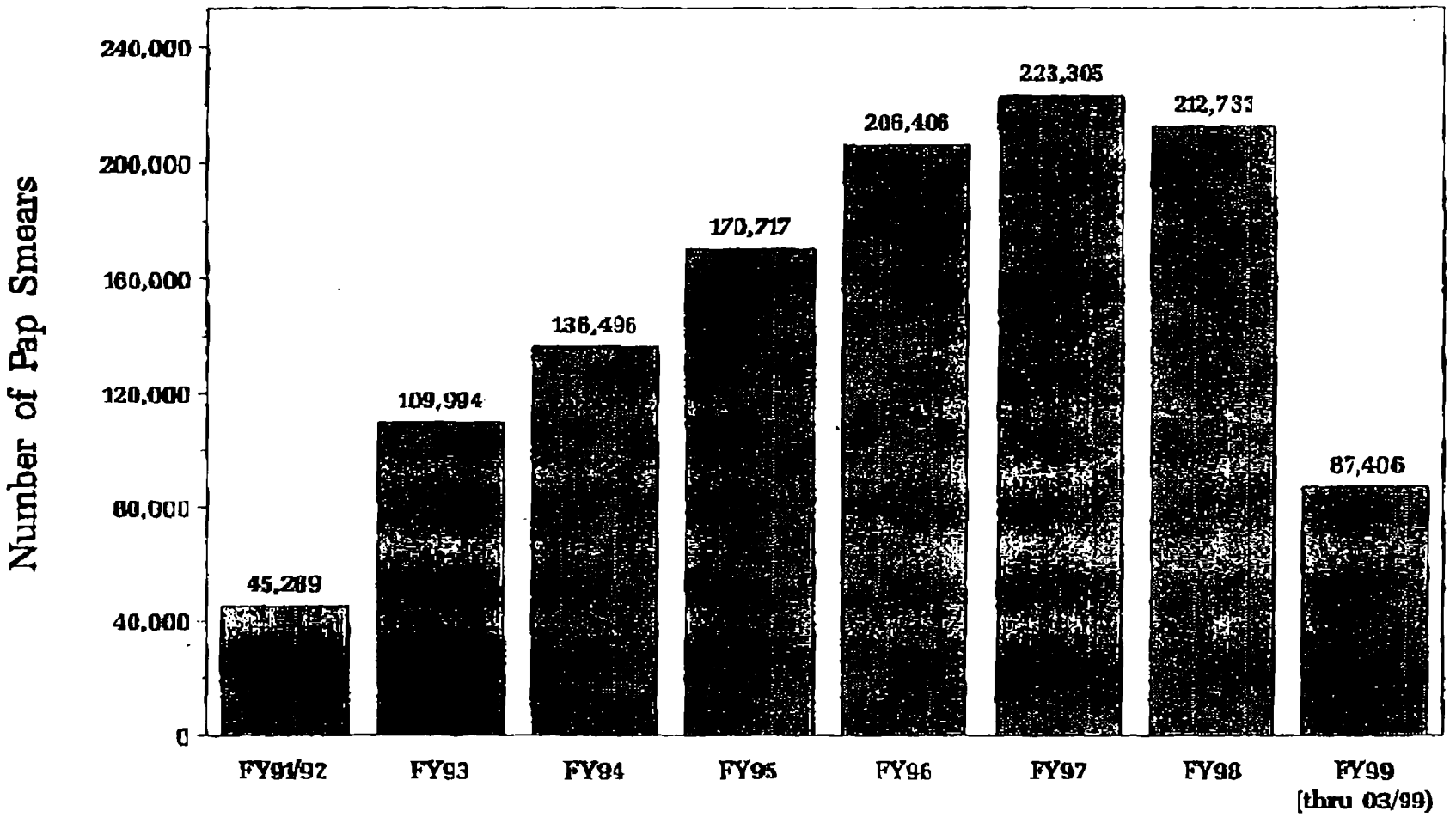
NBCCEDP Accomplishments

Since the programs inception, more than two million screening tests have been provided to underserved women:

- Over one million mammograms provided
- Over one million Pap tests provided
- Over 6,200 breast cancers diagnosed
- Over 34,000 precancerous cervical lesions diagnosed
- Over 550 cervical cancers diagnosed

- Nearly half of all Program screenings were for minority women, who are traditionally underserved.
- The Program includes 68 health agencies and collaborates with more than 60 private, public, and Federal organizations.

Number of Pap smear screenings for Fiscal Years 1991–1999 Among NBCCEDP Participants



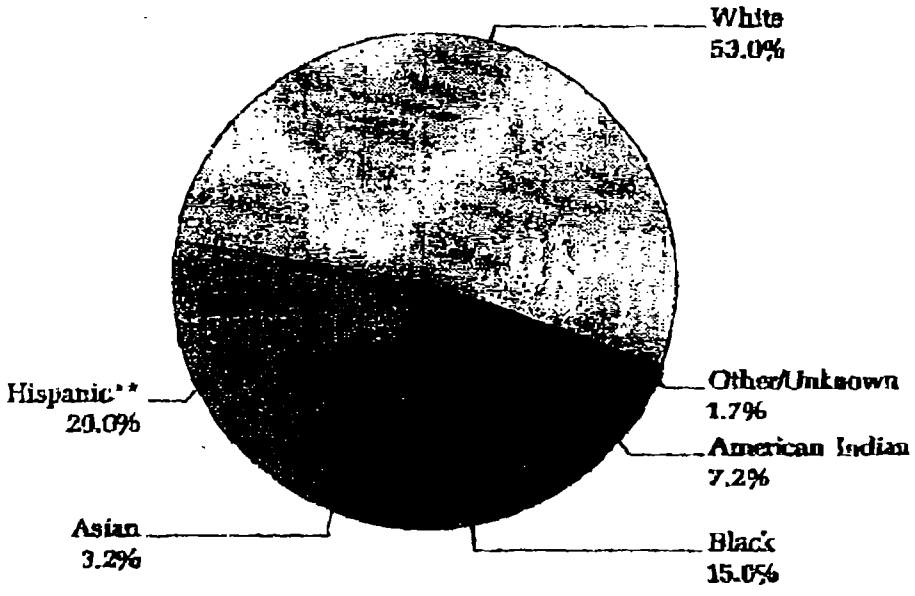
Total Pap smears = 1,192,348

Source: Minimum Data Elements for Pap smears through 03/31/99 paid with NBCCEDP funds

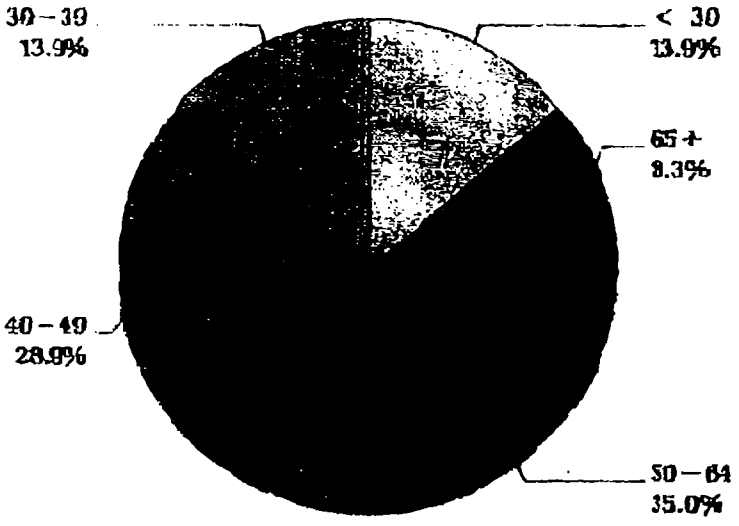
August 25, 1999

Percent Distribution of Women Receiving NBCCEDP Funded Papanicolaou Tests by Race/Ethnicity & Age Group, 1991–1999

By Race/Ethnicity



By Age Group*



Total number of women = 761,822

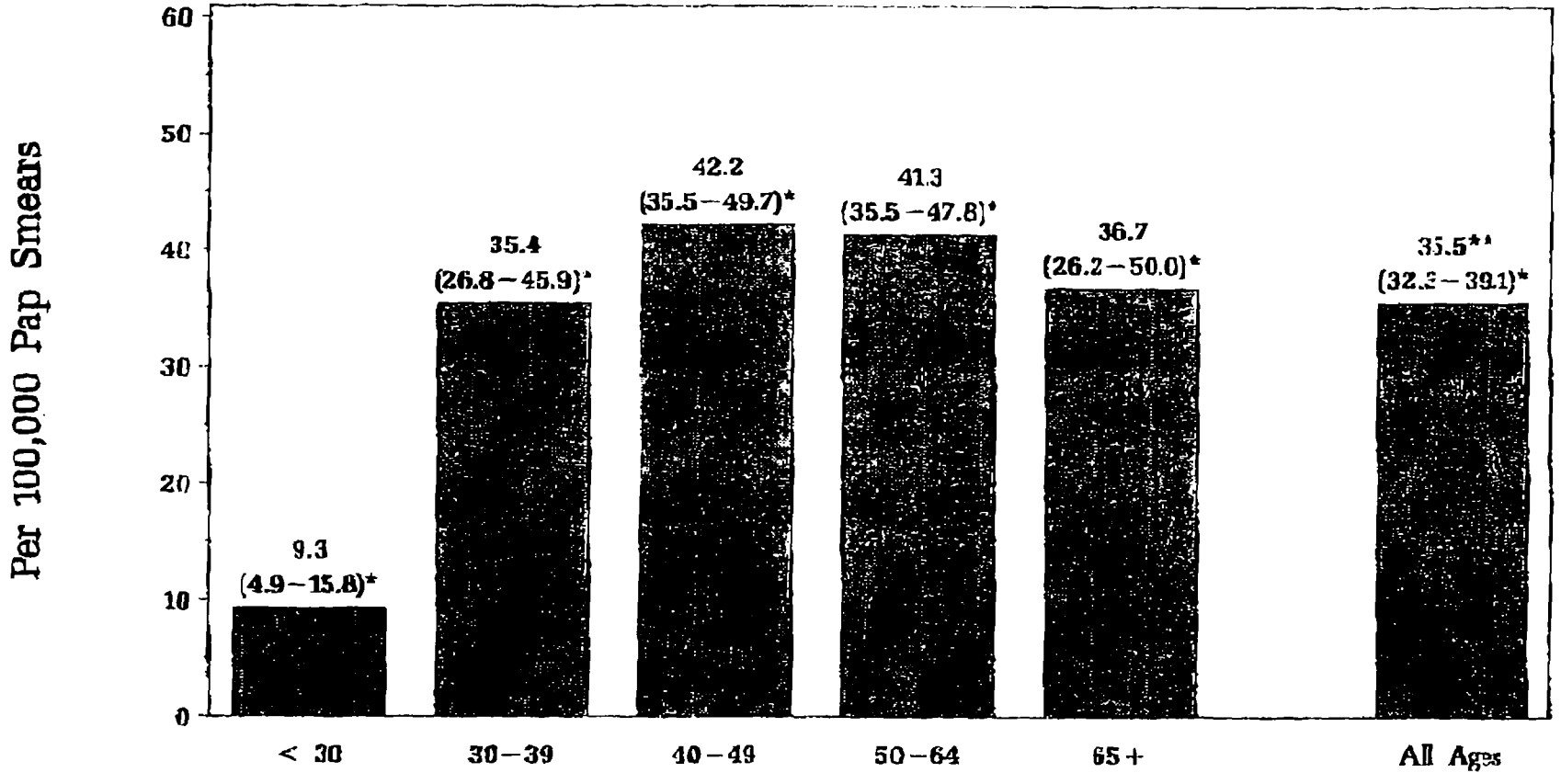
* Age of woman based on first program funded Pap smear

** Includes Hispanics of any race

Source: Minimum Data Elements for Pap smears through 03/31/99 paid with NBCCEDP funds

August 25, 1999

Rate of Invasive Cervical Cancer per 100,000 Pap Smears in each Age Group Among NBCCEDP Participants, 1991–1999



Number of Invasive Cancers	13	57	143	183	40	436
Number of Pap Smears	148,338	161,012	339,051	442,920	198,979	1,132,300

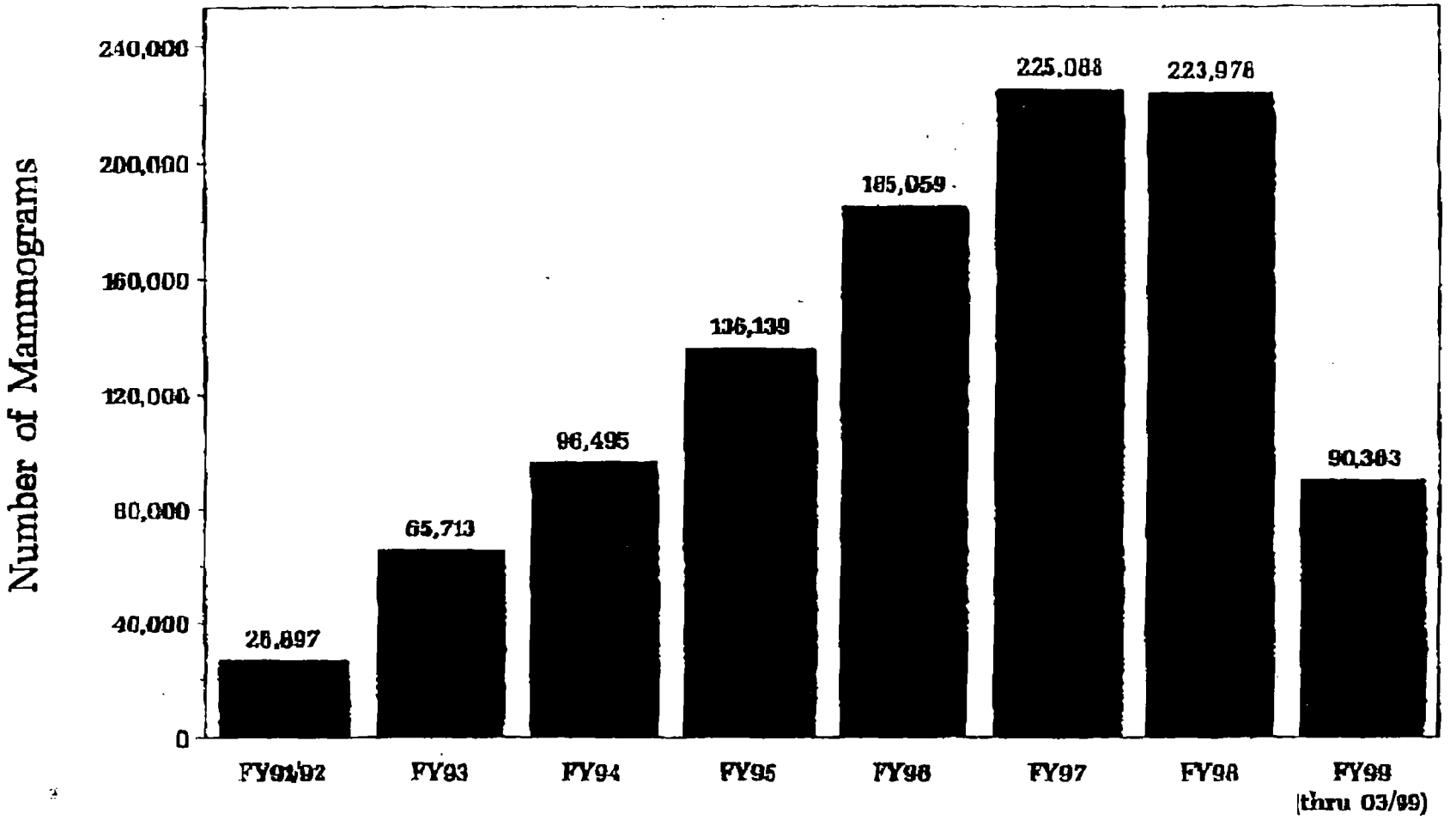
An additional 125 women diagnosed with invasive cervical cancer, not included above, were referred to the NBCCEDP for diagnostic evaluation after an abnormal Pap smear by a provider not in the program.

Source: Minimum Data Elements for Pap Smears through 03/31/99 paid with NBCCEDP funds
Includes: Biopsy–diagnosed Invasive Cervical Carcinoma by age group, and for all ages combined
* 95% Poisson Confidence Intervals
** Adjusted to the age distribution of NBCCEDP participants having Pap Smears performed in calendar year 1995

436 + 125 = 561 over ten years

August 25, 1999

Number of Mammogram screenings for Fiscal Years 1991 – 1999 Among NBCCEDP Participants



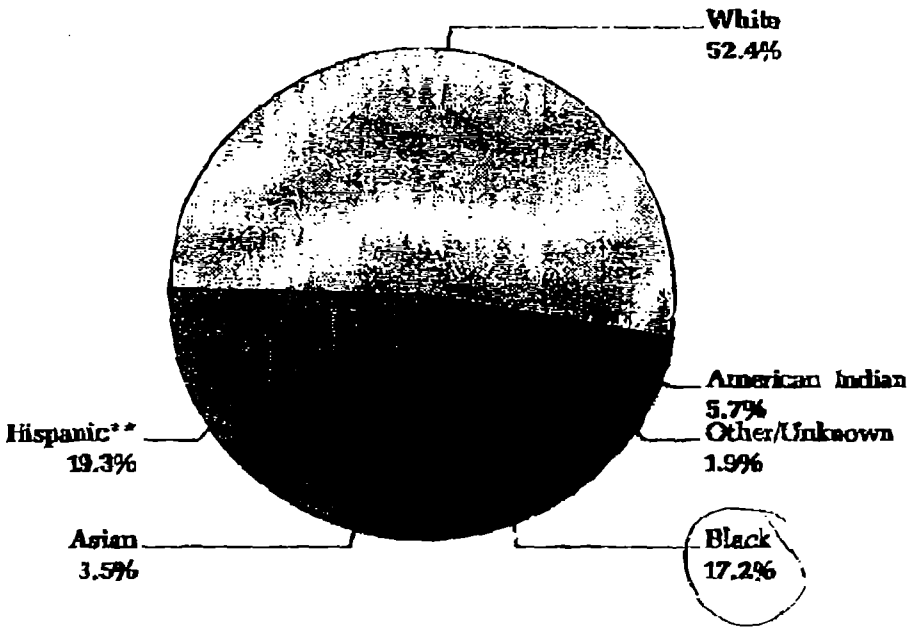
Total mammograms = 1,049,752

Source: Minimum Data Elements for Mammograms through 03/31/99 paid with NBCCEDP funds

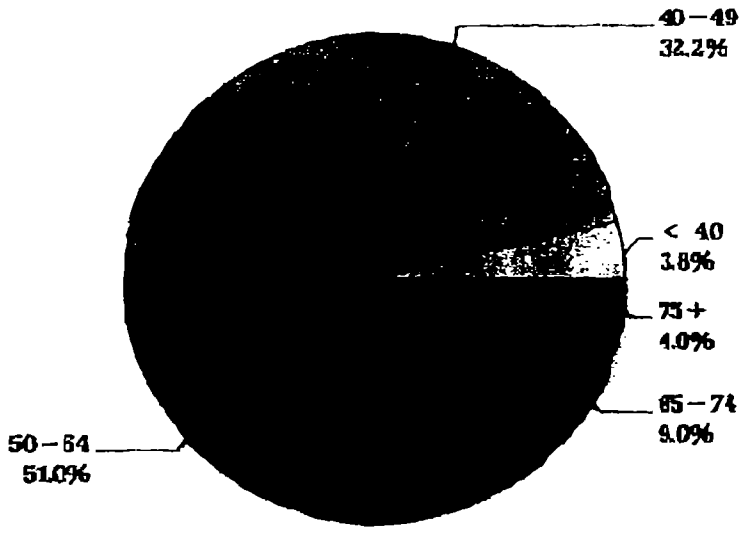
August 25, 1999

Percent Distribution of Women Receiving NBCCEDP Funded Mammograms, by Race/Ethnicity & Age Group, 1991–1999

By Race/Ethnicity



By Age Group*



Total number of women = 676,474

* Age of woman based on first program funded mammogram

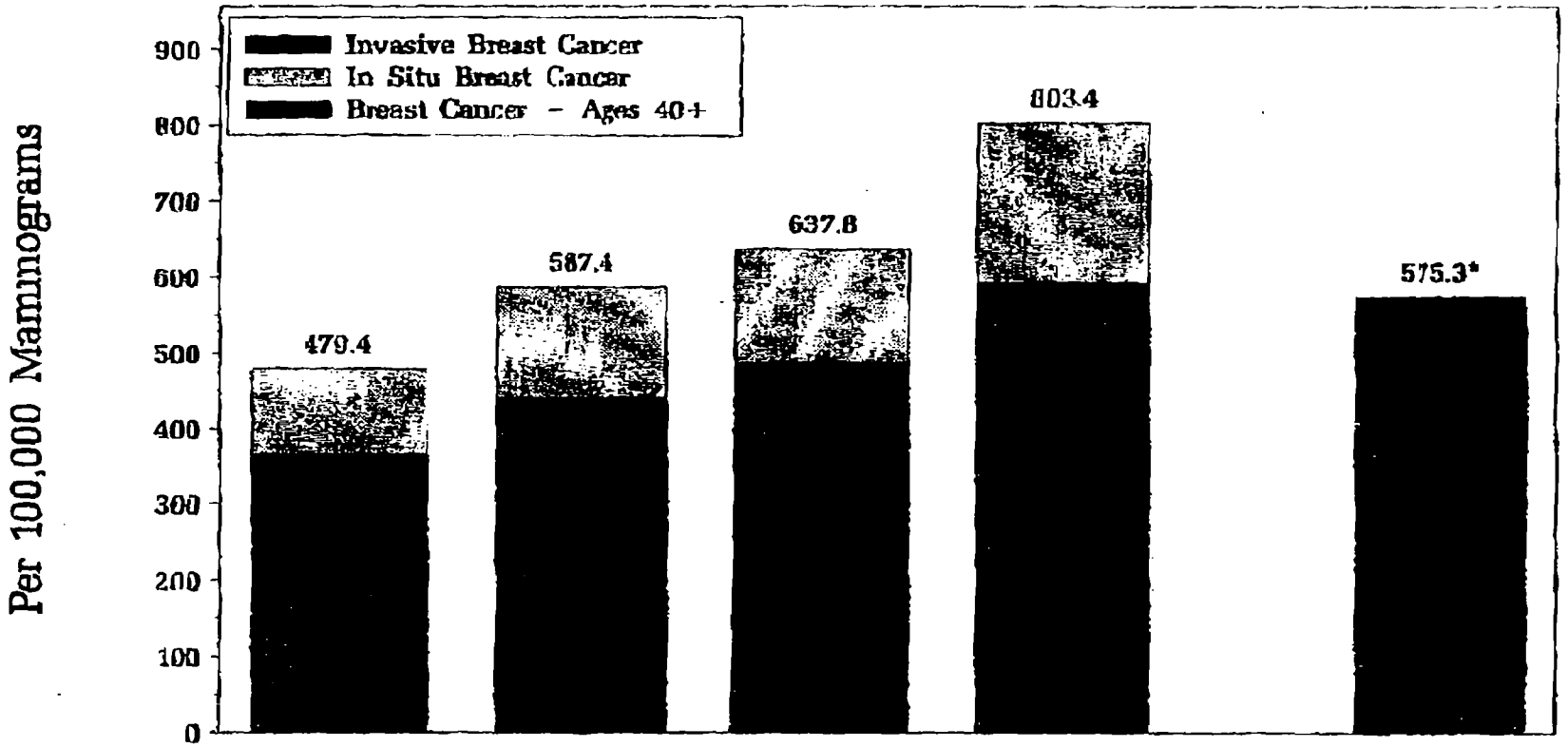
** Includes Hispanics of any race

Source: Minimum Data Elements for Mammograms through 03/31/99 paid with NBCCEDP funds

Includes: Mammograms performed for screening or for evaluation of an abnormal breast exam

August 25, 1999

Rate of Breast Cancers per 100,000 Mammograms Among NBCCEDP Participants 40 Years of Age and Older by Age Group, 1991–1999



In Situ Breast Cancer	336	842	154	93	1,425
Invasive Breast Cancer	1,092	2,545	503	265	4,405
Total Breast Cancers	1,428	3,387	657	358	5,830
Number of Mammograms	297,870	576,654	103,011	44,560	1,022,095

An additional 435 women diagnosed with in situ breast cancer or invasive cancer, not included above, were referred to the NBCCEDP for diagnostic evaluation after an abnormal mammogram by a provider not in the program.

Source: Minimum Data Elements for mammograms through 03/31/99 paid with NBCCEDP funds

Includes: In Situ and Invasive Breast Cancer

* Adjusted to the age distribution of NBCCEDP participants 40 years of age and older having Mammograms performed in calendar year 1995

+ 435

6265 – over Ten years

August 25, 1999

HR 1070 IH

106th CONGRESS

1st Session

H. R. 1070

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.

IN THE HOUSE OF REPRESENTATIVES

270 APPENDIX

March 11, 1999

Mr. LAZIO (for himself, Ms. ESHOO, Ms. ROS-LEHTINEN, Mrs. CAPPS, Mrs. MORELLA, Mrs. KELLY, Mr. BROWN of Ohio, Mr. GEORGE MILLER of California, Mr. HORN, Mr. DIXON, Ms. PELOSI, Mr. LATOURETTE, Mr. WAXMAN, Mr. SERRANO, Mr. GILMAN, Mr. MALONEY of Connecticut, Mr. MEEHAN, Mr. WELDON of Pennsylvania, Mr. UNDERWOOD, Mr. SHOWS, Mr. ABERCROMBIE, Mr. MCHUGH, Mr. ETHERIDGE, Mr. SANDERS, Mrs. CLAYTON, Mr. WALSH, Mr. MCGOVERN, Mr. MCNULTY, Mr. FROST, Mr. NEY, Mr. OLVER, Ms. MILLENDER-MCDONALD, Mr. CROWLEY, Mr. SUNUNU, Mr. CLEMENT, Mr. STARK, Ms. CARSON, Mr. FOLEY, Mr. COYNE, Mr. LANTOS, Mr. INSLEE, Mrs. WILSON, Mr. SHERMAN, Mr. BALDACCI, Mr. BOEHLERT, Mr. LUTHER, Mr. HINOJOSA, Mr. DEFAZIO, Mr. QUINN, Mr. PRICE of North Carolina, Mr. RANGEL, Mr. WEYGAND, Mr. FORBES, Mr. MEEKS of New York, Mr. NADLER, Mr. BARRETT of Wisconsin, Ms. WOOLSEY, Mr. KUCINICH, Mr. KING, Ms. SLAUGHTER, Mrs. TAUSCHER, Mr. BILBRAY, Mr. THOMPSON of Mississippi, Mr. HINCHEY, Mr. KLECZKA, Mr. PAYNE, Mr. WYNN, Mr. JEFFERSON, Mr. SMITH of New Jersey, Mr. MASCARA, Mr. LOBIONDO, Mr. OBERSTAR, Mr. LEACH, Mr. RUSH, Mr. MATSUI, Mr. DINGELL, Mrs. EMERSON, Mr. FILNER, Mrs. MYRICK, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. OPTIONAL MEDICAID COVERAGE OF CERTAIN BREAST OR CERVICAL CANCER PATIENTS.

(a) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP-

(1) IN GENERAL- Section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended--

(A) in subclause (XIII), by striking `or' at the end;

(B) in subclause (XIV), by adding `or' at the end; and

(C) by adding at the end the following:

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.