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*TB disabled
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Date: February 1, 2000

Fax #: 202-456-5557

Pages: **20**, including this cover sheet.

From: Steven Reynolds, MPH

Subject: Treatment Study

Look for the hand written * in the margins. I.E.,

*Program
payer of last
resort →
* either uninsured
or underinsured*

Let me know if you have any questions.

Steve

*Victor
Potnik
15 Amberson
you know
10705*

*Things to know:
 # women w/o treatment
 # women below x%
 poverty level
 uninsured
 % poverty level in
 States*

*mandatory screening?
 how connected to Ryan White*

Q: AIDS

Q: Don't have in certain areas

Q: substitution of Fed for state funds?



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



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MORBIDITY AND MORTALITY WEEKLY REPORT
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**Strategies for Providing Follow-Up and Treatment Services
in the National Breast and Cervical Cancer Early Detection Program —
United States, 1997**

The Breast and Cervical Cancer Mortality Prevention Act of 1990* authorized CDC to establish the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) to increase screening services for women at low income levels who are uninsured or underinsured (1). Although the NBCCEDP covers most diagnostic services that women need after receiving an abnormal mammography or Papanicolaou (Pap) test result, the program does not reimburse for breast biopsies. In addition, the Act prohibits the use of NBCCEDP funds for cancer treatment. Participating health agencies must ensure that NBCCEDP clients receive timely, appropriate diagnostic and treatment services. In 1996, CDC began a case study to determine how early detection programs in seven participating states (California, Michigan, Minnesota, New Mexico, New York, North Carolina, and Texas) identified resources and obtained diagnostic and treatment services. This report summarizes the results of the study (2), which indicate that respondents in these states reported that treatment had been initiated for almost all NBCCEDP clients in whom cancer was diagnosed. However, respondents also considered the strategies used to obtain these services as short-term solutions that were labor-intensive and diverted resources away from screening activities.

In the seven states, NBCCEDP-sponsored screening services had been provided for ≥ 3 years, and breast cancer had been diagnosed in ≥ 60 women. The states were selected to provide a range of geographic locations, a combination of urban and rural populations, and racial/ethnic diversity among program clients. Researchers conducted semi-structured interviews with 192 persons affiliated with the seven state programs. Of these interviewees, 120 (63%) were providers of screening, diagnostic, and/or treatment services; 58 (30%) were state program staff; and 14 (7%) were coalition members. Interviews included topics such as guidelines related to diagnostic and treatment services, strategies used to obtain and pay for services, level of effort required to secure these services, and changes in strategies over time. Each interview was tape recorded and transcribed. Using a systematic scheme derived from the research questions, three researchers coded the same transcripts until an inter-rater agreement of 80% was reached. Thereafter, all transcripts were coded independently. Coding results were entered into text analysis software that sorts text from transcripts into sets of information, themes, and evidence relevant to the specific research questions (3). The results reflect a synthesis of the interviewees' responses.

*Public Law 101-354.

Respondents described several strategies used to ensure necessary diagnostic and treatment services for women screened through the NBCCEDP. State-level strategies in all states included 1) computerized tracking and follow-up systems that used program surveillance data to identify and manage clients in need of diagnostic and treatment services; 2) provisions in contracts requiring screening providers to arrange for diagnostic follow-up and treatment before screening women; and 3) arrangements with provider groups and state professional associations for free or reduced-cost services for NBCCEDP clients. All states also had access to public or private funds to help support services not covered by the program; such revenue sources included state appropriations from general or tobacco tax revenues or funds from private foundations. These funds were available primarily for breast diagnostic services.

Local strategies tailored to the needs of individual clients were used to obtain diagnostic and treatment services. Common strategies reported by respondents included the following: providers billed public or private insurance plans; providers or local health departments helped clients apply for public assistance programs; providers referred clients to public hospitals; county indigent-care funds and hospital community-benefit programs financed services; clients received services through individually negotiated payment plans; and clients paid reduced or full fees for services.

Respondents strongly supported the continued growth of NBCCEDP and its goals but expressed several concerns. First, considerable time and effort were involved in developing and maintaining systems for diagnostic follow-up and treatment. Second, the process of identifying available resources within states for diagnostic and treatment services was considered labor-intensive. Third, the lack of coverage for diagnostic and treatment services negatively affected recruitment of providers and restricted the number of women screened. Fourth, respondents believed that an increasing number of physicians will not have the autonomy, because of changes in the health-care system, to offer free or reduced-fee services to NBCCEDP clients.

Respondents reported that arrangements for treatment were made for almost all NBCCEDP clients who received a diagnosis of breast cancer or invasive cervical cancer. Respondents stated that some women experienced time delays between screening, definitive diagnosis, and initiation of treatment. State program officials reported that, according to 1992-1996 surveillance data, small numbers of clients in whom cancer was diagnosed (i.e., from three to 13 women in each state) subsequently refused treatment. Because these clients were not interviewed, it could not be determined whether financial barriers contributed to their decisions to refuse treatment or their loss to follow-up.

← Respondents were concerned that the NBCCEDP did not provide funding for all diagnostic procedures and treatment for the diseases for which clients were being screened; approaches for delivering services were fragmented; and the process of obtaining resources required substantial effort at the state, local, and provider levels.

← Respondents reported that the continuation of every strategy for diagnostic and treatment services beyond the next few years is uncertain.

Reported by: PM Lantz, PhD, Univ of Michigan School of Public Health, Ann Arbor. LE Sever, PhD, Battelle, Centers for Public Health Research and Evaluation, Seattle, Washington. Program Svcs Br, Office of the Director, Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC.

Editorial Note: During July 1991–March 1997, the NBCCEDP provided 576,408 mammograms to women aged ≥ 40 years, and 3409 cases of breast cancer were diagnosed. During this same period, the program provided 732,754 Pap tests; 23,782 cases of cervical intraepithelial neoplasia and 303 cases of invasive cervical cancer were diagnosed. These totals included women referred to the program for diagnostic evaluation of an abnormal screening result. The NBCCEDP internal estimates suggested that during this period only 12%–15% of uninsured women aged 40–64 years in the United States had been screened by the program (CDC, unpublished data, 1997).



Screening alone does not prevent cancer deaths; it must be coupled with timely and appropriate diagnostic and treatment services. The Congressional mandate for NBCCEDP requires grantees to take all appropriate measures to ensure provision of services required by women who have abnormal screening results. CDC provides funds for case management to help these women access health-care services. To increase the comprehensive nature of the program, CDC recently approved the use of NBCCEDP funds for breast biopsies.



The results of this study indicate that state health departments and their partners in the seven states had developed a wide range of strategies for diagnostic and treatment services in the absence of program resources. However, the time and effort required to arrange and maintain these services diverted resources away from screening activities.

This study was subject to at least two limitations. First, the results were based solely on the experience and opinions of informed professionals affiliated with the program and did not include the perspectives of NBCCEDP clients. Second, the results may not reflect the program experiences in other states. Case-study methods, however, are an appropriate and well-accepted approach to gaining in-depth understanding of complex programs in real-life situations (4). The validity of the findings was enhanced by developing standard instruments to guide the semi-structured interviews, protecting the confidentiality of respondents' remarks, using interview transcripts for data analysis rather than relying on interviewer notes, and obtaining feedback concerning state summary reports from respondents.

As more women are screened by the NBCCEDP, a greater burden will be placed on participating health agencies, providers, and other partners to obtain resources for breast and cervical cancer treatment. Case-management services will continue to be essential in helping underserved women overcome financial, logistical, and other barriers to receiving these services. Other long-term solutions to ensure that women in the program receive necessary treatment services are being pursued.

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FINAL REPORT

Follow-Up and Treatment Issues in the National Breast and Cervical Cancer Early Detection Program: Results from a Multiple-Site Case Study

**Volume 1: Executive Summary
Final Report**

Prepared for

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention

and Health Promotion

Division of Cancer Prevention and Control

December 31, 1997

Final Report

**Contract Number 200-92-0534
Task No. 41**

On

**Follow-Up and Treatment Issues in the
National Breast and Cervical Cancer Early Detection Program: Results
from a Multiple-Site Case Study**

**Volume 1: Executive Summary
Final Report**

To

**Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control**

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December 31, 1997

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Acknowledgments

This research project was a collaborative effort between investigators at the University of Michigan School of Public Health (Dr. Lantz, Dr. Richardson and Ms. Macklem) and Battelle Centers for Public Health Research and Evaluation (Dr. Sever, Dr. Hare, and Ms. Orians). The project was funded by the Centers for Disease Control (CDC) Division of Cancer Prevention and Control. Several people from CDC assisted in the design of this study, including Rosemarie Henson, M.S.S.W, M.P.H., Donna Knutson, Ms.Ed., C.H.E.S., Diane Dunet, M.P.A., Nancy Lee, M.D., and Stephen Wyatt, D.D.M., M.P.H. Program consultants with the National Breast and Cervical Cancer Early Detection Program also assisted investigators by providing information and materials regarding the seven states under study. In addition, two colleagues at Battelle-- Jane Schulman, Ph.D. and Mary Odell Butler, Ph.D.--provided valuable guidance and sage advice over the entire course of this project.

Several graduate students at the University of Michigan provided assistance to the research team in myriad ways. Two doctoral students--Madelaine Pfahler and Lisa Shugarman--assisted in conceptualizing and designing the study, and in analyzing the results. In addition, eight students worked on the project by transcribing audio tapes of interviews and entering data codes into the electronic files of transcripts. Colleagues at the University of Michigan who provided advice, wisdom and support include Kenneth Warner, Ph.D., Catherine McLaughlin, Ph.D., Joel Howell, M.D., Ph.D., Michael Chernew, Ph.D., and Barbara Black.

During the course of this project, nearly 200 people in 7 states participated in interviews. A number of these people also contributed to the project by reviewing the draft summary report for their state and providing editorial comments and edits. The research team members greatly appreciate the time that these individuals gave and the insights that they shared. This research endeavor required additional support and cooperation from the state health department staff with the seven Breast and Cervical Cancer Early Detection Programs under study. The research team extends their gratitude to these individuals for participating in an information session in Ann Arbor, Michigan, for assisting in identifying possible interviewees, for helping to set itineraries for the site visits, and for providing relevant documents and materials. We appreciate their time, expertise and assistance in the research process, as well as their insights regarding the issues under study.

The research team would also like to acknowledge several individuals who contributed to the production of the final report, including Kristine Searcy at the University of Michigan and Lawan Johnson at Battelle.

During the time that this study was designed and data were being collected, Dr. Lisa Richardson was a Robert Wood Johnson Clinical Scholar at the University of Michigan.

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Executive Summary

TITLE: Follow-Up and Treatment Issues in the National Breast and Cervical Cancer Early Detection Program: Results from a Multiple-Site Case Study

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1.0 Introduction

The Breast and Cervical Cancer Mortality Prevention Act was enacted by Congress in August, 1990 (Public Law 101-354, Title XV, Public Health Service Act) to reduce the public health burden of cancers of the breast and cervix. This legislation authorized the Centers for Disease Control and Prevention (CDC) to establish the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). This large initiative is implemented through cooperative agreements with qualifying health agencies, including state and U.S. territorial health departments, and American Indian and Alaska Native tribes and tribal organizations.

The ultimate goal of this public health initiative is to decrease mortality from breast and cervical cancers among U.S. women. Participating programs conduct activities in a number of critical areas: public education, professional education, coalition and partnership development, screening, quality assurance, surveillance, tracking and follow-up, and evaluation. A major objective of the NBCCEDP is to increase access to and utilization of breast and cervical cancer screening services (i.e. clinical breast examinations, screening mammograms, pelvic examinations, and Papanicalou or Pap tests) among low-income and uninsured or underinsured women. Age and income requirements for eligibility vary across the programs, as do their organizational structures. All programs, however, have initiated outreach efforts that target women in

high priority groups, including older women, women in racial and ethnic minority groups, women with disabilities, lesbians, and women who live in rural or other hard-to-reach areas. The 1993 Congressional reauthorization of the legislation mandated that health agencies reimburse participating providers at a rate that is no higher than the current Medicare rate for the procedures.

From July, 1991 through March, 1997, 594,436 mammograms and 732,754 Pap tests were provided through the program. Of the women receiving these screening tests, 7.6% had abnormal mammograms and 3.1% had abnormal Pap tests that required follow-up procedures or a more complete assessment. In addition, during the same time period, 3,064 women were diagnosed with breast cancer, 267 women were diagnosed with invasive cervical cancer, and 11,883 women were diagnosed with cervical carcinoma in situ or cervical intraepithelial neoplasia.

Ensuring that all women with abnormal screening results receive adequate follow-up and a definitive diagnosis is a crucial component of the NBCCEDP. Thus, program providers are also reimbursed for a number of follow-up diagnostic procedures, including diagnostic mammography, breast ultrasound, fine needle aspiration of the breast, and colposcopy. While the program covers the diagnostic follow-up services that most women need after an abnormal Pap test, the program does not reimburse for some of the diagnostic tests that are needed to follow-up on an abnormal breast screen. This includes excisional breast biopsies, stereotactic localization for breast biopsy, or needle core breast biopsy. In addition, the Federal law prohibits the use of program funds for the treatment of cervical intraepithelial neoplasia (CIN), including cervical treatment procedures such as loop electrode excision procedure (LEEP) and cervical cone biopsy (or "cold-knife" conization). The law also prohibits the use of program funds for any component of treatment for breast or cervical cancer, including surgery, radiation therapy, chemotherapy or hormonal therapy.

One of the reasons that Federal dollars cannot be used to pay for treatment stems from a concern that this would lead to the rapid depletion of funds available for screening services. Yet, it is also important to understand that the NBCCEDP is an initiative that has as its foundation a **partnership** between the Federal government and participating health agencies. Through the NBCCEDP, Federal resources are brought to bear on the public health problems of breast and cervical cancer. In fulfilling their part of the partnership, participating health agencies are required to identify and secure resources for diagnostic follow-up services that the program does not cover and for cancer treatment services for women in need, regardless of their ability to pay. Thus, BCCEDPs are required to ensure that the women they screen receive definitive diagnoses after abnormal results and that they receive timely and appropriate treatment services.

We undertook a study with three components to document and assess the strategies and tactics that participating state health agencies are using to provide diagnostic follow-up and treatment services to clients in need. The three components of this study are as follows: 1) a descriptive study of the general strategies and activities regarding diagnostic and treatment services in a select group of 35 programs (state Breast and Cervical Cancer Early Detection Programs or BCCEDPs) administered by state health departments; 2) an in-depth case study of 7 of these 35 state programs; and 3) a study documenting the initiation of treatment and the initial course of treatment received for women diagnosed with breast or cervical cancer by linking data from three state BCCEDPs with data from population-based tumor registries. This report presents the results from the second component--the in-depth case study of seven state programs. The purpose of this multiple-site case study was to achieve an in-depth understanding of the current activities and strategies being used at the state and local level to help ensure that

women screened through the NBCCEDP obtain the diagnostic tests that they need, and that those diagnosed with cancer gain access to and initiate treatment.

2.0 Case Study Methods

A set of criteria was established to guide the selection of states for the case study. The seven states selected for the study were California, Michigan, Minnesota, New Mexico, New York, North Carolina and Texas. Information for the case studies of the states came from two main sources: 1) a review of pertinent documents and materials; and 2) four-day site visits in each of the states, involving teams of three or more researchers. Each team included one or two doctoral-level scientists. The main activity of these site visits was semi-structured interviews with people affiliated with the program, including staff at the state health department, staff with local and regional or district health agencies, staff with community-based organizations, providers of screening, diagnostic and treatment services, and members of coalitions or advisory groups.

Interviews with respondents were tape recorded and subsequently transcribed. The resulting typed transcripts were coded by three members of the research team. The coded transcripts were analyzed through the use of text analysis software. These analyses, in combination with information gleaned from the review of documents, were used to prepare summary reports for each of the case study states. Drafts of each state report were sent to the director of the state BCCEDP and to all other respondents in the state who volunteered to review the draft for accuracy and completeness. In turn, comments from state respondents were incorporated and a final report was produced for each state.

The unit of analysis in this study is state Breast and Cervical Cancer Early Detection Programs, with a focus on the strategies and tactics being used by the programs to ensure that clients receive needed diagnostic and treatment services. The results describe the efforts being made to ensure that clients receive diagnostic follow-up and treatment services in the absence of Federal resources for these activities. For situations in which strategies appear to be working well, we were also able to document the effort and resources required to support these activities as well as concerns about their present form and/or long-term viability.

The data gathered through the case study approach are primarily qualitative in nature. The quality or validity of these data was enhanced by several features of the design: 1) developing a clear set of research questions before data collection commenced; 2) developing a set of instruments for conducting interviews; 3) using more than one interviewer in an interview setting when possible; 4) assuring respondents that their remarks would be protected as confidential data; and 5) obtaining feedback on the state summary reports from respondents in each state. A total of 126 interviews was conducted involving a total of 192 people during the course of the study. A significant portion of the people interviewed (61%) were screening, diagnostic service, and/or treatment providers in local communities.

3.0 Study Results: Strategies Used to Ensure Clients Receive Diagnostic and Treatment Services

A variety of strategies and tactics have been implemented to help ensure that women screened through the NBCCEDP are receiving the diagnostic follow-up and treatment services that they need. Some of these efforts are organized at the state level and thus have an impact throughout the state. Other approaches are organized at the local or institutional level, and thus reach a subset of women within a state.

3.1 Common Strategies at the State Level

We found several approaches that appear to be used similarly across the states. The strategies and tactics that appear to be commonly organized at the state level include:

- Provisions in contracts with screening providers that require that arrangements or agreements with diagnostic and treatment providers be established before screening commences (e.g., a diagnostic and treatment network)
- Tracking and follow-up of clients using management information systems that rely on program surveillance data (the Minimum Data Elements submitted to CDC)
- Appeals to diagnostic and treatment providers, through state and county medical societies and professional associations, to offer free or reduced-cost services to program clients

3.2 Strategies Unique to States

A wide range of innovative and interesting activities is occurring in the seven study states to ensure that program clients receive all necessary diagnostic follow-up and treatment services. Examples of some of the major activities occurring uniquely in the seven states are listed below.

California:

- Funds from a state-sponsored program--the Breast Cancer Early Detection Program--(funded with tobacco tax revenues) are used to pay for breast diagnostic services not covered by the CDC screening program.
- State family planning funds can be used to pay for some cervical diagnostic procedures for women of childbearing age.
- A one-time allocation from the Blue Cross Foundation created the Breast Cancer Treatment Fund, which provides resources to pay for breast cancer treatment during the first year after diagnosis for any uninsured California citizen who meets the eligibility requirements.

Michigan:

- Funds from the Healthy Michigan Fund (from tobacco tax revenues) pay for breast and cervical cancer diagnostic services not covered by CDC.

Minnesota:

- Funds from annual Race for the Cure fundraising events provide breast ultrasound examinations and breast biopsies for program clients.
- Some clients in need of diagnostic tests or cancer therapy are eligible for MinnesotaCare—a state subsidized health insurance program for people with low-income who do not qualify for Medicaid.

New Mexico

- Indigent funds are available in some counties to assist with cancer diagnostic and treatment services.
- The University of New Mexico in Albuquerque serves as “provider of last resort” such that BCCEDP clients can come to this facility to receive care, with financial arrangements made on a case-by-case basis.
- The Breast and Cervical Cancer Diagnosis and Treatment Fund (from a golf tournament fund-raiser) provides small grants to BCCEDP clients in need as a way to make a down payment or a “good faith” payment gesture toward clinical services.

New York:

- Funds from a state-funded program--the Breast Cancer Detection and Education Project--are used to pay for breast diagnostic services not covered by CDC.
- Breast Health Partnerships are coalitions of local agencies that provide education, outreach, screening and support services for both breast and cervical cancer. These partnerships are instrumental in setting up networks of providers for diagnostic follow-up and treatment service provision for BCCEDP clients.

North Carolina:

- The Cancer Control Program provides state funds for cancer diagnostic and treatment services for all state citizens who meet the eligibility criteria.
- State-funded cervical dysplasia clinics provide access to free cervical diagnostic and dysplasia treatment services.

Texas:

- Texas Cancer Council (a state agency) provides state funds for breast diagnostic services.
- University of Texas Medical Branch in Galveston serves as “provider of last resort.”

3.3 Common Strategies at the Local Level

At the local level, there is evidence of a large number of strategies that are commonly used to secure the diagnostic and treatment services that are not covered by Federal or state funds. These strategies include the following.

- Providers bill private or public insurance plans when available
- Providers/local staff assist clients in applying for Medicaid, Hill Burton funds or other types of public assistance
- Clients are referred to public hospitals
- Clients receive care through hospital community benefit programs, donated services, or other types of charity care
- Clients receive services for a reduced fee and/or negotiate payment plans with providers
- In the absence of other options, clients pay fee-for-service for the tests and/or treatment they need

3.4 Summary of Findings Regarding Strategies

Innovative and creative approaches have been implemented to identify and secure resources for the diagnostic and treatment services that clients need but are not covered by CDC funds. In addition, a number of interesting partnerships between public and private organizations have been formed. All of the seven states under study currently have some type of fund that is centralized at the state level that supplements what the NBCCEDP will cover.

The results of the case studies strongly suggest that the strategies that have been implemented in an attempt to ensure that clients receive needed clinical services are very similar for breast and cervical cancer, although we did find that funding from state legislatures and private foundations is more prevalent for breast diagnostic services than for cervical diagnostic services or for cancer treatment in general.

Many financial barriers to diagnostic follow-up and some for cancer treatment have been reduced. However, it is clear that many women are paying some amount of money out of pocket for diagnostic tests and treatment services. The number of women who have had to pay something toward diagnostic follow-up and/or treatment and the amount of these payments is not known at this time.

Women diagnosed with cancer through the NBCCEDP are receiving treatment. Without exception, respondents reported that of their clients diagnosed with breast cancer or invasive cervical cancer, all women *who have wanted* treatment have indeed initiated cancer therapy. There are, however, some concerns regarding loss to follow-up for abnormal Pap tests and regarding the timely treatment of CIN. These difficulties include a perceived lack of urgency on the part of some clients regarding abnormal Pap tests or precancerous cervical lesions, and/or a lack of available low-cost cervical procedures (such as LEEP) or trained providers in some areas.

4.0 Study Results: Strengths and Weaknesses of Current Efforts

Respondents articulated a number of strengths or positive aspects of the strategies or systems that currently are in place to assist with the provision of diagnostic follow-up and treatment services in the NBCCEDP. Strengths mentioned by a number of respondents across states are outlined below.

4.1 Strengths of the Strategies in Place Regarding Diagnostic and Treatment Service Provision

- Women diagnosed with cancer through the program who have wanted to receive treatment have initiated treatment services. In each state, a very small number of women diagnosed with cancer (primarily breast cancer) through the program have not initiated treatment. In all of the cases to date, however, respondents said that great effort was made to get the women to treatment but that for a variety of reasons treatment was refused. Some of the reasons for refusing treatment include that women wanted to pursue alternative therapies, that women wanted to return to their country of origin and perhaps pursue treatment there, or that women did not want to "fight" their cancer.
- Creative partnerships and responses to the lack of Federal dollars for some key diagnostic services and all treatment services have emerged in programs at the state, local and provider levels.
- In all seven states, public and/or private funds have been garnered to assist the program in providing needed clinical services.
- State health department staff with the programs consistently were described as excellent and dedicated professionals who provide technical assistance, guidance and support.
- Both state BCCEDP staff and providers report that the tracking and follow-up systems implemented by the program have had a positive influence on diagnostic follow-up for non-program clients. Participating in the state BCCEDP has increased providers' awareness of the importance of tracking and follow-up systems and the need to work with clients beyond simply making a referral for diagnostic services. The emphasis that the NBCCEDP places on proactive surveillance has stimulated increased activity to ensure proper follow-up and recall of women participating in cancer screening at individual facilities.

4.2 Concerns/Weaknesses of Current Strategies Regarding Diagnostic and Treatment Service Provision:

Despite the many strengths that respondents discussed regarding the provision of diagnostic and treatment services to NBCCEDP clients, they also shared concerns and perceived weaknesses or barriers. Concerns and weaknesses that were common across the states are outlined below.

- The lack of programmatic support for all indicated diagnostic procedures or subsequent treatment was described as questionable public health practice by many respondents, and "unconscionable" by several others.
- The time and effort required to carry out and/or arrange for diagnostic follow-up and treatment services is tremendous because it needs to be done on a case-by-case basis. Many respondents believe that the program does not adequately reimburse providers for the time and effort it takes to coordinate follow-up care for clients. Some reported that the burden associated with follow-up has led to restrictions in the number of women screened.
- Several barriers to the recruitment of providers were discussed by respondents. These include: 1) the lack of programmatic coverage for key breast diagnostic procedures to ensure women receive a definitive diagnosis; 2) the perceived low reimbursement rates for the services that CDC does cover; 3) the need for the



FAX TRANSMISSION

**NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION
DIVISION OF CANCER PREVENTION AND CONTROL
OFFICE OF PROGRAM AND POLICY INFORMATION**

MAILSTOP K-64
4770 BUFORD HIGHWAY, NE
ATLANTA, GEORGIA 30341-3724
PHONE: (770) 488-3075
FAX: (770) 488-4760

To: Devorah Adler **Date:** February 3, 2000
Fax #: 202-456-5557 **Pages:** 4, including this cover sheet.
From: Steven Reynolds, MPH
Subject: Draft Press Release Comments

COMMENTS:

Let me know if you have any questions.

Steve

See Attached for # correlation to edits.

DRAFT: PRESIDENT CLINTON ANNOUNCES NEW INITIATIVE TO ELIMINATE BARRIERS TO TREATMENT FOR BREAST AND CERVICAL CANCER

February 4, 1999

Today, in his weekly radio address, President Clinton will announce that his FY 2001 budget includes a new option for state Medicaid programs to provide desperately needed insurance coverage to uninsured or under-insured women who have cancer detected by Federally supported screening programs. This \$220 million (over 5 years) investment will eliminate current financial barriers to treatment for thousands of women diagnosed with cancer. The proposal has received broad, bipartisan support in the Congress, and similar legislation has been introduced by the late Senator Chafee, Senator Mikulski, and Representatives Lazio and Eshoo. This new initiative, advocated by the Vice President and the First Lady, is strongly endorsed by the National Breast Cancer Coalition and [insert name of add'l group].

TREATMENT OPTIONS FOR LOW-INCOME UNINSURED WOMEN DIAGNOSED WITH BREAST OR CERVICAL CANCER ARE DANGEROUSLY LIMITED.

The National Breast and Cervical Cancer Early Detection Program provides breast and cervical cancer screening to over XXX,000 uninsured or underinsured women annually. Typically, Federal government-sponsored screening programs make every effort to assist individuals diagnosed with disease in accessing the necessary treatment; however, thousands of women still face financial barriers to care.

- **Early detection saves lives.** An estimated 2 million American women will be diagnosed with breast or cervical cancer in this decade, and half a million women – disproportionately minority and low-income women – will lose their lives to these diseases. Many of these deaths could be avoided by early screening – approximately 15 to 30 percent of all deaths from breast cancer among women over the age of 40 and virtually all deaths from cervical cancer. When breast cancer is diagnosed early, the 5 year survival rate is 97 percent; but when it is diagnosed after it has spread, the 5 year survival rate is only 21 percent.
- **Uninsured women with breast and cervical cancer face barriers to receiving lifesaving treatment.** Although state screening programs often find free or low-cost treatment for women who are diagnosed with cancer, hundreds of women remain untreated, and those women who are able to access care are still forced to negotiate the complicated patchwork of charity care services. In addition, the course of treatment these women elect is affected by their ability to pay for services. Women diagnosed with breast cancer may choose mastectomies over breast-conserving surgery because they know that they will be unable to afford the cost of the chemotherapy and radiation that follow the less aggressive treatment.
- **Finding treatment for women without treatment options diverts scarce resources from crucial screening activities.** The time and effort required to ensure that low-income, uninsured women with cancer receive the life saving treatment they need diverts scarce program resources from critical screening activities, imposing limits on the number of women being screened. Because the implicit cross-subsidy of care for the uninsured continues to erode with the advent of managed care and other cost control efforts, identifying sources of free or low-cost care for these women is becoming steadily more difficult.

PRESIDENT CLINTON ANNOUNCES NEW INITIATIVE TO REMOVE BARRIERS TO TREATMENT FOR LOW-INCOME WOMEN WITH BREAST AND CERVICAL CANCER. Today, the President announced that his budget would invest over \$220 million in a new Medicaid option that allows states to provide low-income, uninsured women with access to critical treatment services. This new option is similar to bipartisan legislation sponsored by the late Senator Chafee, Senator Mikulski, and Representatives Lazio and Eshoo, ~~that has received~~ overwhelming bipartisan support, with over 270 cosponsors in the House and 54 cosponsors in the Senate. It will.

- **Provide comprehensive health insurance to low-income, uninsured women diagnosed with breast and cervical cancer.** States will have the option to provide the full Medicaid benefit package to uninsured women diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program for the duration of their treatment, eliminating financial barriers to treatment for these low-income women. These women will be able to access critical health care services necessary to treat their cancer, including radiation treatment, chemotherapy, reconstructive breast surgery, and prosthetics, as well as other health care services, such as basic laboratory and palliative care services, in order to provide a high-quality standard of care to these patients.
- **Allow women to access life saving treatment without delay.** States would also have the option to allow health care providers and other qualified entities to provide critical health care services to women pending official enrollment in Medicaid, increasing the chances of survival for these women and allowing them to focus on fighting these terrible diseases, not about how they will pay for their care.
- **Result in increased state spending on breast and cervical cancer screening programs.** Some states currently supplement the Federal funds they receive for breast and cervical cancer with their own funds for diagnosis and treatment of these diseases. Estimates by the Congressional Budget Office indicate that, under this proposal, states would begin to redirect these funds to supplement their investment in screening for breast and cervical cancer, resulting in a substantial increase in the number of mammograms and pap smears provided. For instance, under this bill, the number of mammograms is expected to increase by 44 percent by 2003.

BUILDS ON THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO FIGHTING BREAST AND CERVICAL CANCER. The Clinton-Gore Administration has responded to the significant threat posed by breast and cervical cancer with increased efforts in research, prevention and treatment. Funding for breast and cervical cancer research, prevention and treatment has increased from approximately \$X million in FY 1993 to \$X million in FY 2000. In January 1998, Medicare coverage expanded to help pay for annual mammograms and pap smears for all Medicare beneficiaries age 60 and over. The Administration co-sponsored a national education campaign about the new annual Medicare mammography benefit and the importance of regularly scheduled screening mammograms. Finally, the President's Medicare reform plan would eliminate all cost sharing for mammograms and pap smears, which should increase the number of older women using these critical services.

64 Please clarify the disabled issue.

Thanks

Here are our comments – all minor. Looks good. Thanks for the opportunity.

Steve

- 1) remove hyphen
- 2) Do you want to say breast and cervical cancer?
- 3) more than 368,000
- 4) early detection through screening -
- 5) state, territory and tribal screening programs
- 6) add hyphen
- 7) aggressive breast-conserving surgery
- 8) add hyphen
- 9) (could use) reducing
- 10) add hyphen
- 11) add hyphen
- 12) to
- 13) which
- 14) more than
- 15) This legislation will (No colon)
- 16) add hyphen
- 17) add hyphen
- 18) lifesaving (one word)
- 19) (will OMB be able to provide these \$ numbers?)

From the Desk Of...
Jennifer L. Katz
 Government Relations Manager
National Breast Cancer Coalition

1707 L Street, NW, Suite 1060
 Washington, D.C. 20036
 Phone: (202) 973-0595
 Fax: (202) 265-6854

Fax

Sharon

973

0581

To: Barbara Wooley

From: Jennifer Katz

Pages: ⁷ (Including cover)

Date: February 3, 2000

Phone: 456-2155

Fax: 456-6218

Re: Stories and contact information

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

● **Comments:**

Barbara:

We're working on getting the rest of the information together for you now.

Call me if you have questions.

Jennifer

526

Bonnie

Steven 6906625

Beeley party sat night?

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. statement	re: personal medical (4 pages)	02/03/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20462

FOLDER TITLE:

Environmental Health [Folder 1]

2012-0463-S

rc743

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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001b. statement	re: personal medical (2 pages)	02/03/2000	P6/b(6)

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. fax	Jeff Morelli to Devorah Adler re: phone numbers (partial) (1 page)	11/23/1999	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20462

FOLDER TITLE:

Environmental Health [Folder 1]

2012-0463-S

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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[002]

Jim Pirkle

P6/(b)(6)

The Nation's Prevention Agency



Centers for Disease Control and Prevention

P6/(b)(6)

TO: DEVORAH ADLER**FROM:** Jeff Morelli
Financial Management Office
Centers for Disease Control and Prevention
Phone: 404-639-7411 Fax 404-639-7479**DATE:** 11/23/99**FAX:** 202-456-**TOTAL NUMBER OF PAGES:** 7

DEVORAH: HERE IS THE ADDITIONAL INFORMATION YOU REQUESTED REGARDING THE CONTRIBUTIONS THE LABORATORIES AT CDC'S NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH) CAN MAKE IN THE FIGHT AGAINST BREAST CANCER. NCEH'S LABS HAVE SIMILARLY IMPRESSIVE CAPABILITIES TO STUDY OTHER FORMS OF CANCER AND BIRTH DEFECTS. WE WILL CONTACT YOU SHORTLY TO DISCUSS FURTHER AND ANSWER YOUR QUESTIONS. I WILL BE AT HOME TOMORROW, SO PLEASE DON'T HESITATE TO CONTACT ME AT MY HOUSE

P6/(b)(6)

IF YOU NEED ADDITIONAL INFORMATION. THANKS.**JEFF MORELLI
CDC**

P6/(b)(6)

The National Center for Environmental Health (NCEH) has an international reputation for conducting high quality research evaluating the links between environmental exposure and disease. NCEH's ability to integrate environmental disease epidemiology with laboratory-based measurements of environmental exposure is unique. The attached inventory describes on-going NCEH research that directly addresses the relationship between diseases specific to women (e.g., breast cancer, ovarian cancer, infertility, endometriosis) and exposure to environmental chemicals (e.g., persistent organic pollutants, pesticides).

There are still too many unanswered questions about the impact of environmental exposures on a woman's health--including the impact on her reproductive health and the health of her children. Only careful and comprehensive research will adequately answer these questions. There are three components necessary to such research:

- 1) Epidemiologic methods and rigor
- 2) Laboratory determination of exposure
- 3) Genetic expertise

NCEH is the only governmental unit where these three components are already in place and working together.

Epidemiology addresses questions of geographical variation in breast cancer occurrence and carefully collects information that can confound or obscure the relationship between disease and exposure. The attached listing of current NCEH research as well as the publication record of NCEH staff testifies to the quality and experience of our epidemiologists.

Biological markers of exposure are imperative in evaluating environmental links to the occurrence of breast cancer. Only laboratory quantified measurements of the body burden of suspected or known carcinogens provide accurate and valid information about actual exposure. It is not adequate to infer exposure based on reports of what an individual ate or what kind of work they do. The environmental health laboratory at the NCEH is a state-of-the art laboratory that quantifies environmental chemicals in human specimens. The close integration of the laboratory into all aspects of the epidemiologic research means that the laboratory is able to develop methods appropriate to the study question.

Genetic predisposition may be the reason why some women are more susceptible to the adverse effects of environmental chemical exposure. NCEH has a strong molecular biology laboratory component that has already begun to apply advances in genetic technology to examine the prevalence of disease genes in the general population and to identify susceptible populations that would benefit most from public health intervention programs. In addition, the laboratory has a nationally representative bank of thousands of DNA samples from women in the United States that could be used to examine important research questions related to breast cancer.

Using these three essential research components, promising avenues for intramural and extramural research will include both identification of potentially highly exposed cohorts of women and identification of groups of women who have unusually high levels of disease. In the highly exposed cohort epidemiological methods would be used to identify and describe established risk factors for breast cancer as well as the prevalence of this and other health outcomes that are biologically plausible following exposure to environmental chemicals. Determining biomarkers of exposure and genetic mapping will allow us to define the relationship between disease and exposure. Similar laboratory methods will be used to closely evaluate any environmental contribution to geographically identified groups with unexpectedly high levels of breast cancer disease.

**Environment and Breast Cancer
Studies and Collaborative Activities
National Center for Environmental Health
Centers for Disease Control and Prevention**

1. Breast Cancer Among Women Exposed to Polybrominated Biphenyls (PBBs)

NCEH is working with the National Institute of Health's National Cancer Institute (NCI) and the Michigan Department of Public Health to evaluate the association between risk for breast cancer and exposure to PBBs by testing the blood and adipose tissue of women heavily exposed to these toxicants. Eligible subjects for the study were the 1,925 women who consumed PBB-tainted food in 1973 or 1974 and who had their serum PBB levels measured when they enrolled in a PBB exposure registry. Case-subjects were 20 women with confirmed breast cancer diagnosed after enrollment. Control subjects were 15 race- and age-matched women selected by population-density sampling. Results, which will be published soon, show that women exposed to PBBs are at higher risk, but the difference in risk is not statistically significant.

2. Environmental Risk Factors and Breast Cancer Among Women in Maryland

NCEH is collaborating on this project with NCI and Johns Hopkins University's School of Hygiene and Public Health. CDC will analyze about 700 serum samples for PCBs and DDE, a metabolite of DDT. The serum for this nested case-control study was collected in 1974 and 1989. The samples will be assayed for antioxidant nutrients, and the glutathione-S transferase (GSTM1) genotype will be determined by using the buffy coat collected in 1989. The purpose of the study is to examine the influence of three factors on the risk for breast cancer: (1) exogenous exposures to organochlorines, (2) GSTM1 genotype as a potential susceptibility factor, and (3) antioxidants as protective factors.

3. Predictive Value for Breast Cancer of Serum Organochlorine Levels

NCEH, in collaboration with NIOSH and the U.S. Department of Defense, is conducting a study of the predictive value for breast cancer of serum organochlorine levels among occupationally exposed women. For this case-control study, the Janus Serum Bank in Norway will provide the serum samples, which were collected 5 to 20 years before any diagnosis of cancer. NCEH will analyze 300 samples for 30 organochlorines, including polychlorinated biphenyls, dioxins, furans, and pesticides. Study subjects were selected on the basis of likelihood of occupational exposure to these compounds. Subjects' parity, diet, location of residence, and family medical history will also be examined.

4. Study of Meta-Analyses of the Association between Hormone Replacement Therapy and Risk for Breast Cancer

Results from five meta-analyses of studies of the risk for breast cancer associated with hormone replacement therapy (HRT) show that estrogen use for less than 5 years has little effect on risk for breast cancer. These analyses, however, show different conclusions about the effect of long-term estrogen use. To understand the differences in the conclusions reached in these meta-analyses of long-term estrogen use and to determine any sources of heterogeneity, NCEH is investigating the differences in studies included in each meta-analysis.

5. Predictive Value of Serum Organochlorine Levels & Seven Different Cancers in Norway

A case-control study of workers exposed to organochlorine compounds is being conducted in collaboration with NCI and Norwegian scientists using the Norwegian Cancer Registry and stored serum specimens collected 5-20 years prior to diagnosis. More than 30 organochlorine compounds including DDT, mirex and dieldrin, and PCBs will be measured. The project will contribute useful information to the current debate on the role of organochlorines in seven different types of cancer.

6. Breast Cancer among Native Alaskan Women Exposed to Organochlorines

A pilot study was conducted by CDC in collaboration with the Indian Health Service (IHS), the National Cancer Institute and Alaska Native Tribal Boards (funding from NIH). The objective of the pilot study was to define the exposure level and breast cancer risk among women who are exposed to man-made chemicals (such as DDT) that bioaccumulate in the Arctic food supply. These chemicals have the potential to mimic hormones in a woman's body and therefore increase her risk of developing breast cancer. Methods included medical chart review of 60 women with pathology-diagnosed breast cancer, and 60 women of similar age without cancer. Banked serum samples that predated cancer diagnosis were analyzed at NCEH for a variety of organochlorine chemicals that have the potential to disrupt endocrine systems. Results were formally communicated to the Indian Health Service and the Alaska Area Native Health Center in August 1997

Subsequently, a follow-up study was initiated by the same collaborators, with funding from the National Action Plan on Breast Cancer. The objective is to further define the relationship between dietary exposure to man-made environmental chemical pollutants and breast cancer, and to assess whether or not levels of human exposure are increasing or decreasing among Alaska Natives. Methods include hospital-based data collection from Native women scheduled for breast biopsy. Serum and adipose tissue will be collected and analyzed for chemicals that may be associated with developing breast cancer. Health and nutrition information will be collected through personal interview. Results of this project will be shared with the community and used to interpret risk and

target breast cancer prevention efforts.

7. Case-Control Study of Breast Cancer Among Asian-American Women

In collaboration with NCI, NCEH is analyzing 500 plasma samples for organochlorine pesticides or their metabolites and for polychlorinated biphenyls. These analyses are part of a population-based, case-control study of breast cancer among women of Chinese, Japanese, or Filipino ethnicity who live in the San Francisco-Oakland SMSA, Los Angeles SMSA, or on Oahu, Hawaii. The study is based on the finding that Asian women have a lower prevalence of breast cancer than women in the western world, but once they relocate to the West, their rate of breast cancer is similar.

8. Levels of Selected Xenoestrogens and Breast Cancer in Denmark

Denmark (like the United States) has one of the highest rates of breast cancer in the world. CDC is collaborating with Danish researchers on a study of women who were between 25 and 75 years of age when first examined in 1976-1978 for the Copenhagen City Heart Study (CCHS). About 270 of the 7712 women examined then had gotten breast cancer by 1992. Each of the 270 case subjects is matched with two control CCHS subjects who have not gotten breast cancer. Serum samples taken in 1976-78 and 1981-83 will be analyzed for individual congener PCBs and selected organochlorine pesticides. The analyses will indicate changes in the serum concentration of these xenoestrogens and the development of breast cancer.

9. Analyses of Serum Pesticides and Polychlorinated Biphenyls for a Study of Breast Cancer

CDC is collaborating with the National Cancer Institute on a study for which we analyzed 344 serum specimens for individual congener PCBs and selected organochlorine pesticides. The Breast Cancer center in Columbia, MO collected the samples between 1977 and 1987 from 7641 women. All were free of cancer when their samples were taken, but since then, 112 have gotten breast cancer. A case-control study is being performed.

④ States & backup \$3
25 to 30 project

epidemiologist 8

etiologic
studies

help figure
out env. health
studies for potential

Environmental exposures and breast cancer

Background

NCEH's Environmental Health Laboratory (EHL) specializes in assessing **individual human exposure** to toxic substances by measuring the toxic substances directly in human specimens, such as blood or urine. These exposure measurements are called *biomonitoring* because they use human specimens. Biomonitoring exposure measurements tell us **who** has been exposed, **what** they have been exposed to and **how much** exposure they have had. Biomonitoring is the only way to measure the body burden of a toxic substance in people. Biomonitoring measurements are the basis for medical management of individuals and public health decisions to protect populations. EHL is recognized nationally and internationally for its expertise in biomonitoring -- the lab is **unique in the world** in its ability to measure exposure to many toxic substances using biomonitoring.

EHL has developed biomonitoring measurements for more than 200 toxic substances, including many that are known or reasonably suspected of causing cancer (i.e., carcinogens). These 200 toxic substances include selected compounds that are endocrine disruptors and may be causally related to breast cancer from their estrogen-mimicking activity. Biomonitoring methods have not yet been developed for at least 50 more substances that are known or suspected of causing cancer, including breast cancer.

Proposed activities

National Exposure Report Card for Carcinogens

EHL would expand its National Exposure Report Card to determine the exposure of the U.S. population to compounds that are known or suspected carcinogens, with emphasis on compounds suspected of causing breast cancer. Blood and urine samples would be obtained from CDC's National Health and Nutrition Examination Surveys (NHANES). **Each year**, the Report Card would report the exposure of Americans to carcinogens, specifically:

- what carcinogens (or suspected carcinogens) Americans are exposed to
- who is exposed (e.g., children, women, elderly, poor, minorities)
- how much are they exposed
- trends in exposure (are levels going up or down)

This exposure information for the population and population subgroups would guide public health action to protect Americans and guide research studies examining causes of breast cancer and other cancers. The trend in exposure levels information would directly measure the effectiveness of public health interventions aimed at reducing exposure of the population to carcinogens. This trend information would also be available for population subgroups that are at increased risk.

Funding: \$8.0 million

right now, working on addtl space—

this will be completed —

① Contracts out to get standards prepared — ~~is~~ ^{is} for 1st year $2\frac{1}{2}$ million
not done in their lab —

② HANES survey specimens —
run addtl April —
Collected for 1st year of 4 million
boxes → backlog of
samples to analyze 18 months
40 - 50 compounds

③ Research to
develop methods $\$4$
to measure

Lonie - hope this is okay - call or page

**DRAFT: WHITE HOUSE ANNOUNCES MAJOR NEW INCREASE IN FUNDING TO
DETERMINE ENVIRONMENTAL CAUSES OF DISEASE**

**Funding Will Provide New Insight Into the Causes of Breast and Prostate Cancer
January 13, 2000**

Today, the White House will announce that the President's FY 2001 budget will include a historic 58 percent increase to explore the environmental causes of disease. This investment will provide new insight into the largely unknown causes of breast and prostate cancer as well as other diseases. This initiative, which is supported by the American Cancer Society and the American Academy of Pediatrics, will provide \$27 million, \$10 million over last year's funding level, for the Center for Disease Control and Prevention (CDC) Environmental Health Lab to: assist communities investigating unusual incidence of cancer or other diseases; identify regions of the country in which individuals are at increased risk of dangerous exposure to carcinogens and other toxic substances; and ensure rapid evaluation of the impact of public health emergencies.

Because of the startling lack of evidence pinpointing the cause of cancers and many other diseases, these environmental studies should play a major role in determining now, more effective, diagnostic tests and preventive techniques to prevent these diseases.

**ENVIRONMENTAL CONDITIONS ARE LINKED TO INCREASED INCIDENCE OF
CANCER AND OTHER DISEASES.** Scientific evidence indicates that more than half of cancers and birth defects are caused by environmental exposures. Studies tracking patterns of cancer development in humans strongly suggest the influence of environmental factors.

- **Environmental contaminants are associated with a wide range of birth defects and other diseases.** Of the 120,000 U.S. babies born each year with a birth defect, 8,000 die during their first year of life, making birth defects the leading cause of infant mortality in the United States and contributing substantially to childhood morbidity and long-term disability. Hundreds of thousands of cases of asthma and lead poisoning, in addition to a significant percentage of birth defects continue to be associated with environmental contaminants.
- **Initial scientific evidence demonstrates that increased risk of breast cancer may be associated with unknown environmental factors.** One out of nine American women will develop breast cancer in her lifetime, and breast cancer is now the leading cause of death for women between the ages of 35 and 54. Despite decades of research, over half of all breast cancer cases cannot be explained by known risk factors, such as genetic predisposition, reproductive history, and diet.
- **Initial scientific evidence demonstrates that increased risk of prostate cancer may be associated with unknown environmental factors.** Prostate cancer is the most common type of cancer found in American men other than skin cancer, and disproportionately impacts African-American men. Researchers estimate that there will be about 180,000 new cases of prostate cancer in the United States this year, 36 percent of all cancer cases, and that about 37,000 men will die of this disease. However, researchers estimate that only 10 percent of prostate cancers are due to genetic predisposition.

stats
from CDC
website.

According
to the
American
Cancer
Society

association between

- Research on the link between environmental exposure and associated breast, prostate and cancer ~~other diseases~~ ^{other} is a critical public health issue. Failure to properly research the impact of environmental contaminants on individual health will prevent the development of potential cures, prevention strategies, and treatments. If exposure to chemicals in the environment was shown to be associated with only 10 percent of breast and prostate cancer cases, and we reduced or eliminated the identified hazards, we could potentially prevent over 30,000 men and women from developing these diseases each year.
- Biomonitoring provides the critical information necessary to link exposure and disease. Biomonitoring is the measurement of toxic substances in the human body, providing information necessary to link exposure to a toxic substance and the incidence of diseases such as cancer and a wide range of birth defects. Without an individual exposure assessment, it is impossible to determine whether individuals have been exposed to a dangerous level of ~~toxin~~ ^{a toxic substance}. It identifies which groups of people are in the most danger from toxic substances, evaluates the success of preventive actions, and improves the response of public health officials to emergencies.

determining what levels of exposure are safe or what levels cause disease.

CLINTON-GORE ADMINISTRATION MAKES MAJOR NEW INVESTMENT TO INVESTIGATE THE ENVIRONMENTAL CAUSES OF CANCER AND OTHER DISEASES.

Today, the White House will announce that the President's FY 2001 budget will include a major increase in funding to explore the environmental causes of disease and provide critical assistance to state and local public health officials to implement disease prevention programs. This \$27 million investment, a \$10 million increase over last year's funding level, will:

- Double the level of assistance provided to state and local public health officials investigating adverse health events potentially linked to environmental exposures. This new investment will allow epidemiologists and toxicologists at the CDC's Environmental Health Lab to double the level of critical technical support services ~~it provides~~ ^{to investigate} to communities who have identified cancer or other disease clusters potentially linked to toxic environmental exposures, including on-site assistance with investigations and specialized laboratory services. As part of these interventions, the CDC will test the exposure of thousands of individuals in the community to toxic substances in order to determine the cause of their illness. Studies that evaluate increase risk of cancer or birth defects from exposure to potential carcinogens or toxic substances will be given funding priority. When dangerous exposures are identified, CDC will work with local public health officials to take measures, including safe and swift evacuation if necessary, to protect residents from further harm.

- Identify regions of the country where individuals are exposed to toxic substances that cause cancer and other diseases. Currently, although the Environmental Health Lab has conducted studies that link exposure to dieldrin and polychlorinated biphenyls (PCBs) to increased risk of breast cancer and non-Hodgkins lymphoma, there is no way to determine the national level of exposure to these dangerous substances. These new funds will allow the Environmental Health Lab to routinely conduct nationwide monitoring of over 100 potentially toxic substances, including dieldrin, PCBs, and over 70 other potential carcinogens. This data would assess exposure to these dangerous substances for women of childbearing age, children, minorities, and the elderly in order to identify exposure to toxic chemicals and develop a blueprint for action to prevent dangerous exposures in the future.

the pesticide to increased risk of breast cancer

- **Ensure rapid evaluation of the impact of public health emergencies.** New funds will ensure that the CDC's Environmental Health Lab, together with state and local public health officials, can immediately address the health repercussions of public health emergencies, such as widespread exposure to a toxic substance through a one-time event such as a chemical spill or contamination of a product through a manufacturing error. Together with epidemiologists, toxicologists, and other public health personnel, the lab will will conduct a comprehensive investigation to identify ~~all~~ ^{work with local} sources of contaminant and protect local residents ^{officials to help} by swiftly acting to preventing further exposure. For example, when methyl parathion, a lethal pesticide, was illegally sprayed in thousands of homes during 1996 and 1997, the Environmental Health Lab created a new method to test for the presence of this dangerous substance and provided the laboratory support services and scientific expertise necessary to accurately prioritize medical treatment for exposed individuals and determine which homes should be evacuated.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. list	re: contact info (partial) (1 page)	n.d.	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20462

FOLDER TITLE:

Environmental Health [Folder 1]

2012-0463-S
rc743

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

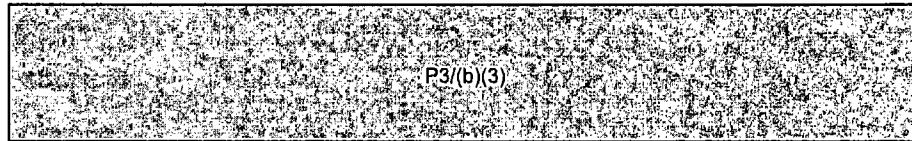
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

TO:



003J

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Francis Collins / Kathy Hudson	301 402 0837 ✓
Gary Claxton / Steve Finan	202 401 7321 ✓
Jane Horvath	202 690 8425 ✓

DEPARTMENT OF JUSTICE

Rosemary Hart	202 514 0563 ✓
Robin Lendhardt	

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Stacy Grundman	202 219 9216 ✓
Dan Maguire	

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Cedric Dumont	202 663 1613

EEOC

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WHITE HOUSE

Eric Liu	6-2878
David Beier	6-6231
Eddie Correia	6-5055 ✓ 62256
Peter Swire	5-3047
Neal Lane / Rachel Levinson	6-6021

FROM: Chris Jennings

**DRAFT: FIRST LADY HILLARY RODHAM CLINTON ANNOUNCES LARGEST
EVER INVESTMENT TO DETERMINE ENVIRONMENTAL CAUSES OF DISEASE**
Funding Will Provide New Insight Into the Causes of Breast and Prostate Cancer
January XX, 2000

Today, First Lady Hillary Rodham Clinton will announce that the President's FY 2001 budget will include the largest increase ever for new research to determine the environmental causes of disease. This historic 58 percent increase will provide new insight into the causes of breast and prostate cancer as well as other diseases. This initiative will provide \$27 million, \$10 million over last year's funding level, for the CDC's Environmental Health Lab to increase assistance to state and local public health officials investigating adverse health events that are potentially linked to environmental exposures; increase efforts to systematically evaluate the exposure of men, women, and children to toxic substances that cause cancer and other diseases; and ensure rapid evaluation the impact of public health disasters. *early unknown & unapplicable*
 Because of the startling lack of evidence pinpointing the cause of cancers and many other diseases, these environmental studies should play a major role in determining new, more effective, diagnostic techniques, preventive efforts, *shorter & tighter*
 and ~~hopefully cures~~ for these diseases. *for*

ENVIRONMENTAL CONDITIONS ARE LINKED TO INCREASED INCIDENCE OF CANCER AND OTHER DISEASES. Scientists estimate that 50 to 70 percent of cancers are caused by environmental exposures. Studies tracking patterns of cancer development in humans strongly suggest the influence of environmental factors.

- **Breast cancer incidence is linked to unknown environmental conditions.** One out of nine American women will develop breast cancer in her lifetime, and breast cancer is now the leading cause of death for women between the ages of 35 and 54. Despite decades of research, two-thirds of all breast cancer cases cannot be explained by known risk factors, such as genetic predisposition, reproductive history, and diet. For example, studies indicate in Asia, women are 4 to 7 times less likely to develop breast cancer than American women. Yet Asian American women with grandparents born in the United States have a 60 percent greater risk of developing breast cancer than women with grandparents born overseas.
- **Prostate cancer incidence is linked to unknown environmental conditions.** Prostate cancer is the most common type of cancer found in American men, other than skin cancer, and disproportionately impacts African-American men. Researchers estimate that there will be about 179,300 new cases of prostate cancer in the United States this year, 36 percent of all cancer cases, and that about 37,000 men will die of this disease. Mortality rates in African-American men are more than twice as high as rates in white men. However, researchers estimate that only 10 percent of prostate cancers are due to genetic predisposition.
- **Environmental contaminants are linked to a wide range of other diseases.** Diseases like asthma, pertussis, lead poisoning, developmental disabilities, and birth defects continue to be associated with environmental contaminants. Additional research in this area is essential in determining causes of illness, disability, and death and preventing people from becoming ill.

- **Research on environmental links to cancer is a critical public health issue.** Failure to properly research the impact of synthetic chemicals and other environmental contaminants will prevent the development of potential cures, prevention strategies, and treatment. If exposure to chemicals in the environment was shown to be associated with only 10 percent of breast and prostate cancer cases, and we acted to reduce or eliminate the identified hazardous chemicals, we would be able to prevent over 30,000 men and women from developing these diseases each year.
- **Biomonitoring is the critical link between exposure and disease.** Biomonitoring is the measurement of toxic substances in the human body, providing the final and conclusive link between exposure to a toxic substance and the incidence of diseases such as cancer and a wide range of birth defects. Without an individual exposure assessment, it is impossible to determine whether individuals have been exposed to a dangerous level of toxin. It identifies which groups of people are in the most danger from toxic substances, evaluates the success of preventive actions, and improves the response of public health officials to emergencies.

CLINTON-GORE ADMINISTRATION MAKES MAJOR NEW INVESTMENT TO INVESTIGATE THE ENVIRONMENTAL CAUSES OF CANCER AND OTHER DISEASES. Today, First Lady Hillary Rodham Clinton announced that the President's FY 2001 budget will the largest increase ever in funding to explore the environmental causes of disease and provide critical assistance to state and local public health officials to implement disease prevention programs. This new \$27 million initiative, a \$10 million increase over last year's funding level, will:

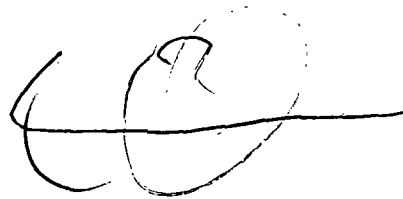
- **Double the level of assistance provided to state and local public health officials investigating adverse health events potentially linked to environmental exposures.** This new investment will allow epidemiologists and toxicologists at the CDC's Environmental Health Lab to double the level of critical technical support services it provides to communities who have identified cancer or other disease clusters potentially linked to toxic environmental exposures, including on-site assistance with investigations and specialized laboratory services. As part of these interventions, the CDC will test the exposure of thousands of individuals in the community to toxins in order to determine the cause of their illness. Those studies that evaluate cancer risk from exposure to potential carcinogens and to risk of birth defects from exposure to potential carcinogens will be given priority for funding. When dangerous exposures are identified, CDC will work with local public health officials to take measures, including safe and swift evacuation if necessary, to protect residents from further harm.
- **Identify regions of the country where individuals are exposed to toxic substances that cause cancer and other diseases.** New funding for the Environmental Health Lab will allow for routine monitoring nationwide of over 100 potentially toxic substances, including an additional 75 toxic substances that are known or reasonably expected to cause cancer. This data would provide the first ever assessment of the exposure to these dangerous substances for population subgroups such as women of childbearing age, children, minorities, and the elderly in order to identify exposure to toxic chemicals and develop a blueprint for action to prevent dangerous exposures in the future.

more
specific
on why link
~~cancer~~
cancer
could /
How it
works
what kind
of studies?

Any high
tech new
application?

- **Ensure rapid evaluation of the impact of public health disasters.** New funds will ensure that the CDC's Environmental Health Lab, together with state and local public health officials, can immediately address the health repercussions of public health disasters, such as widespread exposure to a toxin through a one-time event such as a chemical spill or contamination of a product through a manufacturing error. Epidemiologists, toxicologists, and other public health personnel will conduct a comprehensive investigation that will conclusively identify all sources of contaminant and protect local residents by swiftly acting to preventing further exposure.

↑ ?
Extension of
what they have
done in past
to make more
real



FAX

TO: *Deborah Adler*
202-456-5557

FROM: James L. Pirkle, M.D., Ph.D.
Centers for Disease Control and Prevention
Phone: 770-488-7950
FAX: 770-488-4839

Subject: *Comments*

No. of pages (including this one): *3*

Comments:

Melany Nakagiri 01/05/2000 06:36:08 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP
cc: See the distribution list at the bottom of this message
Subject: TB and Malaria Activities within CDC

I will fax you some information outlining CDC's current TB activities and some of CDC's global health activities related to malaria and TB. For additional information on malaria activities, I would contact Joe McDade at CDC, the Deputy Director of the Center for Infectious Diseases (404) 639-3967, who's usually very helpful.

In terms of funding, I have asked CDC to provide me with some information on funding for malaria since it is embedded in the infectious disease program activity line.

TB Funding: \$128 million in FY 2000 and FY 2001.

Please let me know if you have any questions.

Message Copied To:

Daniel N. Mendelson/OMB/EOP@EOP
Richard J. Turman/OMB/EOP@EOP
Marc Garufi/OMB/EOP@EOP
Barry T. Clendenin/OMB/EOP@EOP
Molly O'Malley/OMB/EOP@EOP
Jennifer Ferguson/OMB/EOP@EOP

Melany Nakagiri 01/06/2000 05:56:48 PM

Record Type: Record

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

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

Subject: FYI - More information from CDC on Malaria Activities

Including funding levels for FY 2000 and FY 2001

1. What is the FY 2001 funding level for malaria?

\$8.7 million (which is the base funding level) no new funding in FY 2001

2. What will the funding be used for?

The mission of the Malaria Epidemiology Branch is to provide technical assistance and recommendations to prevent and control malaria on a national and international level. We accomplish this mission through multi-disciplinary research, surveillance, and service, including providing diagnostic, consultative, and epidemiologic support and training. We carry out our mission in a work place that promotes professional development and recognizes the importance of the individual and the team. Our services are provided through partnerships with health care professionals; state, local and federal agencies within the United States; foreign governments; national and international organizations; and the public.

3. Summary information on CDC current malaria activities

ADDITIONAL SPECIFICS

1) Conducts surveillance and epidemiologic investigations on malaria in the United States and among U.S. citizens abroad; (2) monitors the efficacy and safety of antimalarial drugs for chemoprophylaxis and chemotherapy; (3) provides clinical advice and epidemiologic assistance on the treatment, control, and prevention of malaria in the United States and abroad; (4) provides malaria diagnostic/reference services; (5) conducts epidemiologic investigations in malarious areas; (6) collaborates with others to provide epidemiologic assistance for laboratory- and field-based research projects; (7) serves as the WHO Collaborating Center for Malaria Control in Africa.

<http://www.cdc.gov/ncidod/dpd/kemri.htm> (KEMRI field station in Africa)

4. FY 2000 funding:

Anticipated expenditures for FY 2000 are approximately \$17.7 million. An additional \$9 million appropriated from the Public Health Service Emergency Fund which will be used for malaria activities during FY 2000. (Therefore, \$8.7 million plus \$9 million for FY 2000)