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001. schedule	Schedule for Hillary Rodham Clinton (partial) (4 pages)	09/29/1998	P6/b(6)

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FOLDER TITLE:
Breast Cancer October Event [2]

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RESTRICTION CODES

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P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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DRAFT

9/25/98

BREAST CANCER: FIVE YEARS OF ACCOMPLISHMENTS IN A DEDICATED FIGHT AND COMMITMENT TO ERADICATE THE DISEASE

Highlights: 1993-1998

Breast cancer is the most commonly diagnosed cancer except for skin cancer and the second leading cause of cancer deaths among American women. There is no proven way to lower the risk for breast cancer, so early detection through mammography and clinical breast exams is essential.

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

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

At the same time, **spending on breast cancer research at HHS' National Institutes of Health has increased from $237 million in FY 1993 to an estimated $433 million in FY 1998, and a proposed budget of $458 million in FY 1999.**

CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) offers free low-cost mammography screenings to uninsured, low-income, elderly, minority, and Native American women nationwide. The NBCCEDP, which now encompasses all fifty states, five territories, the District of Columbia, and fifteen American Indian/Alaska Native organizations, has provided screening tests to more than 1.7 million medically underserved women since its inception.

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

The National Cancer Institute's Cancer Information Service (CIS) marked it's 20th anniversary in 1996. **The latest information on breast cancer prevention, detection, and treatment, including locating FDA certified mammography facilities is available free by phone (1-800-4-**

CANCER) and on the Internet (www.nci.nih.gov). The CIS responds to about 600,000 phone calls to its toll-free number each year.

In 1997, President Clinton proposed, and Congress adopted, **the expansion of Medicare coverage which will help pay for annual screening mammograms for all Medicare beneficiaries age 40 and over.** This new benefit became available January 1, 1998.

In 1998, the U.S. Postal Service issued a **breast cancer research stamp**, valid for the 32 cent first-class rate but selling for 40 cents. The additional 8 cents will be donated to breast cancer research, with 70 percent of proceeds going to NIH (less United States Postal Service costs) and 30 percent to the Medical research program of the Department of Defense.

Background

Need to make progress — Progress is important

The lifetime risk of developing breast cancer today is one in every eight women, up from one in every 20 women just two decades ago. Although death rates from breast cancer have been declining in recent years, breast cancer accounts for 31 percent of all cancers among women.

Approximately 180,300 new cases of breast cancer will be diagnosed in 1998, and about 44,000 women are expected to die from breast cancer. Epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women in this decade and that breast cancer will claim nearly half a million lives.

Death rates from the disease are highest among older, black, and low-income women. With early detection and proper treatment, however, the chances of surviving breast cancer are improving. Breast cancer mortality trends among both black and white women have improved markedly in the United States since the 1980s. Between 1982 and 1987, breast cancer incidence for women increased about 4 percent per year, but recently has leveled off.

The death rate for women with breast cancer declined 4.6 percent between 1991 and 1995. The greatest reductions in death rates were among younger women (9.3 percent) and white women (6.6 percent), with more modest reductions among African Americans (1.6 percent) and women age 65 and older (2.8 percent).

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

A study in the journal *Cancer (1998;83:1262-1273)* attributes the decrease or leveling off in breast

cancer incidence and mortality to a trend toward progressively earlier diagnosis which is more treatable than later stage cancers. According to this study, approximately 42 percent of patients diagnosed in 1985 were diagnosed with the earliest stage cancers, stage 1 and stage 1 tumors. By comparison, approximately 46 percent of patients diagnosed in 1995 were diagnosed when the cancer was in stage 0 or stage 1.

HHS Spending On Breast Cancer

HHS discretionary funding for breast cancer research, prevention, detection, and treatment has increased from approximately $274 million in FY 1993 to over $400 million today. As the Centers for Disease Control and Prevention (CDC) have worked to increase access for all women to mammography screening and follow up services, its resources devoted to breast cancer services have increased from an estimated $42 million in FY 1993, to $84 million in FY 1998. Cancer research is vital to our understanding of how to prevent, detect, and treat breast cancer. The Clinton Administration has invested in breast cancer research at the National Institutes of Health by increasing funding from $237 million in FY 1993, to an estimated $433 million in FY 1998, and a President's budget request of $458 million in FY 1999. HHS also helps provide access to treatment for breast cancer through the Medicare and Medicaid programs and through the Indian Health Service.

HHS Action To Combat Breast Cancer

Under President Clinton, a wide array of activities are underway and new initiatives have been launched during the last five years:

New Mammography Benefit

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

Mammography Quality Standards

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

These regulations spell out the details for requiring facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled physicians to interpret

the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that necessary follow-up testing or treatment can begin immediately. The names and locations of FDA's certified mammography facilities are available by calling the NCI's Cancer Information Service at 1-800-4-CANCER. In addition, the FDA has included a list of all FDA certified mammography facilities in the United States on its Internet home page. The address is (http://www.fda.gov/cdrh/faclist.html).

National Action Plan on Breast Cancer

The Public Health Service's Office on Women's Health coordinates the National Action Plan on Breast Cancer (NAPBC). This unique public/private effort was developed in 1993 at the direction of President Clinton under Secretary Shalala's leadership. The Plan identified six priority areas at its inception including biological resources, etiology, hereditary susceptibility, clinical trials, consumer involvement and information dissemination. Six Working Groups were formed to identify and implement specific initiatives within these priority areas.

Through it's six working groups, the NAPBC has played a pivotal role in catalyzing national efforts, and coordinating activities of government and non-government organizations, agencies, and individuals in the fight against breast cancer. Key achievements since its inception include:

One-time Grants. Awarded over $9 million in one-time grants in 1995 for 99 innovative research and outreach projects, *with a special emphasis on the development of public-private partnerships* targeted in six original priority areas that correspond to six NAPBC Working Groups.

Linking Women to Breast Cancer Information. *Designed and introduced an NAPBC Web site (http://www.napbc.org)* which was launched by President Clinton on October 27, 1996. The web site serves as a gateway to information on breast cancer research, prevention, detection, and treatment. The NAPBC Web site provides answers on frequently asked questions about breast cancer, as well as information about the NAPBC, breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences, publications, and government and private resources.

Designed and implemented the Bridging the Gap Initiative pilot project, through which five community-based organizations across the nation are finding innovative ways to link informationally underserved women with breast cancer information through new technology such as the Internet and WebTV.

Genetic Predisposition. *Developed Hereditary Susceptibility to Breast and Ovarian Cancer: An Outline of Fundamental Knowledge Needed by All Health Care Professionals.* The outline serves as a framework for high-quality, customized education and training for health care professionals on the implications of genetic testing for breast cancer susceptibility.

Developed the video, Genetic Testing for Breast Cancer Risk: It's Your Choice, and circulated

over 30,000 copies to medical practitioners, cancer centers and breast cancer organizations. The video addresses the pros and cons as well as psychosocial issues involved in genetic testing to assist consumers in making informed choices about genetic testing.

Played a pivotal role in raising awareness about health insurance and workplace discrimination on the basis of an individual's genetic predisposition to disease by developing recommendations for federal and state policies. Both sets of recommendations were published in *Science.*

Understanding the Causes of Breast Cancer. *Developed and focus group tested the Breast Cancer Comprehensive Questionnaire.* The six modules and long and short versions of a core questionnaire provide a standardized set of questions, for use by all researchers, on risk factors linked to breast cancer.

Published papers on Hormones, Hormone Metabolism, Environment, and Breast Cancer in a supplement to the journal, *Environmental Health Perspectives.*

Published proceedings from the November 1997 workshop on Physical Activity and Breast Cancer in a supplement to the journal, *Cancer.*

Involving Consumers. *Conducted a survey to assess the extent of consumer involvement in activities in areas such as breast cancer research, service delivery, education and outreach, and public policy.* The ultimate goal is to identify and implement ways to bridge the gaps between the current status and potential status of consumer involvement.

Overcoming Barriers to Participation in Clinical Trials . *Conducted an extensive literature search to reveal barriers to participation in clinical trials and identify potential means of reducing those barriers.* This information is now being analyzed and will be compiled into a critical review of the literature that will be submitted for publication in 1998.

Conducted focus groups to design a plan for a marketing campaign designed to demystify breast cancer clinical trials, promote awareness, and encourage women to learn about and enroll in such trials.

Actions to Advance Research. *Designed and implemented through pubic and private partners a network of tissue banks* to assist researchers needing biological materials for breast and other cancer research studies. This network can be accessed through the NAPBC Web site.

Developed guidelines for Institutional Review Boards (IRBs) and others, a model patient consent form, and a patient fact sheet on donating tissue samples for research.

Federal Coordination of Breast Cancer Programs

All Federal agencies have joined in the battle against breast cancer with the 1994 establishment of the Federal Coordinating Committee on Breast Cancer (FCCBC), an interagency coordinating Committee and liaison group to the National Action Plan on Breast Cancer. The committee shares information about breast cancer programs within the Federal government, fosters collaborations, and has developed an Internet-accessible inventory of all government breast cancer activities.

FCCBC Supplement Grant Program. In September 1997, the FCCBC provided supplemental funding for a diverse portfolio of grants that will increase knowledge about the causes of breast cancer, improve early detection, treatment, and prevention of the disease, and will also bring lifesaving outreach and education programs to many medically underserved women across the nation. The Supplemental Funding Program awarded $2.7 million to fund 22 innovative projects, with 50 percent of funding directed to programs to address the needs of underserved populations and with an emphasis on trans-agency collaborations. Highlights of the supplemental grant program include,

- A research project supported by the Agency for Health Care Policy and Research to better understand the frequency of "drive-through" mastectomies in the era of managed care.
- An Indian Health Service's project to expand the training and support of community health aides in the delivery of breast cancer early detection services to Native American women in rural Alaskan villages.
- A project supported by the Health Resources and Services Administration to expand breast cancer services to Hispanic farm workers.
- A research project conducted by the National Institute of Environmental Health Sciences that will provide the foundation for a novel approach to identifying environmental chemicals with the potential to cause breast cancer.
- A National Cancer Institute project that is collecting in-depth survey information to evaluate the impact of a no-cost cancer screening program for low income, African American women.
- The development of a database sponsored by the Health Care Financing Administration to measure the impact of breast cancer screening interventions for Hispanic Medicare beneficiaries.
- A Department of Energy supported project to develop imaging technology to validate positive mammograms and thereby help reduce unnecessary biopsies.
- A Centers for Disease Control and prevention research study to investigate a common variation of the protein p53, which appears to be a susceptibility factor for breast cancer. The study defines the link between this variant and different environmental and occupational exposures and may assist in determining why breast cancer in African-Americans and Hispanics often differs from Caucasians.
- A study by the Food and Drug Administration to reduce toxicity and improve the effectiveness of a chemotherapy drug, amino glutethimide, used to treat breast cancer patients and a standard treatment choice for patients who no longer respond to tomoxifen.

NOTE: *The results of many of the 22-funded projects will be available in mid-October 1998.*

Partnering Workshop. In September 1998, the FCCBC is convening a workshop entitled "Partnering to Eliminate Disparities: Opportunity for Collaboration in Federal Breast Cancer Programs." The workshop is designed to highlight Federal activities related to breast cancer and to encourage the formation of new partnerships while strengthening existing collaborations in breast cancer research, policy, services, and public health.

The Women's Health Initiative (WHI)

The National Heart, Lung, and Blood Institute is leading a consortium of NIH Institutes engaged in the Women's Heath Initiative (WHI). The WHI includes the largest set of clinical trials ever conducted on the causes and prevention of breast cancer. It is testing whether a diet low in fat and high in fruits, vegetables, grains, and cereals will prevent breast cancer in the almost 49,000 women who enrolled in this part of the program. A second trial, which includes over 27,000 women, will evaluate the effectiveness of hormone replacement therapy in preventing heart disease, and breast cancer is being carefully monitored as a potential adverse outcome. Finally, the WHI will test whether supplements of calcium and vitamin D will prevent breast cancer. The observational study of over 92,000 women will be looking for new risk factors, including genetic factors, for breast cancer. The major results of the WHI are expected after 2005.

Discovery of BRCA1 and BRCA2 Genes Linked to Breast Cancer

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

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

The *Cancer Genome Anatomy Project (CGAP)* is working to identify the genetic differences among normal, precancerous, and cancerous cells. This project will help us foster the discovery of genes that are directly expressed in cancer; these can be used to identify early precancerous cells and thus enhance our early detection methods. The CGAP initiative will also aid our ability to

match individual patients with the most appropriate treatments. Although this project is designed to collect data for all cancers, researchers are initially concentrating on five major cancers.

The FDA has put cancer drugs on a fast track for review and approval. For example, promising medications approved in other countries or those found to shrink tumors to a greater extent than available therapies will be made available to treat patients with advanced breast cancer. New treatment approaches are evolving, including the sequencing of chemotherapies, the development of monoclonal antibodies shown to boost the immune systems to fight cancer growth, new drugs for advanced breast cancer, and medications to help prevent the disease from occurring.

Privacy of Genetic Information and Breast Cancer

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

Breast Cancer Prevention Trial (BCPT)

This year, the Breast Cancer Prevention Trial (BCPT), a study of the use of tomoxifen as a breast cancer prevention agent, was unveiled 18 months early because the drug was shown to cause a highly significant reduction in breast cancer incidence in women at greater-than-average risk of breast cancer. The group of women taking tomoxifen in this study had 49 percent fewer cases of invasive breast cancer than the group taking a placebo. The BCPT also documented certain serious side effects of tomoxifen, most notably vascular events and endometrial cancer. The trial was based on earlier observations about the effects of tomoxifen in women who already had breast cancer. It was noted that the women who took tomoxifen had a reduced incidence of new breast cancers in the opposite breast. This observation formed the basis for the BCPT, which has confirmed that tomoxifen can reduce the short-term incidence of breast cancer in healthy women at elevated risk for this disease. Longer follow-up of these women will be needed to assess the durability of the treatment effect, i.e. prevention of breast cancer. The NCI and the NCI-supported National Surgical Adjuvant Breast and Bowel Project will conduct a new large-scale breast cancer prevention trial to compare the effectiveness of tomoxifen and raloxifene. Raloxifene has been approved by the FDA for the treatment of osteoporosis. Data from the clinical trials of this drug also suggested a reduction in the numbers of breast cancers diagnosed in the treatment group. However, less is known about the effectiveness and potential side effects of raloxifene in treating breast cancer.

The FDA's Oncologic Drug Advisory Committee met in September 1998 and discussed Nolvadex (tomoxifen citrate) for the prevention of breast cancer in women at high risk. The committee voted 9-2 recommending approval for tomoxifen for the short-term reduction of the incidence of breast cancer in women at increased risk as defined by the study population.

Breast Cancer Surveillance Consortium

The Breast Cancer Surveillance Consortium was established in 1994 with three main objectives:

- to enhance our understanding of breast cancer screening practices in the United States by assessing the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer mortality and other outcomes, such as survival;

- to foster collaborative research among Consortium participants that examines issues such as regional and health care system differences in the provision of screening and follow-up evaluations; and

- to provide a foundation for conducting clinical and basic science research, especially basic research on biological mechanisms, that can improve our understanding of the natural history of breast cancer.

By the year 2000, it is estimated that the Consortium's database, with data collected from nine participating sites across the country, will contain information on nearly 3.2 million mammographic examinations and over 24,000 cases of breast cancer. These data will allow researchers to study the effect of mammography on the many facets of breast cancer, such as how the biologic characteristics of a breast tumor may affect screening performance. The data will also enable researchers to compare mammography screening practices among different regions of the country.

National Breast and Cervical Cancer Early Detection Program

CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) offers free or low-cost mammography screening to uninsured, low-income, elderly, minority, and Native American women nationwide. FY 1998 appropriations of $145 million for the NBCCEDP enabled CDC to expand this program so that resources devoted to breast cancer screening services have grown from an estimated $42 million in FY 1993 to over $84 million in FY 1998. The program, which now encompasses all fifty States, five territories, the District of Columbia, and fifteen American Indian/Alaska Native organizations, has provided screening tests to more than 1.5 million medically underserved women since its inception. The NBCCEDP is able to screen 12-15 percent of the eligible population for these cancers.

Partnerships are critical to CDC's cancer control efforts. A successful national program to control breast and cervical cancers depends on the involvement of a variety of committed partners and

national organizations. CDC collaborates with state and local governments, health care professionals and organizations, social service and voluntary organizations, and academia. Through partnerships, CDC assists private and public nonprofit organizations in following program areas:

- Developing, implementing, and evaluation national, community-based interventions for cancer prevention and early detection.
- Testing new methods and replicating proven strategies to educate their constituents about breast and cervical cancers.
- Increasing access to breast and cervical cancer screening among underserved women.

CDC and Avon. In 1993, a unique public-private partnership was established among CDC, Avon Products Inc., YWCA of the U.S.A., the National Alliance of Breast Cancer Organizations (NABCO), and the National Cancer Institute. The common goals for this partnership are to educate women about breast health and to improve access to early detection services. Avon's Breast Cancer Awareness Crusade has raised more than $25 million for breast cancer programs nationwide through the sale of its Breast Cancer Awareness pink ribbon products. Since 1993, about 300 community-based programs in 49 states and Puerto Rico have received funding from Avon's Crusade through the YWCA of the U.S.A. and NABCO to educate women about breast cancer and to provide underserved women with access to early detection services. Beginning in 1998, all funding of community-based programs has been consolidated under the Breast Health Access Fund administered by NABCO.

Partnerships for Cancer Control in At-Risk Populations. Partnerships that focus their prevention efforts on those at greater risk are essential for understanding and alleviating the disparities that exist. Deaths due to breast cancer are decreasing among white women, but not among African-American women as among white women. Both mammography and Pap tests are underutilized by women who are members of racial and ethnic minority groups, who have less than a high school education, are older, or live below the poverty level.

To address these differences in the burden of cancer and in the use of cancer prevention services among different populations, CDC funds a strong and effective network of partners that are well-positioned in the communities at risk including:

- The U.S. Conference of Mayors' Research and Education Foundation
- The National Center for Farmworkers Health, Inc.
- The American Social Health Association
- The Association of Asian Pacific Community Health Organizations
- The National Hispanic Council on Aging
- The Baylor College of Medicine sponsors the Salud en Accion Program
- The Institute for the Advancement of Social Work Research
- The Mautner Project for Lesbians with Cancer
- The National Asian Women's Health Organization

- The National Association of Community Health Centers
- The National Education Association Health Information Network
- The National Caucus and Center on Black Aged, Inc.
- The Witness Project
- The World Education

These partners have developed projects that are focused on specific at-risk populations and cover a wide range of prevention and research activities. For example, many projects are involved with developing low literacy, bilingual, and culturally appropriate educational campaigns. These various prevention techniques and research efforts used by the different projects result in the common goal of increasing knowledge and awareness of breast and/or cervical cancer and promoting screening for early detection.

Advances in Treatment

In 1996, President Clinton announced new FDA initiatives to improve access to promising new cancer therapies. These initiatives were aimed at accelerating approval times, expanding patient access, and including cancer patients in advisory panels that review cancer drugs. Recently approved drugs that will provide women with advanced breast cancer other options for treatment are Zoladex (gosereline acetate implant), Arimidex (anastrozole), Taxotere (docetaxel), Xeloda (capcibabine), Femara (letrozole), Fareston (toremifene citrate), and Aredia (pamidronate disodium).

A recent large study, has suggested that an experimental drug called Herceptin® can be beneficial for some patients with breast cancer that has spread to other parts of the body. Herceptin® is a humanized monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. Herceptin's targets are cancer cells that produce a protein called HER2 or HER2/neu. These cells occur in high numbers in about 25 to 30 percent of breast cancers. The protein is a cell-surface receptor that transmits growth signals to the cell nucleus. The clinical trial showed that patients whose tumor cells have extra copies of the HER2 protein do significantly better when Herceptin, which appears to block these signals, is added to standard chemotherapy. The drug has been shown to shrink tumors in some patients with advanced metastatic breast cancer. Overall, the Herceptin arms of the trial had a 53 percent better response rate, a 57 percent improvement in median duration of response, and a 65 percent improvement in time to progression, compared to standard chemotherapy alone. NCI worked with the company which developed Herceptin to open up sites for the expanded access program for the drug. On September 2, 1998, the Oncologic Drugs Advisory Committee (ODAC) recommended that the Food and Drug Administration approve Herceptin for the treatment of breast cancer in certain patients whose disease has spread beyond the breast. The Committee provides independent expert scientific advice to FDA on cancer therapies being considered for approval. The FDA is expected to follow the recommendation and approve Herceptin in the fall of 1998.

Early findings of a large, NCI multi-center trial show that the drug Taxol, when used in

combination with other standard chemotherapy agents, has a small but significant benefit for breast cancer patients whose disease has spread to nearby lymph nodes. Although the survival advantage is small at this point in the trial, the study is considered important because it is the first to show that Taxol may be beneficial in the initial, post-surgical treatment of some women with localized, node positive breast cancer. Longer follow-up of this trial and results from other confirmatory trials are needed before the addition of Taxol or similar drugs becomes routine. Other clinical trials now under way will provide much needed data on the optimal, adjuvant treatment for node positive breast cancer patients. One of these trials should finish recruiting patients soon and early findings could be available in the next one to two years. Another trial using Taxotere, a drug similar to Taxol, in the treatment of node positive patients is still open to new patients.

Breast Cancer Among the Elderly

National Mammography Campaign. The Health Care Financing Administration and the National Cancer Institute have entered into an intra-agency agreement to develop, implement, and promote a short term joint health promotion campaign targeting Medicare beneficiaries. The purpose of this campaign is to increase awareness of the importance of regularly scheduled mammography screening among women ages 65 and older, and the expanded Medicare benefit.

As part of the agreement, NCI has developed mammography publications to target older women. The new publications include a poster and bookmark featuring an older woman and the Medicare message; as well as large-print easy to-read brochure. All materials will include information on Medicare's expanded benefit and will be printed in English and Spanish.

HCFA and NCI plan to launch the campaign with a media event sometime in October during Breast Cancer Awareness Month 1998. HCFA and NCI will work together to prepare and distribute a joint press release and a fact sheet on breast cancer, mammograms and Medicare coverage. In addition, a media packet will be prepared to respond to media requests to mail to selected media outlets, and to be used by NCI and HCFA's networks.

Multi-City Mammography Pilot Projects. The most defining accomplishment of the Multi-City Mammography effort is the forming of community coalitions and partnerships. Not only are they diverse in compositions, contain many professional disciplines, and include several well-known and respected cancer advocacy organizations, but these coalitions and partnerships are strong and they are working. Projects include:

Philadelphia: Focus on African-American Medicare Beneficiaries.

- Organized a diverse partnership of 19 local Philadelphia organizations including representation from public, private, not-for-profit, and industry groups;
- Segmented the promotion of the project for targeting purposes into 3 priority areas--business/education, managed care physician/providers, and social/religious;
- Identified a 12 zip code area within Philadelphia with a high concentration of older African

American women as a target area;
- Personalized the project name from the generic Multi-City Mammography Pilot Project to PRIDE, or Philadelphians Recognizing Impact of Detection and Education;
- Will soon be initiating a poster and postcard campaign to raise awareness among the intended audience;
- Will conduct a survey to track the rate of mammograms of 500 women; and
- Will publish a bi-weekly newsletter for partners, called MCMP3, to enhance communications.

Chicago: Focus on African-American and Hispanic Medicare beneficiaries.
- Organized a diverse, multi-discipline partnership to plan and implement the project;
- Formed four priority committees to direct the project including, general project support, communications, resource guide development, and physician speakers bureau;
- Developed a project design which includes direct and indirect interventions. Direct interventions will target physicians and consumers and indirect interventions will focus on existing and ongoing initiatives, such as the National Black Leadership Initiative on Cancer and "Meals on Wheels."
- Conducted on-site visits in which 65 local organizations participated and 85 organizations provided information for a breast cancer resource guide.
- Segmented the city into 55 community areas for targeting -- 45 community areas are African-American, 3 areas are Hispanic, and 7 areas are both African-American and Hispanic; and
- Trained physicians participating in the speakers bureau in September and October 1998, with the project scheduled to commence in October.

San Antonio: Focus on Hispanic Medicare beneficiaries.
- Organized a diverse, multi-discipline partnership of 22 committed organizations, groups and individuals;
- Identified over 13,000 women as their target population;
- Created a beneficiary and provider intervention task force;
- Conducted focus groups totaling 40 women to identify barriers to screening and how they get information;
- Developed a volunteer "navigators" (comadres) program and physician's tool kit; and
- Used established interventions, such as "Tell-A-Friend" and the "Breast Health and You" video.

Los Angeles: Focus on African-American and Hispanic Medicare beneficiaries.
- Organized community partnerships consisting of state and local government organizations, health plans, hospitals, and consumer advocacy groups;
- Responded to 128,000 requests by physician's offices for tools and materials to increase the use of screening mammograms;
- Conducted a targeted direct mailing to 100,000 African-American Hispanic beneficiaries;
- Distributed a physician tool kit to 4,200 physicians throughout Los Angeles and distributed

materials and information to 700 Community Based organizations in English and Spanish; and
- Obtained endorsement for the project from the California Medical Association.

Cleveland: Focus on African-American Medicare beneficiaries.
- Organized the Horizons Breast Health Coalition comprised of 18 diverse and multi-discipline organizations, providers and professionals;
- Created a project working plan consisting of 7 strategic elements, including project coordination, measures, community organization and outreach activities, consumer education and professional training and support, public information and public relations, local service delivery, and policy and legislative changes;
- Organized a "Mother's Day in November" campaign;
- Developed a Professional Education Package which was distributed to all Cleveland hospitals and distributed a Consumer Health Information Packet (H.I.P.s in Motion) to 5000 beneficiaries; and
- Customized a project slogan "Mammogram-A Picture of Health" which is being used consistently in all aspects of the project.

Atlanta: Focus on African-American Medicare beneficiaries.
- Identified prospective audiences, barriers, and potential interventions based on community input during a city-wide planning meeting;
- Organized a diverse partnership coalition consisting of local cancer advocacy organization, health professionals, and many Atlanta based African-American churches with congregations ranging from 35-12,000 members;
- Focused on the faith community as vehicle for intervention delivery;
- Conducted a "Bells for Remembrance" program in 55 churches reaching over 35,000 members, what will be an annual event; and
- Produced "Bells for Remembrance" materials suggested by coalition member, including pamphlets, shopping bags and hand-held fans bearing the "Bells" logo.

Mammography Television Spots. HCFA will air a series of 30-second television ads in 5 of the 6 Multi-City Mammography cities (Atlanta, Philadelphia, Chicago, Cleveland, and Los Angeles), and in Washington, D.C. The TV spots are geared to African-American Medicare beneficiaries. This effort is building on the success of using the same 30-second ads during a 1998 Mother's Day campaign in Washington, D.C. During October (Breast Cancer Awareness Month), HCFA has purchased air time on selected stations in the cities to assure prime placement to maximize the number of impressions.

In the context of an expanding older-aged segment of the U.S. population, the National Institute on Aging (NIA), Geriatrics Program, has supported a variety of breast cancer related activities. The burden of malignant breast tumors for the 65+ age group is illustrated by a cancer mortality rate of 58.2 percent in the latest five-year period (1990-94) (NCI Surveillance, Epidemiology, and End Results (SEER) Program Statistics, 1997). In FY97, the NIA awarded over $4.6 million in

support of breast cancer research.

The Agency for Health Care Policy and Research (AHCPR) is currently funding a five-year Patient Outcomes Research Team (PORT) study on the care, costs, and outcomes of early stage breast cancer. The goal of this study is to compare the determinants and cost-effectiveness of three options for treating local breast cancer: modified radical mastectomy; breast-conserving surgery with radiotherapy; and breast-conserving surgery without radiotherapy. Despite evidence from clinical trials and NCI guidelines, as of the late 1980s, fewer than 20 percent of the elderly with localized cancers received breast conserving surgery. Of those who die, fewer than half had follow-up radiotherapy.

New Frontiers In Breast Cancer Early Detection

The Federal Multi-Agency Consortium on Imaging to Improve Women's Health is exploring the applications of technologies from other fields to improve the early detection and diagnosis of illnesses and conditions affecting women. Collaborations are being facilitated between the Department of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer. In particular, the computer technologies that have been used to improve spy satellites may help improve breast cancer detection and treatment at its earliest stages. The FDA has also sponsored a conference "The Transfer of Defense, Intelligence, Space and Energy Technologies to the Early Detection and Control of Cancers in Women" in an effort to facilitate such public/private partnerships. Clinical trials of new technologies are also being supported.

Inter-departmental Collaborations are underway for developing a Mobile Breast Care Center that will generate and transmit a patient's digital mammogram to a breast screening center, where a radiologist would interpret the images and relay any need for additional evaluation back to the mobile unit. The Mobile Breast Care Center should benefit medically underserved populations and women living in rural and remote areas in particular.

The FDA has approved several different types of devices for the detection and treatment of breast cancer. There are serum tumor markers (CA15-3 and CA27-29) used to monitor breast cancer patients response to therapy and for recurrence of disease. There are assays to measure HER2 protein in breast cancer tissues. There is an ultrasound system (Advanced Technology Labs HDI 3000) to be used as an adjunct with mammography to help in differentiating benign from malignant or suspicious lesions. There is a computer based system (R2 Technology Model M1000 Image Checker) that identifies regions of interest on routine screening mammograms to bring them to the attention of the radiologist after the initial reading has been completed. Radiation therapy systems have been approved for treatment.

National Centers of Excellence

On October 1, 1996, the Department of Health and Human Services established six National

Centers of Excellence in Women's Health to serve as national models for improving the health care of American women. The Centers of Excellence program, with facilities located at academic institutions in different areas of the country, unites women's health research, medical training, clinical care, public health education, community outreach, and the promotion of women in academic medicine around a common mission -- to improve the health status of diverse women across the life span. With less than $3.5 million to date in funding from the Public Health Service's Office on Women's Health, the Centers have leveraged more than $41 million in additional funds to promote the advancement of women's health. Six more centers were established in 1997, and six more are being established in 1998, with a special emphasis on the health of minority women.

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of breast cancer, AHCPR, developed a Clinical Practice Guideline--Quality Determinants of Mammography-- in October 1994. The guidelines include separate versions for mammography providers, health care professionals, and consumers. Additionally, they provide information on the roles and responsibilities of each health care professional involved in mammography services, as well as information and recommendations for women. Copies of the consumer brochure "Things to Know About Quality Mammograms" can be obtained by calling 1-800-358-9295.

Mammography for Women with Addictive and Mental Disorders

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

Environmental Factors and Breast Cancer

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

Studies of the role of the environment in cancer risk in the Northeastern mid-Atlantic portion of the U.S. are being completed through support by the National Cancer Institute and the National Institute of Environmental Health Sciences (NIEHS). These studies looked at risk from organochlorine compounds such as DDT, DDE, and other pesticides as well as PCBs. Although there does not seem to be an overall increased risk of breast cancer associated with blood levels of

DDT and DDE in most studies, there are some subgroups of the population which may be more susceptible to the effects of these chemicals. Women who never breast-fed and some women who have a common polymorphism of the P450 CYP 1A1 associated with metabolism of these compounds may be at increased risk. Total PCBs may not be related to an overall increase in breast cancer risk, but taken individually some congeners may be more estrogenic than others and may be involved in disease pathogenesis. More work in this area is needed and is currently underway. Many questions about exposure levels and metabolism of these chemicals still need to be addressed. Studies to date look at adult women, where risk may be highest from exposures during childhood or adolescence when background levels of estrogen are lower and the breast experiences rapid development making it more vulnerable.

Additionally, the NIEHS is funding research on the development of transgenic mice with BRCA1 and BRCA2 mutations to study the effects of irradiation and environmental agents on breast cancer development.

Office of Cancer Survivorship

On October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. There now are more than 8 million cancer survivors of which about 2 million American women are breast cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects, factors that predispose survivors to second malignancies, reproductive problems following cancer treatment, and their unique insurance and employment issues. In August 1998, NCI committed $15 million over the next five years to cancer survivorship grants that will be overseen by this office. These grants support top-of-the-line research on issues faced by long-term cancer survivors.

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Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. schedule	Schedule for Hillary Rodham Clinton (partial) (4 pages)	09/29/1998	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Eric Morse (Events)
OA/Box Number: 21192

FOLDER TITLE:
Breast Cancer October Event [2]

2011-0619-S
rc291

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]

SCHEDULE FOR HILLARY RODHAM CLINTON
TUESDAY, SEPTEMBER 29, 1998
FINAL*

WASHINGTON, DC / SAN JUAN, PUERTO RICO / SANTIAGO, CHILE

SAN JUAN

LEAD ADVANCE:	BAIN ENNIS	ROOM 503
	GRAND HOTEL EL	CONVENTO
	787-723-9020	PHONE
	787-721-2877	FAX
[001]	P6/(b)(6)	CELL PHONE
	1-800-SKYPAGE	#216-9818
PRESS ADVANCE:	CHRISTINA DELL	ROOM 410
SITE ADVANCE:	TYLER DENTON	ROOM 514
SITE ADVANCE:	MWITU NDUGU	ROOM 519

SANTIAGO

LEAD ADVANCE:	KATHY NEALY	
	HYATT HOTEL	ROOM 609
	562-218-1234	PHONE
	562-218-1261	FAX
	P6/(b)(6)	CELL PHONE
PRESS ADVANCE:	DAVID NESLEN	ROOM 703
	P6/(b)(6)	CELL PHONE
SITE ADVANCE:	ERIN FISHER	ROOM 907
	P6/(b)(6)	CELL PHONE fax: 011 56 - 2 218 - 1261
SITE ADVANCE:	DENVER PEACOCK	ROOM 510
	P6/(b)(6)	CELL PHONE fax:
RON ADVANCE:	KAREN PETERSON	ROOM 810 → P6/(b)(6)
SCHEDULER:	EVAN RYAN	
	202/456-6751	PHONE
	202/456-5340	FAX
	P6/(b)(6)	HOME
	WHCA PAGER	#4223

PREV RON The White House

BAGGAGE CALL: 6:00 am at the White House - Room 87 OEOB
8:00 am at Andrews AFB

7:20 am [redacted P6/(b)(6)]

8:50 am **DEPART** South Portico
EN ROUTE Andrews Air Force Base
[drive time: 25 minutes]

9:15 am **ARRIVE** Andrews Air Force Base

9:30 am **WHEELS UP** Andrews Air Force Base
EN ROUTE San Juan, Puerto Rico
[flight time: 3 hours, 25 minutes]

12:55 pm **WHEELS DOWN** Luis Munoz Marin International Airport, San Juan, Puerto Rico

GREETERS:
41 greeters (see briefing book)

1:15 pm **DEPART** Luis Munoz Marin International Airport
VIA Helicopters for Flyover of Utuado
EN ROUTE Guayama, Puerto Rico
[flight time: 35 minutes]

1:50 pm **ARRIVE** Guayama

GREETERS: TBD

2:15 pm **DEPART** Guayama
VIA Helicopters
EN ROUTE Luquillo, Puerto Rico
[flight time: 25 minutes]

2:40 pm **ARRIVE** Luquillo Landing Zone

NO GREETERS

2:50 pm **DEPART** Landing Zone
EN ROUTE Brisas del Mar School
[drive time: 5 minutes]

2:55 pm **ARRIVE** Brisas del Mar School

GREETERS:
Ana Carmen Allemany, Secretary of Housing
Mayor Edna J. Figueroa

2:55 pm-
3:10 pm

TOUR Shelter
Brisas del Mar School
Translation: Consecutive
Hold: Office
Phone: n/a
Fax: n/a
Staff Hold: Outside
POOL PRESS

NOTE: Delegation enters second classroom.

FORMAT:
-The First Lady enters first classroom, accompanied by Governor Rosello, Maga Nevares Rosello, Representative Romero, and Lynn Canton, FEMA, where families from the Fortuna Pipaya Juan Martin Casa Blanca Communidad Sabana are staying.
PRE-SET STILLS/PRINT PRESS

-The First Lady informally meets and talks to families.

-The First Lady proceeds with Delegation to courtyard.

PARTICIPANTS: 2 Families

CONTACT: Brie Rodriguez P6/(b)(6)

3:15 pm-
3:55 pm

REMARKS
Courtyard
Rain Site: Dining Room
Translation: Consecutive
Brisas del Mar School
Hold: Office
Staff Hold: Outside
OPEN PRESS

FORMAT:
-Representative Romero makes opening remarks and introduces Lynn Canton, Regional Director, FEMA.

-Lynn Canton, Regional FEMA Director, makes remarks and introduces Governor Rosello.

-Governor Pedro Rosello make remarks and introduces the First Lady.

-The First Lady makes remarks.

-The First Lady, Governor Rosello, Mayor Figueroa and Delegation plant a tree next to stage symbolizing that the path to recovery is rooted in the joint efforts of the community and the government.

-The First Lady works a ropeline on departure.

PARTICIPANTS: 230 guests expected.

CONTACT: Brie Rodriguez P6/(b)(6)

4:05 pm **DEPART** Brisas del Mar
EN ROUTE Luquillo Landing Zone
[drive time: 5 minutes]

4:10 pm **ARRIVE** Luquillo Landing Zone

4:15 pm **DEPART** Landing Zone
VIA Helicopters
EN ROUTE Airport
[flight time: 15 minutes]

4:30 pm **ARRIVE** Airport

4:45 pm **WHEELS UP** San Juan Airport
EN ROUTE Santiago, Chile
[flight time: 7 hours, 35 minutes, +1 hour]

1:20 am **WHEELS DOWN** Arturo Merino Benitez International Airport, Santiago, Chile

GREETERS:
Helmut Lagos, Protocol

1:30 am **DEPART** Arturo Merino Benitez International Airport
EN ROUTE Hyatt Hotel
[drive time: 30 minutes]

2:00 am **ARRIVE** Hyatt Hotel

RON Hyatt Hotel
Santiago, Chile

WEATHER FORECAST FOR WASHINGTON, DC: Mostly sunny and cooler. Winds northwest at 8 to 12 knots. Low 60. High 74.

WEATHER FORECAST FOR SAN JUAN, PUERTO RICO: Variably cloudy with a chance for afternoon showers and isolated thunderstorms. Low 70. High 91.

WEATHER FORECAST FOR SANTIAGO, CHILE: Partly cloudy, occasionally mostly cloudy. Low 40. High 72.

National Mammography Campaign
National and Corporate Commitments
October 21, 1998

National Commitments

- **Avon**
  - Breast Cancer 3-Day fund-raising event, which over 3,000 people will walk to raise money for non-profit breast health programs.

- **Eli Lilly**

- **Zenecca, Inc.**
  - Increase awareness of the importance of early detection of brease cancer by communicating this message through a nationwide educational campaign to all audiences.
  - One of the two original founders of the National Breast Cancer Awareness Month and is the sole provider of the campaign (through the Zeneca Healthcare Foundation).

- **Eastman Kodak Company**

  *On-site mammography screening for Kodak employees - November, 1998.
  *Revised "For You. For Life." breast health educatioan materials which are made available to our mammography film-buying customers or distribution to their patients - October, 1998.

Corporate Commitments

- **American Association of Health Plans**
  - Announce in the Medical Affairs Issues Report to over 1000 people about the initiative
  - Publish *Advancing Women's Health: Health Plans' Innovative Programs* in Breast Cancer, a technical report for health plans and a consumer summary, which includes 10 key questions women can ask about their health plan.
  - Devised innovative programs to increase screening mammography among women and been a proud co-sponsor of the National Race for the Cure.

- **American Greetings**
  - Create electronic greeting cards for people to send to women to encourage them to receive mammograms.

- **BE & K Engineering and Construction**
  - Provide on-site mammograms during the work day fo all employees, retirees, and spouses

- Distribute brochures emphasizing the importance of early detection
- Hold seminars on breast cancer prevention and awareness

♦ **Direct Selling Association**
- Encourage over 400 firms through publications, through personal efforts by staff, and through dedicating a portion of annual convention to communicate the importance of mammograms to industry's saleforce, over 6 million female direct sellers.

♦ **Florida Association of Health Maintenance Organizations, Inc.**
- Host an HMO Day in Florida's Capitol on March 25, 1999, where they plan to offer mammography screening during this event.
- Purse having a Proclamation signed by Florida's Governor and Resolutions offered in both the Florida House of Representatives and the Florida Senate supporting the Medicare Mammography Initiative.

♦ **Food Marketing Institute**
- Develop a Take a Step Toward Good Health brochure to stress the importance of maintaining good health.
- Distributed this brochure to more than 18,000 attendees of the National Urban League convention.

♦ **National Community Pharmacists Association**
- Promote the breast cancer initiative and awareness through the American Pharmacists Journal and through the NCPA Newsletter.
- Promote mammography screening awareness to patients and pharmacists and their staff through public service announcements on NCPA's television network.

♦ **1-800-FLOWERS**
- Implement a special mammogram reminder program on our Web and AOL sites.
- Add a special payroll message reminding employees to go in for their mammograms.