

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. bio	re: Anna T. Meadows [partial] (1 page)	n.d.	b(6)
002. bio	re: Anna T. Meadows [partial] (1 page)	09/24/1996	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Cancer Event

2014-0046-S

rc1424

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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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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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 29, 1996

BRIEFING BY THE VICE PRESIDENT
AND DR. DAVID KESSLER, FEDERAL DRUG ADMINISTRATION

The Briefing Room

3:44 P.M. EST

VICE PRESIDENT GORE: I'm going to make a statement about some figures that were released by the CBO very late last night. I'm going to say a few words about the promises kept. And I'm going to turn this briefing over to Dr. David Kessler, who will elaborate on the announcement the President just made in the East Room and respond to your questions about that.

But first of all, let me talk just a bit about the new CBO figures released last night. When Bill Clinton campaigned for the presidency, he promised that he would cut the federal budget deficit in half during his first four years in office. He put that promised in writing in the book that he and I put out during the campaign, called Putting People First.

In fact, I think I might be able to find it right here. "Our plan will cut the deficit in half within four years and assure that it continues to fall each year after that," on page 4 of Putting People First. Yesterday, late last night, the Congressional Budget Office, using its traditionally conservative estimates, released brand new figures projecting that the budget deficit at the end of the current fiscal year will be half -- actually less than half -- of the deficit that President Clinton and I inherited. Bill Clinton made good on his promise.

When Bill Clinton campaigned for the presidency, he also promised eight million new jobs would be created in America by the end of his first four years in office. Earlier this month, the Bureau of Labor Statistics reported that we have crossed the eight-million job threshold. Since Bill Clinton became President, the American economy has added more than 8.4 million new jobs. Bill Clinton made good on his promise. And incidentally, more than half of these new jobs have wages higher than the average wage in the economy.

If you will look at this, from the day that President Clinton took office, the economy has created 8.4 million new jobs.

And from the day he took office, the deficit has come down from \$290 billion to the new figure of \$140 billion at the end of this fiscal year.

Paul Volker, former chairman of the Federal Reserve Board, was recently quoted as saying, "The deficit has come down and I give the Clinton administration and President Clinton himself a lot of credit for that, and I think we're seeing some benefits."

The Congressional Budget Office in 1994, in its Economic and Budget Outlook, on page 13, said, the dramatic improvement in the deficit since last January is largely the result of the enactment in August of the Omnibus Budget Reconciliation Act of 1993. You may remember that measure passed a one-vote margin in the House, went to the Senate where it was tied 50 to 50, causing momentary despair -- (laughter) -- and then due to a provision in the Constitution I was

able to vote. In any event we're very happy with these new figures, because the deficit has indeed been cut in half, and it will, as promised, continue to go down in the years ahead, because we're on the way to a balanced budget.

Incidentally, on this same page, I was noticing as I went through this material that just above the promise that I cited on cutting the deficit in half, was the promise that we would revolutionize government by cutting 100,000 federal jobs. As you may know, we have eliminated 205,000 federal jobs. Seven of the 14 Cabinet departments have had personnel reductions of more than 10 percent. Every single Cabinet department has had dramatic reductions except for the Justice Department, because there we are adding more personnel as part of the anti-crime bill.

Also, on the very same page, is the pledge to provide affordable quality health care by, among other things, reducing paperwork. And we talked about reinventing government in this same list of promises to the American people four years ago. And in the event in the East Room just concluded, the President announced the result of the National Performance Review effort at FDA, run by the people at FDA and run by Dr. David Kessler, which is resulting in much speedier approval of new drugs, new medications, new life-saving treatments -- in this case for cancer patients, but for all patients really.

And you have seen the difference for AIDS patients and for cancer patients particularly. And the announcement was one that was particularly moving for anyone who is part of a family that has been touched by cancer. And, again, as the President did earlier, I want to express gratitude to Dr. David Kessler and Secretary Donna Shalala, who was here earlier, and their whole team for the tremendous work that they have done.

And now I would like to turn over the podium to Dr. Kessler, who will elaborate on that announcement.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date September 24, 1996

From Joe Harford, Ph.D.
Associate Director for Special Projects, NCI

Subject Material re. Survivorship

To Elizabeth Drye, Domestic Policy Council, Office of Policy Development
The White House (By Fax @ 202-456-7028)

Pursuant to our telephone conversation, I am sending you the following materials:

1. A "For Response to Inquiries" description of the Office of Cancer Survivorship (OCS) that contains some information re. Dr. Anna T. Meadows who has been named by Dr. Klausner to head the Office (2 pages).
2. A more detailed biographic sketch of Dr. Meadows (1 page).
3. A description of the Children's Hospital of Pennsylvania in Philadelphia (CHOP) (2 pages). This institution has grants from the NCI, and it is the current home institution of Dr. Meadows. Note that CHOP boasts the first follow-up program for long-term survivors of childhood cancer.
4. A description of the University of Pennsylvania Cancer Center in Philadelphia (1 page).
5. A description of the Fox Chase Cancer Center in Philadelphia (1 page).
6. Description of a conference in Albuquerque, NM on Oct. 3-6 sponsored by the National Coalition for Cancer Survivorship (NCCS) in partnership with People Living Through Cancer (PLTC) (1 page). Dr. Klausner is scheduled to address this conference.
7. A narrative from 1987 describing the "Legislative History of the National Cancer Institute" with a description of the National Cancer Act of 1971, the twenty-fifth anniversary of which we are celebrating this year (1 page). I include with this document a bullet-point version of this history that is up-to-date (3 pages).
8. A draft of a press release concerning the formation of the National Cancer Policy Board (NCPB) within the National Academy of Sciences, the establishment of which is occurring at the request of Dr. Klausner in his role as coordinator of the National Cancer Program pursuant to the National Cancer Act of 1971 (3 pages).

Note that we are in the process of preparing additional material containing facts and figures relevant to the subject of cancer survivorship. I will forward these to you as they become available.

For Response to Inquiries



Office of Cancer
Communications

Building 31, Room 10A24
Bethesda, Maryland 20892

National Institutes of Health

August 1, 1996

Francis X. Mahaney, Jr.
NCI Press Office
301-496-6641

Anna T. Meadows, M.D., Is Named To Head Office of Cancer Survivorship

Anna T. Meadows, M.D., has been named head of the newly established Office of Cancer Survivorship (NCI-OCS) by Richard D. Klausner, M.D., director of the National Cancer Institute. The office has been designed to explore the physical, psychological, and economic well-being of individuals following cancer treatment.

"We need to look at questions beyond the acute diagnosis and treatment of cancer-- beyond prevention-- and deal with the many research issues that survivors of cancer face in their daily lives so that there will be a better quality of life for all," Klausner said. "Meadows has the experience and the enthusiasm to bring these issues into focus."

The NCI-OCS will explore the entire spectrum of concerns facing cancer survivors including:

- long-term medical and psychological effects of cancer treatment
- factors that predispose cancer survivors to the development of second malignancies
- reproduction and fertility problems following treatment
- genetic factors that increase the risks of any of the above

As a first step, the office will organize a meeting of experts in a variety of disciplines to discuss and help set a research agenda. The NCI-OCS will then take advantage of existing programs and will also develop new research initiatives. Allocation of resources for this activity will be decided after an initial research agenda is developed. The new office will be located within the Division of Cancer Treatment, Diagnosis and Centers. Meadows joined the NCI

(more)

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part-time July 1 through an institutional personnel agreement. She will continue her duties at the Children's Hospital of Philadelphia.

"In establishing this office, Klausner has recognized the growing number of cancer survivors and their need for a 'home' at NCI. The burden of a cancer diagnosis does not end when treatment is complete; this office provides the focus for issues that concern survivors and their care-givers. I am excited to be given an opportunity to explore these important questions on a national level," said Meadows.

Meadows is currently a professor of pediatrics at the University of Pennsylvania Medical School, and since 1989 has been the director of the Division of Oncology at the Children's Hospital of Philadelphia. She directs one of the world's largest pediatric and adolescent oncology services: 250 new cases are seen each year.

She has published extensively on the topics of pediatric cancer treatment, genetics and epidemiology, and the long-term effects of treatment. Meadows chairs the Late Effects Study Group, an international consortium of 13 pediatric cancer centers, and is an active member of the Children's Cancer Group. Her experience in areas of patient care, clinical research, and teaching has resulted in numerous academic and professional honors, memberships in medical and scientific societies, and editorial positions with academic journals.

Born in (b)(6) Meadows is a 1969 graduate of the Medical College of [001] Pennsylvania. She completed postgraduate training in pediatrics at St. Christopher's Hospital for Children and in pediatric hematology/oncology at the Children's Hospital of Philadelphia.

She is a member of the American Society of Clinical Oncology, the American Association of Cancer Research, and the International Society of Pediatric Oncology.

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The Cancer Information Service provides a nationwide telephone service for cancer patients and their families, the public, and health care professionals. The toll-free number is 1-800-4-CANCER (1-800-422-6237); services are provided in English and Spanish. People with TTY equipment may call 1-800-332-8615.

This document is available through the NCI's CancerNet services on the Web (<http://cancernet.nci.nih.gov>) and through Cancer Fax (301-402-5874 from the handset on your fax machine).

Dr. Meadows is the Director of the Oncology program at the Childrens Hospital of Philadelphia (CHOP) and a Professor of Pediatrics at the University of Pennsylvania School of Medicine. The oncology program at CHOP is one of the largest in the nation, with 250 new patients diagnosed and treated annually. More than 2000 children and adolescents, who have discontinued therapy, are being followed. The program has 15 faculty, 6 psychosocial staff members and 5 nurse practitioners. It recruits 4 new fellows annually and trains additional graduate students and post doctoral fellows in molecular genetics and biology of cancer, neuro-oncology, psychology and epidemiology.

Dr. Meadows received her medical degree from the Medical College of Pennsylvania more than a decade after completing her training for an earlier career as an educational psychologist. Her pediatric training took place in Philadelphia at St. Christopher's Hospital for Children, where she also began a fellowship in pediatric hematology-oncology. She completed a research fellowship in oncology at the Children's Hospital.

She has been on the faculty of the University of Pennsylvania and the staff of CHOP since 1974 when she completed her training. In 1989 she became director of the program and has since expanded the research programs in fundamental biology, neuro-oncology, bone marrow transplantation, and psychosocial aspects of childhood cancer.

Her research concerns the study of long term effects of childhood cancer and its therapy, and the epidemiology and genetics of childhood cancer. The Greater Delaware Pediatric Tumor Registry, a population-based cancer registry housed at CHOP and developed exclusively for children, has served as the focus for epidemiologic studies. Dr. Meadows chairs the Late Effects Study Group, an

As an active member of the Children's Cancer Group, she has been able to initiate epidemiologic and late effects studies within that group, many of which have been conducted under the aegis of peer reviewed grant support. She has been the Chair of the Lymphoma Strategy Group and in that role directed clinical trials in Hodgkin's disease and non-Hodgkin's lymphoma.

She has served as a member of several policy-making groups in the National Institutes of Health, the University of Pennsylvania and The Children's Hospital of Philadelphia. These include the Cancer Center Support Committee and the Clinical Cancer Investigation Review Committee of the National Cancer Institute, the Appointments and Promotions Committees of the Medical School and of the Department of Pediatrics. She has served as Chair of the Steering Committee of the Medical Faculty Senate, and Chair of the Clinical Research Center Advisory Board.

Her publications reflect her research interests in the epidemiology and genetics of childhood cancer, the long term effects of treatment in survivors, the results of clinical trials in leukemia and lymphoma, and the delivery of medical care.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

Founded in 1855 as the nation's first pediatric hospital, the Children's Hospital of Philadelphia is committed to improving the health of today's children through its clinical care programs, and the health of tomorrow's children through its basic and clinical research programs and training of the next generation of pediatric health care professionals.

Children's Hospital provides comprehensive care, both inpatient and outpatient, for children from birth through age 19. With 304 beds, 20 percent of which are allocated to intensive care, the Hospital admits over 15,000 inpatients and handles over 200,000 emergency and outpatient visits annually.

Critically ill children and those suffering from unusual or hard-to-diagnose diseases are sent here from the Delaware Valley, the nation and the world, for such services as: the only pediatric trauma service in eastern Pennsylvania; one of the largest pediatric oncology services in the nation; a Comprehensive Sickle Cell Centers infant intensive care for premature newborns; liver, heart and bone marrow transplantation; and cardiovascular surgery for children with rare or complicated heart defects. Because of such specialized programs, Children's Hospital placed second among all pediatric hospitals in the United States in the 1995 physicians' rating of America's best hospitals in U.S. News and World Report.

Children's Hospital takes pride in its role as the community caregiver for the disadvantaged children of West and South Philadelphia. As a result of this commitment, the Hospital last year absorbed more than \$31 million in uncompensated care expenses.

The advancement of pediatrics through research and education is also central to the mission of the Children's Hospital of Philadelphia. In May of 1995, the Hospital dedicated its state-of-the-art research facility. The 13-story Leonard and Madlyn Abramson Pediatric Research Center houses the Joseph Stokes, Jr., Research Institute which receives \$30 million annually in research funding.

Research undertaken at the Hospital has resulted in many advances in the prevention, diagnosis and treatment of childhood disease, including the development of the following: the first closed incubator for newborn; the cardiac balloon catheter technique for curing specific congenial heart defects in infants; and vaccines against rubella and mumps.

Each year Children's Hospital's graduate medical training programs train more than 150 pediatric professionals in 26 different subspecialties who then go on to careers in academic medicine, medial research or community practice. The Hospital is also a pediatric training ground for medical students from the University of Pennsylvania School of Medicine, clinical and research fellows from universities worldwide and for nursing students from eight schools of nursing.

For more information please contact (215)590-4100

First in Pediatric Care

The Children's Hospital of Philadelphia has been a pioneer of pediatric medicine, responsible for clinical innovations such as:

- the first pediatric day surgery unit in the U.S.
- the first neonatal surgical and pediatric intensive care unit in the nation
- the first pediatric bone marrow transplantation program in the Delaware Valley
- the first multidisciplinary home-care program in the U.S. For children who need mechanical ventilators to survive
- the first designated Pediatric Regional Resource Trauma Center (Level I) in eastern Pennsylvania
- the first follow-up program for long-term survivors of childhood cancer
- the first clinic in the nation for the treatment of childhood speech defects
- the first pediatric MRI in Philadelphia, used to create high-resolution images of soft body tissue

Item # 4

ABOUT THE UNIVERSITY OF PENNSYLVANIA CANCER CENTER

The University of Pennsylvania Cancer Center is a national leader in cancer research, patient care, education and training of health care professionals in cancer, and community education and outreach. The preeminent position of the Cancer Center is reflected in its designation by the National Cancer Institute as one of only ~~25~~ ²⁷ cancer centers in the country approved and designated as a Comprehensive Cancer Center.

The University of Pennsylvania Cancer Center takes seriously its commitment to serve as a regional and national leader in developing and offering innovative cancer treatments that improve the chance for recovery while preserving the quality of life. The Cancer Center is equally committed to understanding the underlying causes of cancer through basic, translational, clinical and cancer control research, and to educating health care professionals, patients, families and our community. This commitment reflects the Cancer Center's goal of reducing the incidence and mortality of cancer in our region and throughout the country. As an NCI-designated Comprehensive Cancer Center, the University of Pennsylvania Cancer Center is able to meet the desire of community hospitals to have a relationship with a national leader in cancer research and treatment.

As an institute of the University of Pennsylvania, our Cancer Center benefits substantially from the vast clinical, educational and research resources available through the University of Pennsylvania. Cancer treatment is enhanced because patients experiencing non-cancer-related problems can receive comprehensive care by full-time Penn faculty who practice at the University of Pennsylvania Medical Center. Cancer Center members have access to the substantial research capabilities throughout the Penn campus. Thus, by being part of one of the nation's leading academic medical centers, the University of Pennsylvania Cancer Center's ability to provide the latest cancer treatments, conduct leading-edge research, educate health care professionals, and serve the needs of our community are clearly enhanced.

Mission of the Center

Throughout its ²³ ~~25~~-year history, the University of Pennsylvania Cancer Center has provided the organizational framework required to promote and enhance interdisciplinary cancer research, education and patient care.

The University of Pennsylvania Cancer Center was initially founded in 1973 as the focus for cancer-related research and education at the University of Pennsylvania. At that time, the Cancer Center's original research mission was defined through six primary objectives, including:

- Development of basic science and clinical research programs.
- Recruitment of faculty with expertise in cancer.
- Development of interdepartmental and interdisciplinary

educational programs in cancer.

- Development of cancer prevention and control research programs.
- Development of NCI-funded Shared Resource facilities that provide cancer researchers with advanced technology needed to conduct innovative research.
- Provision of technical services that facilitate innovative cancer research.
- Development of new cancer research space.

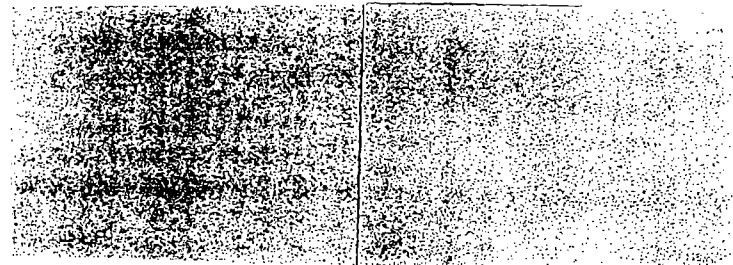
In 1990, the Cancer Center's mission was officially expanded to include a strong clinical initiative. This patient care mission is achieved through the following objectives:

- Expand the range of cancer-related services and interdisciplinary cancer programs.
- Improve patient and referring physician access.
- Enhance the image of the Cancer Center.
- Increase the level of clinical cancer activities.
- Increase clinical research, emphasizing translational research opportunities.
- Expand community outreach activities.

The mission and priorities of the University of Pennsylvania Cancer Center are in concert with those of community hospitals in our region. The development and maintenance of a strong network of select community hospitals meets the Cancer Center's research, clinical, community outreach, education and training responsibilities. At the same time, a well-organized, integrated collaborative relationship with an NCI-designated Comprehensive Cancer Center provides invaluable access to the community hospital and its physicians, and the opportunity to participate directly in innovative clinical, research and educational programs. Most importantly, such cooperative efforts enable the University of Pennsylvania Cancer Center and the Cancer Network hospital to enhance their collective ability to serve the multiple needs of our community.

Designation as a Comprehensive Cancer Center by the National Cancer Institute

The University of Pennsylvania Cancer Center has been continuously funded by the Centers' Program of the National Cancer Institute since its inception in the early 1970s. The Cancer Center is formally approved and designated as a Comprehensive Cancer Center by the National Cancer Institute, a status enjoyed by only 26 cancer centers. This designation is in recognition of the Cancer Center's excellence in cancer research, patient care, community service and outreach, cancer information services, and the education and training of health care professionals.



Item #5

FACT SHEET

CONTACT: Eric Rosenthal
(215) 728-2700

Fox Chase Cancer Center

Fox Chase Cancer Center is one of 27 National Cancer Institute-designated comprehensive cancer centers in the nation. Fox Chase's activities include basic, clinical and prevention research; detection and treatment of cancer; and community outreach programs. In 1974 Fox Chase was formed by the union of American Oncologic Hospital (the nation's first cancer hospital, established in 1904) and the Institute for Cancer Research (founded in 1927). Today it has more than 1800 employees and an annual budget of \$127 million. Research is conducted in more than 75 laboratories by a staff of more than 300 physicians and scientists who hold M.D.s, Ph.D.s or both.

Fox Chase's 100-bed hospital is one of the few facilities in the country devoted entirely to cancer care. More than 130 clinical trials of new prevention, diagnostic and treatment techniques are under way at any one time. Almost 1,000 new patients a year participate in clinical trials. Annual hospital admissions average about 3,400 a year and outpatient visits to physicians exceed 37,000 a year. Combining research in many disciplines with patient care enables Fox Chase to translate new research findings into medical applications that may become models for improved comprehensive cancer care.

Fox Chase is structured around three divisions: medical science, basic science and population science. Medical science is committed to providing excellent patient care and conducting a broad-based program of clinical research. The division of basic science is renowned worldwide for its work in understanding both normal and abnormal cell growth and development. The goal of the division of population science is to identify people at high risk for cancer and to develop strategies to reduce these risks through programs of prevention and early detection.

Fox Chase is also involved in developing trials to test new agents that may prevent cancer in high-risk individuals, and is an active participant in the national trials to prevent breast cancer and prostate cancer. For women at high risk for breast or ovarian cancer, Fox Chase offers the Margaret Dyson Family Risk Assessment Program providing state-of-the-art medical care, cancer genetic counseling and education.

In 1986 Fox Chase established partnerships with community hospitals in the region. Fox Chase Network now includes 19 hospitals throughout the Philadelphia area and as far as Pittsburgh, Pa. and central and southern New Jersey. This program has been successful in raising the quality of cancer care in the community and increasing the number of patients enrolled in clinical trials. In 1995 the center was a founding member of the National Comprehensive Cancer Network, an alliance of 15 of the nation's best cancer centers. In 1996 Fox Chase announced the formation of the Oncology Physician Network, an organization of medical oncologists in Pennsylvania, New Jersey and Delaware sharing common practice philosophies and contracting needs.

Fox Chase operates the NCI's regional Cancer Information Service (1-800-4-CANCER) serving eastern Pennsylvania, New Jersey and Delaware. The regional Cancer Information Service receives more than 35,000 calls and conducts more than 1,900 cancer-related data-bank searches for patients and physicians each year, and maintains an active outreach program.

Fox Chase investigators have received numerous awards and honors including a Nobel Prize for medicine; membership in the National Academy of Sciences; General Motors Cancer Research Foundation Prizes; American Cancer Society Medals of Honor; and induction into the National Inventors Hall of Fame. The president of Fox Chase, Dr. Robert C. Young, is past president of the American Society of Clinical Oncology, one of the world's largest oncology societies.

FOX CHASE
CANCER CENTER

#3037/8-96

In Honor of the 10th Anniversary of the
National Coalition for Cancer Survivorship...

OF, BY, AND FOR CANCER SURVIVORS

A Conference in Partnership with
People Living Through Cancer (PLTC)

Albuquerque, New Mexico, October 3-6, 1996

The National Coalition for Cancer Survivorship teams with People Living Through Cancer, the Albuquerque grassroots cancer support organization from which NCCS grew, to highlight valuable links between the national cancer survivorship movement and regional and local organizations.

The program includes information-packed workshops and plenary sessions around Resources for Action and Resources for Living and showcases successful cancer peer support, information access, and networking opportunities. Plus the Conference celebrates NCCS' 10 years of service to the survivorship movement with display of the NCCS Ribbon of Hope™ — a huge sunburst of gold ribbons signed throughout the past year in honor of people touched by cancer — a Paintfest presented by the Foundation for Hospital Art, NCCS awards, exhibits, and a special morning excursion to witness the International Balloon Fiesta.

Space is limited! Register today!

ABOUT YOUR CO-HOSTS

The National Coalition for Cancer Survivorship (NCCS), founded by a small number of cancer survivors and supporters in 1986, has grown in 10 years into the largest network of independent organizations and institutions representing people with all types of cancer. NCCS helps cancer survivors find answers to their questions and attain a better quality of life following diagnosis by linking them to direct service and peer support organizations, addressing professional, legal, and health dilemmas, and participating in and shaping public policy on health care and cancer survivorship research.

People Living Through Cancer (PLTC), a grassroots organization founded in 1983 by cancer survivors, sponsors a variety of support groups, including an innovative support network serving Santo Domingo and other pueblos in New Mexico. PLTC also offers one-to-one support, New Mexico's largest lending library of cancer related material for healthcare consumers, and a Telephone LifeLine program. NCCS has its roots in PLTC, which generously provided a home base for NCCS during the coalition's formative years.

Item #6

SCHEDULE OF EVENTS *(subject to change)*

THURSDAY, OCTOBER 3

3-7pm Registration
7pm Welcome Reception: a multimedia retrospective on the survivorship movement

FRIDAY, OCTOBER 4: RESOURCES FOR ACTION

8-9am Continental Breakfast
Registration
8am-5pm Exhibits
9-10:30am Opening Session: a panel of cancer survivors and leaders of the survivorship movement assesses the state of the movement today and trends for the future.
10:45-11:45am Networking Groups: exploring today's vital issues.
Poster Presentations
12-1pm The New NCCS Almanac: A special luncheon presenting the expanded, updated version of *A Cancer Survivor's Almanac: Charting Your Journey*.
1:30-4:30pm Information Fair: The new wave of cancer information resources
Book Fair: over 100 titles of the best of survivorship literature, plus other special items
6-9pm NCCS Town Hall Meeting: with buffet reception

SATURDAY, OCTOBER 5: RESOURCES FOR LIVING

7-8am NCCS Annual Business Meeting & Continental Breakfast
7-8:30am Book Fair
7:30am Registration
8am-5pm Exhibits
8:30-10:15am Keynote Address: Michael Lerner, PhD
10:45am-12:15pm Workshops: Your choice of 10 sessions reflecting the theme of Choices—in healing, mainstream medicine, complementary therapies, pain management, and end-of-life issues.
12:15-1:30pm Networking Luncheon
1:30pm NCCS Public Policy Meeting
1:30-3pm Afternoon Workshops: Some morning workshops to be repeated, plus new selections
1:30-4:30pm Paintfest
3:30-4:15pm Closing Ceremony
5:30-9pm Celebratory dinner at the Indian Pueblo Cultural Center with music, museum tours, 50% shopping discount

SUNDAY, OCTOBER 6

5:30am Buses depart for 25th Anniversary Albuquerque International Balloon Fiesta, most-photographed sports event in the world
7:30am Mass Ascension: 850 hot-air balloons go sky-high
11am Buses arrive back at hotel

PROFILE: Michael Lerner

Although securely anchored in mainstream medicine, Michael Lerner, PhD, explores complementary and mainstream therapies without bias. His *Choices in Healing* won widespread acclaim as a balanced inquiry into traditional and nontraditional approaches. Lerner is president of Commonweal, a health and environmental research institute that he founded in 1976 in Bolinas, California.

Legislative History of the National Cancer Institute

Mary C. Knipmeyer¹

On August 5th, 1937, President Franklin D. Roosevelt signed into law the National Cancer Institute Act (P.L. 244) establishing the National Cancer Institute. The law mandated the new Institute "to provide for, foster, and aid in coordinating research relating to cancer." In 1944, the Public Health Service Act consolidated much of the Nation's health efforts, including designating the National Cancer Institute as part of the National Institutes of Health.

The next major legislative step in the Federal effort to fight cancer occurred with the signing of the National Cancer Act (P.L. 92-218) on December 23, 1971 by President Richard Nixon. This legislation was enacted following the report of the National Panel of Consultants on the Conquest of Cancer appointed by Senator Ralph Yarborough. The Act found a middle ground between those who thought the National Cancer Institute should be an independent agency and those who thought it belonged within the National Institutes of Health. The 1971 legislation met the concerns of both perspectives by enlarging the authorities and responsibilities of the Institute Director and initiating a National Cancer Program. Special authorities included appointment of the Director by the President, the development of an annual By Pass Budget, special peer review and training authorities, and the authority to hire expert consultants to enter into contracts and to award construction projects. It also established a 3-member President's Cancer Panel, charged with reporting to the President any delays or blockages in the rapid execution of the National Cancer Program. The National Cancer Advisory Board also was established with 18 Presidentially appointed members in addition to 5 ex-officio members. The first cancer centers were authorized by this new law, which called for 15 new research, training, and demonstration cancer centers. The Act also established cancer control programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer. An Information Dissemination Program for the collection, analysis, and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer was established as well as the International Cancer Research Data Bank.

Three years after signing the original Act, President Nixon signed the National Cancer Act Amendments of 1974 (P.L. 93-352). This law included new provisions for disseminating information on nutrition as related to the treatment or causation of cancer as well as a peer review system of grant applications and contract projects.

The next significant set of amendments to the National Cancer Act came in 1978 when the Act was amended to emphasize education and demonstration programs in cancer treatment and prevention. The amendments (P.L. 95-622) also stipulated that the National Cancer Institute devote more resources to prevention, focusing particularly on environmental, dietary, and occupational cancer causes.

In 1985, the Health Research Extension Act (P.L. 99-158) recodified the portion of the Public Health Service Act related to the National Institutes of Health. The special authorities of the National Cancer Institute were maintained with the clear intent of continuing to provide for an expedited cancer research program. The mission of the National Cancer Institute continues to be to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer. The 1985 law placed additional emphasis on the continuing care of cancer patients and their families.

The legislative history of the National Cancer Institute reflects the Nation's continuing commitment to the goal of eradicating cancer through a multifaceted national research program and the desire of the Congress to provide the authority and flexibility needed to facilitate its achievement.

¹ Legislative Analyst/Congressional Liaison, Office of the Director, National Cancer Institute.

Legislative History of the
National Cancer Institute and the National Cancer Program

HIGHLIGHTS

August 5, 1937

National Cancer Institute Act of 1937 [P.L. 244]

- o Established the National Cancer Institute within the Public Health Service
- o Sec. 2 (b) directs the Surgeon General, through the Institute, **"To promote the coordination of researches conducted by the Institute and similar researches conducted by other agencies, organizations, and individuals;"**
- o Established the National Advisory Cancer Council

December 23, 1971

National Cancer Act of 1971 [P.L. 92-218]

- o Outgrowth of the report of the National Panel of Consultants on the Conquest of Cancer (the Yarbrough Commission)
- o Elevated and expanded certain authorities of the National Cancer Institute director, including appointment by the President and preparation and submission of the annual budget estimate (Bypass Budget) directly to the President
- o Established the President's Cancer Panel and the National Cancer Advisory Board
- o Initiated the **National Cancer Program** under Sec. 407 of the PHS Act as follows: "(a) The Director of the National Cancer Institute shall **coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program.** (b) In carrying out the National Cancer Program, the Director of the National Cancer Institute shall: (1) With the advice of the National Cancer Advisory Board, **plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the other research institutes, and other Federal and non-Federal programs.**"
- o Authorized the first cancer centers
- o Established cancer control programs as necessary for cooperation with State and other health agencies
- o Established an information dissemination program
- o Established the International Cancer Research Data Bank (ICRDB)

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

July 23, 1974

National Cancer Amendments of 1974 [P.L. 93-352]

- o Broadened authority to collect, analyze and disseminate "information" (replaced "data")
- o Authorized award of construction grants for new construction or alteration/renovation of basic research laboratory facilities
- o Authorized expanded information dissemination activities for scientists, health professionals and the general public

November 9, 1978

Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978 [P.L. 95-622]

- o Recodified the 1971 Act; reorganized and consolidated duties and functions of the NCI Director (in the process, the language regarding the scope of the National Cancer Program as including other Federal and non-Federal programs was dropped)
- o Called for an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens
- o Reduced minimum number of President's Cancer Panel meetings from 12 to 4 per year
- o Expanded the mission of cancer centers to include basic research and prevention
- o Expanded and strengthened the cancer control mandate to emphasize the importance of education and demonstration programs initiated within local communities and hospitals
- o Added several ex-officio members to the NCAB, reflecting the importance of environmental and occupational carcinogenesis research and required that five of the appointed members be knowledgeable in environmental carcinogenesis

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

- | | |
|-------------------|---|
| November 20, 1985 | <u>Health Research Extension Act [P.L. 99-158]</u> <ul style="list-style-type: none">o Established the position of Associate Director for Preventiono Added to NCI's mission and cancer control activities research on continuing care of cancer patients and their familieso Consolidated cancer communications activities and highlighted the ICRDB |
| November 4, 1988 | <u>Health Omnibus Programs Extension of 1988 [P.L. 100-607]</u> <ul style="list-style-type: none">o Added rehabilitation research to NCI's missiono Further expanded NCI's information dissemination programs |
| June 10, 1993 | <u>The NIH Revitalization Amendments of 1993 [P.L. 103-43]</u> <ul style="list-style-type: none">o Requires intensified and expanded research programs in breast/women's cancers and prostate cancero Mandates a set-aside of NCI's appropriation for cancer control activities (FY94-7%; FY95-9%; FY96-10%)o Mandates a case control study of elevated breast cancer rates on Long Island; requires study of potential environmental risk factors and establishment of a geographic information system |

National Cancer Policy Board To Be Formed

This year, nearly 1-1/2 million people will be diagnosed with cancer. Up to 40 percent of us will eventually be diagnosed with this disease over our lifetime. The impact of the many different diseases we call cancer on our society is enormous. Today, there are over 10 million cancer survivors in the U.S. Hundreds of organizations representing Federal and state governments, academic institutions, professional societies, patient and advocate organizations, private organizations and others have responded to the enormous challenges of cancer. The National Cancer Program represents the sum of all of these activities. To articulate the differing viewpoints of all of the stakeholders in this Nation's commitment to reduce the burden of cancer, the National Cancer Institute (NCI), the President's Cancer Panel, and the National Cancer Advisory Board, have requested that the National Academy of Sciences form a National Cancer Policy Board (NCPB). The governing boards of the Academy's National Research Council (NRC) and Institute of Medicine (IOM) approved the formation of the Board in July. The NCPB would bring together representatives of the diverse participants in the Nation's cancer effort, which encompasses both Federal and non-Federal activities aimed at reducing the burden of cancer in the United States. These would include members of the cancer research community, cancer care providers, relevant professional organizations, and patient advocacy groups. While the National Cancer Act of 1971 designated the Director of the NCI as coordinator of the National Cancer Program, it is clear that the issues and questions related to cancer policy exceed the scope and authority of any single organizational entity.

In describing this new endeavor, the NCI Director, Dr. Richard Klausner states, "We believe that the issues that the National Cancer Program needs to confront vis-à-vis major societal issues, requires some forum that can produce useful advice, guidelines, or recommendations independent of the constraints of a particular Federal agency, any particular advocacy group, or any particular set of interests within the National Cancer Program." The NCPB will provide this forum in which various sectors of the society can discuss overarching issues related to the Nation's cancer effort in a neutral and independent environment. The Board will survey current and possible outcomes of the Nation's cancer effort and deliberate on issues of broad national significance related to the movement of cancer research findings to implementation at all levels of society.

Dr. Klausner describes the new NCPB as "... a roof under which all of us can gather to deal with issues such as standards of care, cancer control policy issues, insurance and privacy issues, payment for clinical trials, standards of clinical trials, manpower needs, informational and educational needs, environmental/occupational policy in cancer, smoking policy, etc."

While the NCI will provide core support for the formation of the NCPB, the Academy will also solicit support from other Federal agencies with an interest in cancer issues, as well as from foundations and other organizations. The Board will consist of approximately 20 individuals who collectively represent the diversity of interests in the Nation's endeavors to eradicate cancer. Board members will have various relevant expertise and will have distinguished themselves through their prior contributions. The Academy will seek nominations for Board membership and ideas for topics the Board

should address from the broad range of groups that comprise the Nation's cancer constituency. Once established, the NCPB will operate under the existing policies of the NRC and IOM which include independent, carefully reviewed studies on topics deemed to be in the Nation's interests. The NCPB will publish the outcomes of these studies and thereby advise the Nation regarding cancer policy issues.



Fax Transmittal

Office of Cancer Communications
Office of the Associate DirectorBuilding 31, Room 10A31
Bethesda, Maryland 20892301-496-6631
Fax 301-402-4945

Date 10/24/96
To Elizabeth Dye
Fax Number (202) 456-7028
From John Bucklow
Cover Sheet plus 1 Pages Transmitted

Message

Answers to questions
about cancer survivorship
We will send you more
information on costs
associated with the new
PDO information program
on survival issues for
health professionals

John Burklow
301-496-6631

Woman's Issues

1:00

Oral office - announcement

Women's Health Issues

Office of Cancer Survivorship

10 million

~200,000 childhood cancer survivors

Nov. 1st

Rose Garden - Audience /

Women for
Clinton-Gore -

women's roll out. —

\$ Just in last

10:30. Friday =

6-6265

1-800
- Hotline

Breast cancer
(- VP - Press)

New \$ at NIH
directed toward
highest priority
cancer research

\$15 million

with

NATIONAL
CANCER
INSTITUTE

FAX COVER SHEET

301-496-5615

OFFICE OF THE ASSOCIATE DIRECTOR FOR SPECIAL PROJECTS
9000 ROCKVILLE PIKE, BLDG. 31, ROOM 11A48
BETHESDA, MARYLAND 20892

PHONE: (301) 496-5534

FAX: (301) 496-2471

DATE: 9/24

TOTAL PAGES 17
(including cover sheet)

TO: ELIZABETH DRYE

FAX NUMBER: (202) 456 - 7028

FROM: JOE HARFORD, Ph.D., ASSOCIATE DIRECTOR FOR SPECIAL PROJECTS, OO

SENT BY: DIANNE BROADHURST, SECRETARY

MESSAGE:

One page may have
been skipped in prev.
transmission
JDR



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date September 24, 1996

From Joe Harford, Ph.D.
Associate Director for Special Projects, NCI

Subject Technical Review of Proposal for National Cancer Policy Board

To Elizabeth Drye, Domestic Policy Council, Office of Policy Development
The White House (By Fax @ 202-456-7028)

Pursuant to our telephone conversation, I am sending you the following materials:

1. A "For Response to Inquiries" description of the Office of Cancer Survivorship (OCS) that contains some information re. Dr. Anna T. Meadows who has been named by Dr. Klausner to head the Office (2 pages).
2. A more detailed biographic sketch of Dr. Meadows (1 page).
3. A description of the Children's Hospital of Pennsylvania in Philadelphia (CHOP) (2 pages). This institution has grants from the NCI, and it is the current home institution of Dr. Meadows. Note that CHOP boasts the first follow-up program for long-term survivors of childhood cancer.
4. A description of the University of Pennsylvania Cancer Center in Philadelphia (1 page).
5. A description of the Fox Chase Cancer Center in Philadelphia (1 page).
6. Description of a conference in Albuquerque, NM on Oct. 3-6 sponsored by the National Coalition for Cancer Survivorship (NCCS) in partnership with People Living Through Cancer (PLTC) (1 page). Dr. Klausner is scheduled to address this conference.
7. A narrative from 1987 describing the "Legislative History of the National Cancer Institute" with a description of the National Cancer Act of 1971, the twenty-fifth anniversary of which we are celebrating this year (1 page). I include with this document a bullet-point version of this history that is up-to-date (3 pages).
8. A draft of a press release concerning the formation of the National Cancer Policy Board (NCPB) within the National Academy of Sciences, the establishment of which is occurring at the request of Dr. Klausner in his role as coordinator of the National Cancer Program pursuant to the National Cancer Act of 1971 (3 pages).

Note that we are in the process of preparing additional material containing facts and figures relevant to the subject of cancer survivorship. I will forward these to you as they become available.

- Started to —
recruit people
in July —

— Anna Meadows
-215-590-2804—
-215 590-2810—
- Fax
215-590-4183 —

For Response to Inquiries



Office of Cancer
Communications

Building 31, Room 10A24
Bethesda, Maryland 20892

National Institutes of Health

August 1, 1996

Francis X. Mahaney, Jr.
NCI Press Office
301-496-6641

Anna T. Meadows, M.D., Is Named To Head Office of Cancer Survivorship

Anna T. Meadows, M.D., has been named head of the newly established Office of Cancer Survivorship (NCI-OCS) by Richard D. Klausner, M.D., director of the National Cancer Institute. The office has been designed to explore the physical, psychological, and economic well-being of individuals following cancer treatment.

"We need to look at questions beyond the acute diagnosis and treatment of cancer-- beyond prevention-- and deal with the many research issues that survivors of cancer face in their daily lives so that there will be a better quality of life for all," Klausner said. "Meadows has the experience and the enthusiasm to bring these issues into focus."

The NCI-OCS will explore the entire spectrum of concerns facing cancer survivors including:

- long-term medical and psychological effects of cancer treatment
- factors that predispose cancer survivors to the development of second malignancies
- reproduction and fertility problems following treatment
- genetic factors that increase the risks of any of the above

As a first step, the office will organize a meeting of experts in a variety of disciplines to discuss and help set a research agenda. The NCI-OCS will then take advantage of existing programs and will also develop new research initiatives. Allocation of resources for this activity will be decided after an initial research agenda is developed. The new office will be located within the Division of Cancer Treatment, Diagnosis and Centers. Meadows joined the NCI

(more)

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002: bio	re: Anna T. Meadows [partial] (1 page)	09/24/1996	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Cancer Event

2014-0046-S

rc1424

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]

Item # 1

2

part-time July 1 through an institutional personnel agreement. She will continue her duties at the Children's Hospital of Philadelphia.

"In establishing this office, Klausner has recognized the growing number of cancer survivors and their need for a 'home' at NCI. The burden of a cancer diagnosis does not end when treatment is complete; this office provides the focus for issues that concern survivors and their care-givers. I am excited to be given an opportunity to explore these important questions on a national level," said Meadows.

Meadows is currently a professor of pediatrics at the University of Pennsylvania Medical School, and since 1989 has been the director of the Division of Oncology at the Children's Hospital of Philadelphia. She directs one of the world's largest pediatric and adolescent oncology services: 250 new cases are seen each year.

She has published extensively on the topics of pediatric cancer treatment, genetics and epidemiology, and the long-term effects of treatment. Meadows chairs the Late Effects Study Group, an international consortium of 13 pediatric cancer centers, and is an active member of the Children's Cancer Group. Her experience in areas of patient care, clinical research, and teaching has resulted in numerous academic and professional honors, memberships in medical and scientific societies, and editorial positions with academic journals.

Born in [REDACTED] (b)(6) Meadows is a 1969 graduate of the Medical College of [002] Pennsylvania. She completed postgraduate training in pediatrics at St. Christopher's Hospital for Children and in pediatric hematology/oncology at the Children's Hospital of Philadelphia.

She is a member of the American Society of Clinical Oncology, the American Association of Cancer Research, and the International Society of Pediatric Oncology.

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The Cancer Information Service provides a nationwide telephone service for cancer patients and their families, the public, and health care professionals. The toll-free number is 1-800-4-CANCER (1-800-422-6237); services are provided in English and Spanish. People with TTY equipment may call 1-800-332-8615.

This document is available through the NCI's CancerNet services on the Web (<http://cancernet.nci.nih.gov>) and through Cancer Fax (Jial 301-402-5874 from the handset on your fax machine).

Sep. 24. 1996

5:33PM

NIH/NCI/OCC

The Children's Hospital of Philadelphia
34th & Civic Center Boulevard
Philadelphia, PA 19104

No. 9856 P. 5/17
Item → 2

Dr. Meadows is the Director of the Oncology program at the Childrens Hospital of Philadelphia (CHOP) and a Professor of Pediatrics at the University of Pennsylvania School of Medicine. The oncology program at CHOP is one of the largest in the nation, with 250 new patients diagnosed and treated annually. More than 2000 children and adolescents, who have discontinued therapy, are being followed. The program has 15 faculty, 6 psychosocial staff members and 5 nurse practitioners. It recruits 4 new fellows annually and trains additional graduate students and post doctoral fellows in molecular genetics and biology of cancer, neuro-oncology, psychology and epidemiology.

Dr. Meadows received her medical degree from the Medical College of Pennsylvania more than a decade after completing her training for an earlier career as an educational psychologist. Her pediatric training took place in Philadelphia at St. Christopher's Hospital for Children, where she also began a fellowship in pediatric hematology-oncology. She completed a research fellowship in oncology at the Children's Hospital.

She has been on the faculty of the University of Pennsylvania and the staff of CHOP since 1974 when she completed her training. In 1989 she became director of the program and has since expanded the research programs in fundamental biology, neuro-oncology, bone marrow transplantation, and psychosocial aspects of childhood cancer.

Her research concerns the study of long term effects of childhood cancer and its therapy, and the epidemiology and genetics of childhood cancer. The Greater Delaware Pediatric Tumor Registry, a population-based cancer registry housed at CHOP and developed exclusively for children, has served as the focus for epidemiologic studies. Dr. Meadows chairs the Late Effects Study Group, an

As an active member of the Children's Cancer Group, she has been able to initiate epidemiologic and late effects studies within that group, many of which have been conducted under the aegis of peer reviewed grant support. She has been the Chair of the Lymphoma Strategy Group and in that role directed clinical trials in Hodgkin's disease and non-Hodgkin's lymphoma.

She has served as a member of several policy-making groups in the National Institutes of Health, the University of Pennsylvania and The Children's Hospital of Philadelphia. These include the Cancer Center Support Committee and the Clinical Cancer Investigation Review Committee of the National Cancer Institute, the Appointments and Promotions Committees of the Medical School and of the Department of Pediatrics. She has served as Chair of the Steering Committee of the Medical Faculty Senate, and Chair of the Clinical Research Center Advisory Board.

Her publications reflect her research interests in the epidemiology and genetics of childhood cancer, the long term effects of treatment in survivors, the results of clinical trials in leukemia and lymphoma, and the delivery of medical care.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

Founded in 1855 as the nation's first pediatric hospital, the Children's Hospital of Philadelphia is committed to improving the health of today's children through its clinical care programs, and the health of tomorrow's children through its basic and clinical research programs and training of the next generation of pediatric health care professionals.

Children's Hospital provides comprehensive care, both inpatient and outpatient, for children from birth through age 19. With 304 beds, 20 percent of which are allocated to intensive care, the Hospital admits over 15,000 inpatients and handles over 200,000 emergency and outpatient visits annually.

Critically ill children and those suffering from unusual or hard-to-diagnose diseases are sent here from the Delaware Valley, the nation and the world, for such services as: the only pediatric trauma service in eastern Pennsylvania; one of the largest pediatric oncology services in the nation; a Comprehensive Sickle Cell Centers infant intensive care for premature newborns; liver, heart and bone marrow transplantation; and cardiovascular surgery for children with rare or complicated heart defects. Because of such specialized programs, Children's Hospital placed second among all pediatric hospitals in the United States in the 1995 physicians' rating of America's best hospitals in U.S. News and World Report.

Children's Hospital takes pride in its role as the community caregiver for the disadvantaged children of West and South Philadelphia. As a result of this commitment, the Hospital last year absorbed more than \$31 million in uncompensated care expenses.

The advancement of pediatrics through research and education is also central to the mission of the Children's Hospital of Philadelphia. In May of 1995, the Hospital dedicated its state-of-the-art research facility. The 13-story Leonard and Madlyn Abramson Pediatric Research Center houses the Joseph Stokes, Jr., Research Institute which receives \$30 million annually in research funding.

Research undertaken at the Hospital has resulted in many advances in the prevention, diagnosis and treatment of childhood disease, including the development of the following: the first closed incubator for newborn; the cardiac balloon catheter technique for curing specific congenial heart defects in infants; and vaccines against rubella and mumps.

Each year Children's Hospital's graduate medical training programs train more than 150 pediatric professionals in 26 different subspecialties who then go on to careers in academic medicine, medial research or community practice. The Hospital is also a pediatric training ground for medical students from the University of Pennsylvania School of Medicine, clinical and research fellows from universities worldwide and for nursing students from eight schools of nursing.

For more information please contact (215)590-4100

First in Pediatric Care

The Children's Hospital of Philadelphia has been a pioneer of pediatric medicine, responsible for clinical innovations such as:

- the first pediatric day surgery unit in the U.S.
- the first neonatal surgical and pediatric intensive care unit in the nation
- the first pediatric bone marrow transplantation program in the Delaware Valley
- the first multidisciplinary home-care program in the U.S. For children who need mechanical ventilators to survive
- the first designated Pediatric Regional Resource Trauma Center (Level I) in eastern Pennsylvania
- the first follow-up program for long-term survivors of childhood cancer
- the first clinic in the nation for the treatment of childhood speech defects
- the first pediatric MRI in Philadelphia, used to create high-reduction images of soft body tissue

Item #4

ABOUT THE UNIVERSITY OF PENNSYLVANIA CANCER CENTER

The University of Pennsylvania Cancer Center is a national leader in cancer research, patient care, education and training of health care professionals in cancer, and community education and outreach. The preeminent position of the Cancer Center is reflected in its designation by the National Cancer Institute as one of only 28 cancer centers in the country approved and designated as a Comprehensive Cancer Center.

The University of Pennsylvania Cancer Center takes seriously its commitment to serve as a regional and national leader in developing and offering innovative cancer treatments that improve the chance for recovery while preserving the quality of life. The Cancer Center is equally committed to understanding the underlying causes of cancer through basic, translational, clinical and cancer control research, and to educating health care professionals, patients, families and our community. This commitment reflects the Cancer Center's goal of reducing the incidence and mortality of cancer in our region and throughout the country. As an NCI-designated Comprehensive Cancer Center, the University of Pennsylvania Cancer Center is able to meet the desire of community hospitals to have a relationship with a national leader in cancer research and treatment.

As an institute of the University of Pennsylvania, our Cancer Center benefits substantially from the vast clinical, educational and research resources available through the University of Pennsylvania. Cancer treatment is enhanced because patients experiencing non-cancer-related problems can receive comprehensive care by full-time Penn faculty who practice at the University of Pennsylvania Medical Center. Cancer Center members have access to the substantial research capabilities throughout the Penn campus. Thus, by being part of one of the nation's leading academic medical centers, the University of Pennsylvania Cancer Center's ability to provide the latest cancer treatments, conduct leading-edge research, educate health care professionals, and serve the needs of our community are clearly enhanced.

Mission of the Center

Throughout its 23-year history, the University of Pennsylvania Cancer Center has provided the organizational framework required to promote and enhance interdisciplinary cancer research, education and patient care.

The University of Pennsylvania Cancer Center was initially founded in 1973 as the focus for cancer-related research and education at the University of Pennsylvania. At that time, the Cancer Center's original research mission was defined through six primary objectives, including:

- Development of basic science and clinical research programs.
- Recruitment of faculty with expertise in cancer.
- Development of interdepartmental and interdisciplinary

educational programs in cancer.

- Development of cancer prevention and control research programs.
- Development of NCI-funded Shared Resource facilities that provide cancer researchers with advanced technology needed to conduct innovative research.
- Provision of technical services that facilitate innovative cancer research.
- Development of new cancer research space.

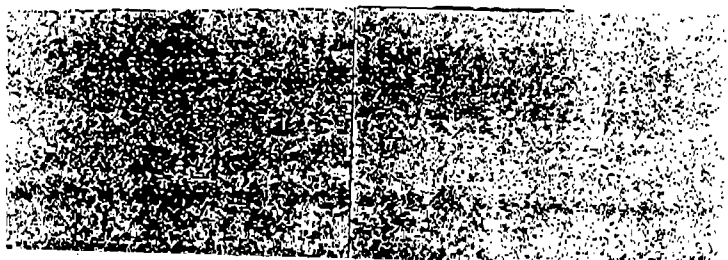
In 1990, the Cancer Center's mission was officially expanded to include a strong clinical initiative. This patient care mission is achieved through the following objectives:

- Expand the range of cancer-related services and interdisciplinary cancer programs.
- Improve patient and referring physician access.
- Enhance the image of the Cancer Center.
- Increase the level of clinical cancer activities.
- Increase clinical research, emphasizing translational research opportunities.
- Expand community outreach activities.

The mission and priorities of the University of Pennsylvania Cancer Center are in concert with those of community hospitals in our region. The development and maintenance of a strong network of select community hospitals meets the Cancer Center's research, clinical, community outreach, education and training responsibilities. At the same time, a well-organized, integrated collaborative relationship with an NCI-designated Comprehensive Cancer Center provides invaluable access to the community hospital and its physicians, and the opportunity to participate directly in innovative clinical, research and educational programs. Most importantly, such cooperative efforts enable the University of Pennsylvania Cancer Center and the Cancer Network hospital to enhance their collective ability to serve the multiple needs of our community.

Designation as a Comprehensive Cancer Center by the National Cancer Institute

The University of Pennsylvania Cancer Center has been continuously funded by the Centers' Program of the National Cancer Institute since its inception in the early 1970s. The Cancer Center is formally approved and designated as a Comprehensive Cancer Center by the National Cancer Institute, a status enjoyed by only 26 cancer centers. This designation is in recognition of the Cancer Center's excellence in cancer research, patient care, community service and outreach, cancer information services, and the education and training of health care professionals.



Item #5

FACT SHEET

CONTACT: Eric Rosenthal
(215) 728-2700

Fox Chase Cancer Center

Fox Chase Cancer Center is one of 27 National Cancer Institute-designated comprehensive cancer centers in the nation. Fox Chase's activities include basic, clinical and prevention research; detection and treatment of cancer; and community outreach programs. In 1974 Fox Chase was formed by the union of American Oncologic Hospital (the nation's first cancer hospital, established in 1904) and the Institute for Cancer Research (founded in 1927). Today it has more than 1800 employees and an annual budget of \$127 million. Research is conducted in more than 75 laboratories by a staff of more than 300 physicians and scientists who hold M.D.s, Ph.D.s or both.

Fox Chase's 100-bed hospital is one of the few facilities in the country devoted entirely to cancer care. More than 130 clinical trials of new prevention, diagnostic and treatment techniques are under way at any one time. Almost 1,000 new patients a year participate in clinical trials. Annual hospital admissions average about 3,400 a year and outpatient visits to physicians exceed 37,000 a year. Combining research in many disciplines with patient care enables Fox Chase to translate new research findings into medical applications that may become models for improved comprehensive cancer care.

Fox Chase is structured around three divisions: medical science, basic science and population science. Medical science is committed to providing excellent patient care and conducting a broad-based program of clinical research. The division of basic science is renowned worldwide for its work in understanding both normal and abnormal cell growth and development. The goal of the division of population science is to identify people at high risk for cancer and to develop strategies to reduce these risks through programs of prevention and early detection.

Fox Chase is also involved in developing trials to test new agents that may prevent cancer in high-risk individuals, and is an active participant in the national trials to prevent breast cancer and prostate cancer. For women at high risk for breast or ovarian cancer, Fox Chase offers the Margaret Dyson Family Risk Assessment Program providing state-of-the-art medical care, cancer genetic counseling and education.

In 1986 Fox Chase established partnerships with community hospitals in the region. Fox Chase Network now includes 19 hospitals throughout the Philadelphia area and as far as Pittsburgh, Pa. and central and southern New Jersey. This program has been successful in raising the quality of cancer care in the community and increasing the number of patients enrolled in clinical trials. In 1995 the center was a founding member of the National Comprehensive Cancer Network, an alliance of 15 of the nation's best cancer centers. In 1996 Fox Chase announced the formation of the Oncology Physician Network, an organization of medical oncologists in Pennsylvania, New Jersey and Delaware sharing common practice philosophies and contracting needs.

Fox Chase operates the NCI's regional Cancer Information Service (1-800-4-CANCER) serving eastern Pennsylvania, New Jersey and Delaware. The regional Cancer Information Service receives more than 35,000 calls and conducts more than 1,900 cancer-related data-bank searches for patients and physicians each year, and maintains an active outreach program.

Fox Chase investigators have received numerous awards and honors including a Nobel Prize for medicine; membership in the National Academy of Sciences; General Motors Cancer Research Foundation Prizes; American Cancer Society Medals of Honor; and induction into the National Inventors Hall of Fame. The president of Fox Chase, Dr. Robert C. Young, is past president of the American Society of Clinical Oncology, one of the world's largest oncology societies.

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FOX CHASE
CANCER CENTER

#3037/8-96

**In Honor of the 10th Anniversary of the
National Coalition for Cancer Survivorship...**

O'F, B'Y, A'ND F'OR C'ANCER S'URVIVORS

**A Conference in Partnership with
People Living Through Cancer (PLTC)**

Albuquerque, New Mexico, October 3-6, 1996

The National Coalition for Cancer Survivorship teams with People Living Through Cancer, the Albuquerque grassroots cancer support organization from which NCCS grew, to highlight valuable links between the national cancer survivorship movement and regional and local organizations.

The program includes information-packed workshops and plenary sessions around Resources for Action and Resources for Living and showcases successful cancer peer support, information access, and networking opportunities. Plus the Conference celebrates NCCS' 10 years of service to the survivorship movement with display of the NCCS Ribbon of Hope™ — a huge sunburst of gold ribbons signed throughout the past year in honor of people touched by cancer — a Paintfest presented by the Foundation for Hospital Art, NCCS awards, exhibits, and a special morning excursion to witness the International Balloon Fiesta.

Space is limited! Register today!

ABOUT YOUR CO-HOSTS

The National Coalition for Cancer Survivorship (NCCS), founded by a small number of cancer survivors and supporters in 1986, has grown in 10 years into the largest network of independent organizations and institutions representing people with all types of cancer. NCCS helps cancer survivors find answers to their questions and attain a better quality of life following diagnosis by linking them to direct service and peer support organizations; addressing professional, legal, and health dilemmas; and participating in and shaping public policy on health care and cancer survivorship research.

People Living Through Cancer (PLTC), a grassroots organization founded in 1983 by cancer survivors, sponsors a variety of support groups, including an innovative support network serving Santo Domingo and other pueblos in New Mexico. PLTC also offers one-to-one support, New Mexico's largest lending library of cancer related material for healthcare consumers, and a Telephone LifeLine program. NCCS has its roots in PLTC, which generously provided a home-base for NCCS during the coalition's formative years.

SCHEDULE OF EVENTS *(subject to change)*

THURSDAY, OCTOBER 3

3-7pm Registration
7pm Welcome Reception: a multimedia retrospective on the survivorship movement

FRIDAY, OCTOBER 4: RESOURCES FOR ACTION

8-9am Continental Breakfast
Registration
8am-5pm Exhibits
9-10:30am Opening Session: a panel of cancer survivors and leaders of the survivorship movement assesses the state of the movement today and trends for the future.
10:45-11:45am Networking Groups: exploring today's vital issues.
Poster Presentations
12-1pm The New NCCS Almanac: A special luncheon presenting the expanded, updated version of *A Cancer Survivor's Almanac: Charting Your Journey*.
1:30-4:30pm Information Fair: The new wave of cancer information resources
Book Fair: over 100 titles of the best of survivorship literature, plus other special items
6-9pm NCCS Town Hall Meeting: with buffet reception

SATURDAY, OCTOBER 5: RESOURCES FOR LIVING

7-8am NCCS Annual Business Meeting & Continental Breakfast
7-8:30am Book Fair
7:30am Registration
8am-5pm Exhibits
8:30-10:15am Keynote Address: Michael Lerner, PhD
10:45am-12:15pm Workshops: Your choice of 10 sessions reflecting the theme of Choices—in healing, mainstream medicine, complementary therapies, pain management, and end-of-life issues.
12:15-1:30pm Networking Luncheon
1:30pm NCCS Public Policy Meeting
1:30-3pm Afternoon Workshops: Some morning workshops to be repeated, plus new selections
3:30-4:15pm Paintfest
5:30-9pm Closing Ceremony
Celebratory dinner at the Indian Pueblo Cultural Center with music, museum tours, 50% shopping discount

SUNDAY, OCTOBER 6

5:30am Buses depart for 25th Anniversary Albuquerque International Balloon Fiesta, most-photographed sports event in the world
7:30am Mass Ascension: 850 hot-air balloons go sky-high
11am Buses arrive back at hotel

PROFILE: Michael Lerner

Although securely anchored in mainstream medicine, Michael Lerner, PhD, explores complementary and mainstream therapies without bias. His *Choices in Healing* won widespread acclaim as a balanced inquiry into traditional and nontraditional approaches. Lerner is president of Commonweal, a health and environmental research institute that he founded in 1976 in Bolinas, California.

Legislative History of the National Cancer Institute

Mary C. Knipmeyer¹

On August 5th, 1937, President Franklin D. Roosevelt signed into law the National Cancer Institute Act (P.L. 244) establishing the National Cancer Institute. The law mandated the new Institute "to provide for, foster, and aid in coordinating research relating to cancer." In 1944, the Public Health Service Act consolidated much of the Nation's health efforts, including designating the National Cancer Institute as part of the National Institutes of Health.

The next major legislative step in the Federal effort to fight cancer occurred with the signing of the National Cancer Act (P.L. 92-218) on December 23, 1971 by President Richard Nixon. This legislation was enacted following the report of the National Panel of Consultants on the Conquest of Cancer appointed by Senator Ralph Yarborough. The Act found a middle ground between those who thought the National Cancer Institute should be an independent agency and those who thought it belonged within the National Institutes of Health. The 1971 legislation met the concerns of both perspectives by enlarging the authorities and responsibilities of the Institute Director and initiating a National Cancer Program. Special authorities included appointment of the Director by the President, the development of an annual By Pass Budget, special peer review and training authorities, and the authority to hire expert consultants to enter into contracts and to award construction projects. It also established a 3-member President's Cancer Panel, charged with reporting to the President any delays or blockages in the rapid execution of the National Cancer Program. The National Cancer Advisory Board also was established with 18 Presidentially appointed members in addition to 5 ex-officio members. The first cancer centers were authorized by this new law, which called for 15 new research, training, and demonstration cancer centers. The Act also established cancer control programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer. An Information Dissemination Program for the collection, analysis, and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer was established as well as the International Cancer Research Data Bank.

Three years after signing the original Act, President Nixon signed the National Cancer Act Amendments of 1974 (P.L. 93-352). This law included new provisions for disseminating information on nutrition as related to the treatment or causation of cancer as well as a peer review system of grant applications and contract projects.

The next significant set of amendments to the National Cancer Act came in 1978 when the Act was amended to emphasize education and demonstration programs in cancer treatment and prevention. The amendments (P.L. 95-622) also stipulated that the National Cancer Institute devote more resources to prevention, focusing particularly on environmental, dietary, and occupational cancer causes.

In 1985, the Health Research Extension Act (P.L. 99-158) recodified the portion of the Public Health Service Act related to the National Institutes of Health. The special authorities of the National Cancer Institute were maintained with the clear intent of continuing to provide for an expedited cancer research program. The mission of the National Cancer Institute continues to be to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer. The 1985 law placed additional emphasis on the continuing care of cancer patients and their families.

The legislative history of the National Cancer Institute reflects the Nation's continuing commitment to the goal of eradicating cancer through a multifaceted national research program and the desire of the Congress to provide the authority and flexibility needed to facilitate its achievement.

¹ Legislative Analyst/Congressional Liaison, Office of the Director, National Cancer Institute.

Legislative History of the National Cancer Institute and the National Cancer Program

HIGHLIGHTS

August 5, 1937

National Cancer Institute Act of 1937 [P.L. 244]

- o Established the National Cancer Institute within the Public Health Service
- o Sec. 2 (b) directs the Surgeon General, through the Institute, **"To promote the coordination of researches conducted by the Institute and similar researches conducted by other agencies, organizations, and individuals;"**
- o Established the National Advisory Cancer Council

December 23, 1971

National Cancer Act of 1971 [P.L. 92-218]

- o Outgrowth of the report of the National Panel of Consultants on the Conquest of Cancer (the Yarbrough Commission)
- o Elevated and expanded certain authorities of the National Cancer Institute director, including appointment by the President and preparation and submission of the annual budget estimate (Bypass Budget) directly to the President
- o Established the President's Cancer Panel and the National Cancer Advisory Board
- o Initiated the **National Cancer Program** under Sec. 407 of the PHS Act as follows: "(a) The Director of the National Cancer Institute shall **coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program.** (b) In carrying out the National Cancer Program, the Director of the National Cancer Institute shall: (1) With the advice of the National Cancer Advisory Board, **plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the other research institutes, and other Federal and non-Federal programs.**"
- o Authorized the first cancer centers
- o Established cancer control programs as necessary for cooperation with State and other health agencies
- o Established an information dissemination program
- o Established the International Cancer Research Data Bank (ICRDB)

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

July 23, 1974

National Cancer Amendments of 1974 [P.L. 93-352]

- o Broadened authority to collect, analyze and disseminate "information" (replaced "data")
- o Authorized award of construction grants for new construction or alteration/renovation of basic research laboratory facilities
- o Authorized expanded information dissemination activities for scientists, health professionals and the general public

November 9, 1978

Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978 [P.L. 95-622]

- o Recodified the 1971 Act; reorganized and consolidated duties and functions of the NCI Director (in the process, the language regarding the scope of the National Cancer Program as including other Federal and non-Federal programs was dropped)
- o Called for an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens
- o Reduced minimum number of President's Cancer Panel meetings from 12 to 4 per year
- o Expanded the mission of cancer centers to include basic research and prevention
- o Expanded and strengthened the cancer control mandate to emphasize the importance of education and demonstration programs initiated within local communities and hospitals
- o Added several ex-officio members to the NCAB, reflecting the importance of environmental and occupational carcinogenesis research and required that five of the appointed members be knowledgeable in environmental carcinogenesis

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

November 20, 1985

Health Research Extension Act [P.L. 99-158]

- o Established the position of Associate Director for Prevention
- o Added to NCI's mission and cancer control activities research on continuing care of cancer patients and their families
- o Consolidated cancer communications activities and highlighted the ICRDB

November 4, 1988

Health Omnibus Programs Extension of 1988 [P.L. 100-607]

- o Added rehabilitation research to NCI's mission
- o Further expanded NCI's information dissemination programs

June 10, 1993

The NIH Revitalization Amendments of 1993 [P.L. 103-43]

- o Requires intensified and expanded research programs in breast/women's cancers and prostate cancer
- o Mandates a set-aside of NCI's appropriation for cancer control activities (FY94-7%; FY95-9%; FY96-10%)
- o Mandates a case control study of elevated breast cancer rates on Long Island; requires study of potential environmental risk factors and establishment of a geographic information system

National Cancer Policy Board To Be Formed

This year, nearly 1-1/2 million people will be diagnosed with cancer. Up to 40 percent of us will eventually be diagnosed with this disease over our lifetime. The impact of the many different diseases we call cancer on our society is enormous. Today, there are over 10 million cancer survivors in the U.S. Hundreds of organizations representing Federal and state governments, academic institutions, professional societies, patient and advocate organizations, private organizations and others have responded to the enormous challenges of cancer. The National Cancer Program represents the sum of all of these activities. To articulate the differing viewpoints of all of the stakeholders in this Nation's commitment to reduce the burden of cancer, the National Cancer Institute (NCI), the President's Cancer Panel, and the National Cancer Advisory Board, have requested that the National Academy of Sciences form a National Cancer Policy Board (NCPB). The governing boards of the Academy's National Research Council (NRC) and Institute of Medicine (IOM) approved the formation of the Board in July. The NCPB would bring together representatives of the diverse participants in the Nation's cancer effort, which encompasses both Federal and non-Federal activities aimed at reducing the burden of cancer in the United States. These would include members of the cancer research community, cancer care providers, relevant professional organizations, and patient advocacy groups. While the National Cancer Act of 1971 designated the Director of the NCI as coordinator of the National Cancer Program, it is clear that the issues and questions related to cancer policy exceed the scope and authority of any single organizational entity.

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In describing this new endeavor, the NCI Director, Dr. Richard Klausner states, "We believe that the issues that the National Cancer Program needs to confront vis-à-vis major societal issues, requires some forum that can produce useful advice, guidelines, or recommendations independent of the constraints of a particular Federal agency, any particular advocacy group, or any particular set of interests within the National Cancer Program." The NCPB will provide this forum in which various sectors of the society can discuss overarching issues related to the Nation's cancer effort in a neutral and independent environment. The Board will survey current and possible outcomes of the Nation's cancer effort and deliberate on issues of broad national significance related to the movement of cancer research findings to implementation at all levels of society.

Dr. Klausner describes the new NCPB as "... a roof under which all of us can gather to deal with issues such as standards of care, cancer control policy issues, insurance and privacy issues, payment for clinical trials, standards of clinical trials, manpower needs, informational and educational needs, environmental/occupational policy in cancer, smoking policy, etc."

While the NCI will provide core support for the formation of the NCPB, the Academy will also solicit support from other Federal agencies with an interest in cancer issues, as well as from foundations and other organizations. The Board will consist of approximately 20 individuals who collectively represent the diversity of interests in the Nation's endeavors to eradicate cancer. Board members will have various relevant expertise and will have distinguished themselves through their prior contributions. The Academy will seek nominations for Board membership and ideas for topics the Board

Item #8

should address from the broad range of groups that comprise the Nation's cancer constituency. Once established, the NCPB will operate under the existing policies of the NRC and IOM which include independent, carefully reviewed studies on topics deemed to be in the Nation's interests. The NCPB will publish the outcomes of these studies and thereby advise the Nation regarding cancer policy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MELISSA SKOLFIELD

Assistant Secretary for Public Affairs

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Date:

10/11/96

Total Number of Pages: _____

Comments:

Sorry for the delay.

Here is some information, as we discussed. I hope it is somewhat clear now + helpful.

We'd be happy to get you more information next week if you need it.

Please call if you have any questions

lby 690-7854



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Washington DC 20201

October 1996

Dear Colleague,

In 1996, an estimated 184,300 women will develop breast cancer and 44,300 will die of the disease. Breast cancer is the most common form of cancer and the second leading cause of cancer death in American women. An estimated 1 in every 8 American women will develop breast cancer in her lifetime.

October is **Breast Cancer Awareness Month**. This national health observance is an opportunity to inform the public about research advances, new programs, the importance of early detection, and the increased national focus on women's health that is bringing hope to the fight against breast cancer.

The U.S. Public Health Service's Office on Women's Health (PHS OWH), working with other agencies and offices of the Department of Health and Human Services (DHHS), is dedicated to reversing the toll that breast cancer takes on the lives of American women. The mission of the U.S. Public Health Service's Office on Women's Health is to direct, stimulate, and coordinate women's health research, health care services, and public and health care professional education across the agencies and offices of the Department of Health and Human Services, and to collaborate with other government organizations, foundations, private industry, and consumer and health care professional groups to advance women's health. We also work to strengthen and support comprehensive diagnostic, treatment, and prevention programs for women nationwide and to foster the recruitment, retention, and promotion of women in the health professions and in research careers.

A health concern of top priority to us is breast cancer. Many new programs on breast cancer in the Department of Health and Human Services and other government agencies reflect an intensified Federal commitment to fighting this disease. Federal funding for breast cancer research, prevention, and treatment has increased sixfold—from \$90 million in 1990 to over \$600 million today. DHHS funding for breast cancer programs nearly doubled between 1993 and 1996, from \$271 million to over \$476 million today.

Examples of initiatives being implemented by the U.S. Public Health Service's Office on Women's Health include the following:

- ◆ *The National Action Plan on Breast Cancer (NAPBC)*, an innovative public/private partnership that is catalyzing new actions in research, service delivery, and education to eradicate breast cancer as a threat to the lives of women. The NAPBC's six priorities are to: (1) disseminate information using state-of-the-art information technologies, (2) create an integrated system of national biological resource banks; (3) ensure consumer involvement, (4) expand etiology research, (5) enhance clinical trials accessibility, and (6) address the needs of women carrying breast cancer susceptibility genes and the need for education among consumers, healthcare professionals, and at-risk patient groups.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 10, 1996

Dear Colleague:

As you are aware, October is National Breast Cancer Awareness Month. As part of our observance, the Office of Women's Health at the Food and Drug Administration (FDA) would like to bring you up-to-date on breast cancer related activities at the FDA. We are pleased to take this opportunity to share with you the many product approvals, regulatory actions, research and outreach projects that FDA has accomplished in the past year.

Breast Cancer Approvals

The following are oncologic product approvals specific for breast cancer:

- On December 18, 1995, Zeneca Pharmaceuticals received approval to market Zoladex (goserelin acetate implant) for palliative treatment of advanced breast cancer in pre and postmenopausal women.
- On December 27, 1995, Zeneca Pharmaceuticals received approval to market Arimidex (anastrozole) tablets for the treatment of advanced breast cancer in postmenopausal women who have progressed following tamoxifen citrate therapy.
- Taxotere (docetaxel) for Injection, sponsored by Rhone-Poulenc Rorer, received accelerated approval on May 14, 1996 for patients whose advanced breast cancer has progressed after standard cancer treatment regimens with drugs such as doxorubicin.
- Aredia (pamidronate disodium for injection), sponsored by Ciba-Geigy Corporation, was approved on July 17, 1996 for use in conjunction with standard antineoplastic therapy for treatment of osteolytic bone metastases. This supplemental approval is indicated for treatment of those patients with lytic bone lesions from breast cancer who are receiving chemotherapy and those patients who are receiving hormonal therapy.
- On March 29, 1996, FDA approved the first blood test to help determine whether a woman's breast cancer has returned. The test measures CA 27.29, a tumor marker, found in the blood of patients with breast cancer and certain other types of cancer. As breast cancer progresses, the level of CA 27.29 antigen in the blood rises. In clinical studies, the new test accurately detected the breast cancer antigen in 60 percent of women who had a recurrence. TRUQUANT-BR RIA, an *in vitro* diagnostic device sponsored by Biomira Diagnostics, Inc., received premarket approval for quantitative determination of CA 27.29 antigen in serum or EDTA plasma of patients previously treated for Stage II or Stage III breast cancer. Serial Testing for the antigen with TRUQUANT-BR RIA in patients who are clinically free of disease should be used in conjunction with other clinical

methods used for the early detection of recurrence.

- **Abbott PRG-ICA Monoclonal**, a device for the detection of human progesterone receptor (PgR) in breast tumor tissue, sponsored by Abbott Laboratories, received premarket approval September 26, 1995. This device is to be used as an aid in assessing the likelihood of response to hormonal therapy, and as an aid in the prognosis and management of breast cancer patients.
- **Chemoresponse Assay**, a device sponsored by Bartels Prognostic, Inc., for determining the resistance of breast cancer cells to 5-fluorouracil (5-FU), was approved in August 1996. The test determines whether 5-FU would be ineffective for treatment of relapsed breast cancer patients. The determination of resistance of the breast cancer cells is made when the cells continue to multiply in the presence of 5-FU under laboratory conditions. If the cells are found to be resistant to 5-FU, the physician would know to select another drug for treatment.

Proposed Final MQSA Regulations

In 1993, FDA was charged with implementation of the Mammography Quality Standards Act (MQSA), which seeks to ensure that all mammography facilities provide high quality mammograms. On March 29, 1996, FDA proposed regulations that will expand and strengthen interim regulations in place since late 1993. When final, the new rules will be a major step toward the FDA's full implementation of MQSA. In addition to requiring that mammography facilities meet quality standards, MQSA requires facilities to be accredited by an FDA-approved accreditation body, certified by the FDA, and inspected annually. To date, nearly 10,000 facilities have been accredited and 80% have had their first inspection. Prior to 1992, only about 46% of facilities were accredited and many facilities were never inspected.

The proposed MQSA regulations would strengthen interim requirements to ensure that mammography personnel are adequately trained and qualified to conduct mammography examinations and interpret mammograms; strengthen requirements to ensure that mammography equipment meets appropriate design and performance characteristics; expand requirements for reporting results of mammograms to ensure that doctors and patients are quickly and fully informed of results so that any follow-up testing or treatment can begin immediately; add a consumer complaint requirement to ensure that complaints from patients are followed up on appropriately; and add requirements to ensure that women with breast implants are examined properly. The 90-day comment period on these proposed regulations closed at the end of June. Final regulations are expected to be published in 1997.

Telephone Information Service

FDA has collaborated with the National Cancer Institute (NCI) in developing a telephone information service that includes the names and locations of FDA-certified mammography

facilities. This service may be reached by dialing 1-800-4-CANCER (1-800-422-6237) and is available in English and Spanish. A line for the hearing impaired can be reached by calling 1-800-332-8615.

New Use of Ultrasound

In the past year, FDA approved a new use for an ultrasound breast imaging system, the Ultramark 9 High Definition Imaging (HDI) Ultrasound System Level 3 made by Advanced Technology Laboratories. The new use will enable doctors to look at solid breast lumps and judge whether they are likely to be benign. Those which appear highly likely to be benign could be treated without biopsy. The device was approved for use along with mammography and physical breast examination.

Sensor Pad

FDA cleared for marketing a plastic pad that can be used as an aid to self-examination for breast lumps by women who are trained in the pad's use. The Sensor Pad is available through health care providers, clinics and other institutions where women can receive the necessary instruction in its proper use.

FDA Office of Women's Health Research and Program Initiatives Program

Since last October, the Office of Women's Health has funded several new projects, both research and program initiatives, on breast cancer and related topics such as breast implants.

Research

The research projects include:

- In vitro prediction of time to neutropenic nadir: Antineoplastic alkylating agents as prototype drugs
- DNA adducts of tamoxifen
- IP-10: A potential new therapeutic for breast cancer
- A novel molecular approach to risk assessment of hormonally active compounds
- Development of an estrogen knowledge base for research and regulation
- Mechanisms of immunotoxicity and carcinogenicity associated with silicone breast implants

- Development of a safe, economical assay for silicone contamination in blood and tissue.
- The effects of tamoxifen on neonatal rat uterine growth and differentiation
- Mechanism of tamoxifen developmental toxicity and neoplasia: tamoxifen effects on the rat uterine insulin-like growth factor system.

Program Initiatives

The program initiatives include:

- Workshop on "The FDA Role in the Transfer of Defense, Intelligence, Space and Energy Technologies to the Early Detection and Control of Cancers in Women." This conference will be held on October 22-24, 1996, at the Radisson Plaza Hotel at Mark Center, Alexandria, VA. We have enclosed a brochure providing more information, including how to register, about this meeting.
- "Things to Know about Quality Mammography" (available by calling 1-800-358-9295) is a consumer brochure published by the Agency for Health Care Policy and Research in collaboration with FDA. This brochure has been translated into Spanish, Chinese, Korean, Vietnamese, Laotian, and Tagalog. In addition, in the past year, the FDA Office of Women's Health has funded translation of this brochure into Thai, Cambodian, and Samoan.
- Workshops on MQSA for mammography facilities.
- Production and performance of a play about breast cancer prevention, detection, and treatment, "Before Time Runs Out" in African American churches in Texas.
- Development of a Web page on the Internet with screening information on breast and cervical cancer for Asian Pacific Islanders.

New Director Named for FDA Oncologic Drugs Division

In June, 1996, Robert DeLap, M.D., Ph.D., was named Director of the Division of Oncology Drug Products in the Center for Drug Evaluation and Research at FDA. Dr. DeLap joined FDA as a Medical Officer in 1993, and has served as Acting Division Director since October 1995. Dr. DeLap earned both his medical degree and Ph.D. in Biochemistry and Molecular Biology from New York University in 1977. He subsequently had specialty training in Internal Medicine at the University of Michigan; and in Medical Oncology at Yale University. From 1983 to 1990, Dr. DeLap worked for two pharmaceutical companies (Warner Lambert-Parke Davis and Lederle Laboratories), supervising clinical studies of new drugs for cancer treatment. Prior to joining FDA, Dr. DeLap held a full-time faculty position at Georgetown University School of Medicine in

Washington, D.C. At Georgetown, he conducted clinical trials of new agents for cancer prevention and cancer treatment, and conducted other types of cancer related research.

As you can see, there is a great deal of activity and much good news. Of course, FDA will continue the fight until we can declare victory against breast cancer. In this endeavor, we look forward to working and communicating with you.

Sincerely,



Audrey Sheppard
Acting Director
Office of Women's Health

Enclosure

- ◆ *New Frontiers in Breast Imaging: Missiles to Mammograms*, an innovative project to transfer satellite and other imaging technology from the defense and intelligence communities used for missile and target recognition to improve the early detection of breast cancer. A Capitol Hill Briefing on this program was held recently, and a meeting cosponsored by the U.S. Public Health Service's Office on Women's Health and the Food and Drug Administration on October 22-24 will explore the steps required to transfer these cutting-edge imaging technologies from the research bench to clinical settings.
- ◆ *Clinical Trials of New Breast Imaging Technologies*. The U.S. Public Health Service's Office on Women's Health is supporting a multi-site clinical trial conducted by the University of Pennsylvania to evaluate how effectively these new imaging technologies transferred from the intelligence community will work to detect breast cancer earlier and more accurately. This clinical trial will include testing in two major areas: computer-aided diagnosis in digital x-ray mammography and computer-aided diagnosis for magnetic resonance imaging (MRI). An extensive digital image database library also will be created and will serve as a national resource for other researchers working in this field.
- ◆ *The Federal Coordinating Committee on Breast Cancer*, which fosters the sharing of information about breast cancer programs across the agencies of the Federal Government, stimulates collaborations, and has developed a searchable inventory of all government breast cancer activities that will be accessible via the Internet.
- ◆ *The Medicare Mammography Initiative*. The U.S. Public Health Service's Office on Women's Health worked with the White House and the Health Care Financing Administration to encourage women older than 65 years of age to use their screening mammography benefit provided by Medicare. Women in this age group account for over half of all newly diagnosed breast cancer cases, yet nearly two-thirds do not take advantage of their Medicare-covered mammography screening benefit.
- ◆ *The National Women's Health Information Center*. This new national resource, which will be launched at the end of October, will provide a single point of entry, via both a toll-free telephone line and the Internet, for access to free Federal and private sector resources on a broad range of women's health issues.

Enclosed is some information on breast cancer that we have prepared and which we hope you will find useful. The breast cancer fact sheet provides statistics on breast cancer incidence and mortality rates as well as information about the etiology, detection, diagnosis, treatment, and prevention of this disease. It also describes current DHHS breast cancer initiatives. "Waging the Battle Against Breast Cancer: A Progress Update" provides a description of major Federal initiatives in the fight against breast cancer, including the significant increase in funding for breast cancer programs, new partnerships to implement a national strategy to fight breast cancer, and advances in early detection and treatment.

With your help, we can inform the public about breast cancer, emphasize the importance of early detection, and increase research to discover the causes of breast cancer and to develop new treatments and prevention strategies.

We appreciate your dedicated efforts to improve the health of American women and look forward to working with you to end the toll that breast cancer takes on women's lives.

Sincerely,



Susan J. Blumenthal, M.D., M.P.A.
Deputy Assistant Secretary for Health
(Women's Health)
Assistant Surgeon General

Enclosures

In connection with this action, a question has arisen as to whether Federal civilian employees and military personnel will be entitled to a second pay increase in October 1972, unless I submit to the Congress, as I did last August, an alternative plan postponing or otherwise modifying the raises that would be prescribed by the machinery established by the Pay Comparability Act. Therefore, I believe it is appropriate for me to state my understanding of the law at this time.

The purpose of section 3 of the Stabilization Act Amendments was to provide equal treatment for Federal employees and military personnel as compared with

employees in the private sector who are subject to the Phase 2 pay guidelines. The raises I am implementing today do precisely that. Should a second raise be granted next October, Federal employees and military personnel would be receiving preferential treatment—raises in excess of the Phase 2 guidelines. That would be plainly inconsistent with the overall intention of the Congress, which is to relate Federal pay to the guidelines of the Pay Board.

Therefore I am authorizing an annual increase consistent with these guidelines, interpreting the law to mean there will be no automatic October adjustment.

408 Remarks on Signing the National Cancer Act of 1971. December 23, 1971

Members of the Senate, Members of the House, ladies and gentlemen:

We are here today for the purpose of signing the cancer act of 1971. I hope that in the years ahead that we may look back on this day and this action as being the most significant action taken during this Administration. It could be, because when we consider what cancer does each year in the United States, we find that more people each year die of cancer in the United States than all the Americans who lost their lives in World War II.

This shows us what is at stake. It tells us why I sent a message to the Congress the first of this year, which provided for a national commitment for the conquest of cancer, to attempt to find a cure.

Now, with the cooperation of the Congress, with the cooperation of many of the people in this room, we have set up a procedure for the purpose of making a total national commitment. I am not go-

ing to go into the details of that procedure, except to say this: As a result of what has been done, as a result of the action which will come into being as a result of signing this bill, the Congress is totally committed to provide the funds that are necessary, whatever is necessary, for the conquest of cancer. The President is totally committed—we have a Presidential panel headed by Benno Schmidt, which will report directly to the President so that the President's influence, whenever necessary, can be used to reach this great goal.

And, in addition to that, all of the agencies of government, the National Institutes of Health, HEW, et cetera, are totally committed.

Now, having said that, I have spoken exclusively of government up to this point. In this room are scores of people who have worked voluntarily for this cause for many, many years. The American Cancer Society, of course, is the best known or-

ganization, but there are many others as well.

In saying that there will be a Presidential commitment, in saying that there will be a Congressional commitment, a government commitment, I should emphasize that a total national commitment means more than government. It means all the voluntary activities must also continue. We have to realize that only one-sixth of everything that is produced in America is produced by what government does. Five-sixths of what we do in America is produced by what people do in their voluntary and cooperative capacities.

So, we need the continued cooperation of all the volunteer organizations. You will have, of course, the total commitment of government, and that is what the signing of this bill now does.

Finally I should emphasize, as Benno Schmidt mentioned just a moment ago, that we would not want to raise false hopes by simply the signing of an act, but we can say this: That for those who have cancer and who are looking for success in this field, they at least can have the assurance that everything that can be done by government, everything that can be done by voluntary agencies in this great, powerful, rich country, now will be done and that will give some hope, and we hope those hopes will not be disappointed.

Now, ladies and gentlemen, for those of you who have not participated in signing ceremonies—and that, of course, does not include the Members of the House and Senate who are here; I see that many of them have been here previously—the custom is always to sign with the Presidential pen. I will use two pens for the signature, but a souvenir pen will be available to everybody in the audience here. We had to stretch a little to find that many, but we did it.

Incidentally, it is a very good pen, but the box is worth more than the pen.

[At this point, President Nixon signed the act. He then resumed speaking.]

Benno, you get the "Richard." Dr. Letton, if you will step forward—the president of the American Cancer Society—you get the last name.

NOTE: The President spoke at 12 noon in the State Dining Room at the White House.

Dr. A. Hamblin Letton's response is printed in the Weekly Compilation of Presidential Documents (vol. 7, p. 1711).

As enacted, the bill (S. 1828) is Public Law 92-218 (85 Stat. 778).

On the same day, the White House released an announcement of the signing and a fact sheet on the provisions of the act.

An announcement of the appointment of Benno C. Schmidt as Chairman of the President's Cancer Panel was also released on December 23, 1971, and is printed in the Weekly Compilation of Presidential Documents (vol. 7, p. 1712).

409 Statement About the National Cancer Act of 1971. *December 23, 1971*

HOPE and comfort, the relief of suffering and the affirmation of life itself—these are qualities which have traditionally been associated with the Christmas

season. There could be no more appropriate time than this to sign into law the National Cancer Act of 1971. For this legislation—perhaps more than any legis-

lation I have signed as President of the United States—can mean new hope and comfort in the years ahead for millions of people in this country and around the world.

The enactment of this legislation culminates a yearlong effort to launch an unprecedented attack against cancer. I called for such a program in my State of the Union Message in January 1971, and I expanded on that call in my special message to the Congress concerning health on February 18. Early in May, I submitted to the Congress very specific proposals for a cancer cure program—proposals which are reflected in all important respects in the legislation I have signed today.

The effort to mobilize a concerted national campaign against cancer has continued to make significant progress since those proposals were submitted. One of the most important steps was the approval by the Congress of the additional \$100 million I requested to support an expanded attack on cancer. This additional \$100 million, when added to the regular appropriation for this fiscal year, gives the national cancer program a current operating level of \$337.5 million, compared to only \$180 million during the first half of fiscal year 1972. Another important component in our campaign was put in place in October when I announced that the bacteriological warfare research facilities at Fort Detrick, Maryland, would be converted into a leading center for cancer research.

Now this year of preparation for an all-out assault on cancer comes to a climax with the signing of the National Cancer Act. The new organizational structure which this legislation establishes will enable us to mobilize far more effectively both our human and our financial re-

sources in the fight against this dread disease.

I appreciate deeply the months of hard and careful effort which so many Members of the Congress gave to this cause. I am especially pleased that the new national cancer program incorporates the basic recommendations I made last May. It allows the President to appoint the Director of the National Cancer Institute and provides that the budget of the National Cancer Institute be submitted directly to the President. It creates a 3-member President's Cancer Panel to monitor its development and execution on a regular basis and a 23-member National Cancer Advisory Board to offer general guidance. Both of these groups are to be appointed by the President and will report directly to him. The important result of all these provisions is to place the full weight of the Presidency behind the national cancer program. As I recommended in May, the President will be able to take personal command of the Federal effort to conquer cancer so that its activities need not be stymied by the familiar dangers of bureaucracy and redtape.

Having asked for this authority—and this responsibility—I now pledge to exercise it to the fullest. Biomedical research is, of course, a notoriously uncertain enterprise, and its rate of progress cannot be predicted with confidence. But I can say with the greatest confidence that there will be no uncertainty about the Government's role in this effort. I am determined that the Federal will and Federal resources will be committed as effectively as possible to the campaign against cancer and that nothing will be allowed to compromise that commitment.

I make this statement with even greater confidence knowing that Benno C.

Schmidt has accepted my invitation to become the first Chairman of the President's Cancer Panel. As chairman of the National Panel of Consultants on the Conquest of Cancer, Mr. Schmidt has played an active role in the development and enactment of the National Cancer Act. He is an effective leader of men and a dedicated community servant. The Nation is fortunate that he will be heading this important panel in its critical first year.

Even as the plans for our national cancer program were being completed in the past few months, other developments have continued to fuel our hopes for further substantial progress in discovering the causes and cures of cancer. Scientists in all parts of the world have continued to contribute important new findings to the growing pool of knowledge about this disease. There continues to be every reason for believing that cancer research, of all of our research endeavors, may be in the best position to benefit from a new application of human and financial resources.

This is the case, however, only because so many men and women have already given so much to the battle against cancer in the past. Their energies and talents and sacrifices have built the foundations on which all future progress must rest.

As we plan for future progress, we should also remember that the expansion

of the Federal campaign against cancer in no way diminishes the continuing importance of private and voluntary activities. It is essential, for example, that an organization such as the American Cancer Society—which has raised so much money for this cause and which has done so much to promote research and education in this field—continue to play its full effective role. The new national cancer program must not replace our present efforts to fight cancer; it must supplement them and build on them.

As this year comes to an end, cancer remains one of mankind's deadliest and most elusive enemies. Each year it takes more lives in this country alone than we lost in battle in all of World War II. Its long shadow of fear darkens every corner of the earth. But just as cancer represents a grim threat to men and women and children in all parts of the world, so the launching of our great crusade against cancer should be a cause for new hope among people everywhere.

With the enactment of the National Cancer Act, the major components for our campaign against cancer are in place and ready to move forward. I am particularly happy that the year 1971—at the beginning of which I issued my call for a new campaign against cancer—can end with the signing of this landmark legislation.

410 Christmas Message. *December 23, 1971*

CHRISTMAS is a season of joy and of love, and also a time for reflection.

We think, in this season, of those who are closest to our hearts, even though they may be far away in miles. We pause to give special thought to those in need, and

to the universal bonds that link all mankind in brotherhood under God. In doing so, we touch something basic and good in the human spirit; that special grace that makes this a time of giving, and of forgiving—a time of goodwill,



Fax Transmittal

**Office of Cancer Communications
Office of the Associate Director**Building 31, Room 10A31
Bethesda, Maryland 20892301-496-6331
Fax 301-402-4945

Date 10/24/96
To Elizabeth Dye
Fax Number 202-456-7028
From John Buklow
Cover Sheet plus 4 Pages Transmitted

Message

Draft background
on the Cancer
Genome Project

DRAFT

NCI Fact Sheet: Cancer Genome Anatomy Project

Earlier this year, the National Cancer Institute issued its 1997-1998 budget proposal, "The Nation's Investment in Cancer Research." It presented five specific areas of research opportunity that could lead to major advances in the fight against cancer. One of these areas is developmental diagnostics, i.e., developing diagnostic tools to convert our growing knowledge of tumor cell biology into practical advances in patient care. After much planning, the NCI announces the creation of its first initiative in this area, the Cancer Genome Anatomy Project (CGAP).

BACKGROUND: The Promise of "Fingerprinting" Tumor Cells

Over the last 25 years, it has become clear that cancer is fundamentally a genetic disease. This discovery not only solves a longstanding biological question, it tells us that the human genome holds the key to improved cancer detection, diagnostics, and treatment. The challenge now is to record the patterns of gene expression within a cell at all stages of tumor development. By knowing which genes are turned on and off, it will be possible to create distinct genetic profiles of normal, precancerous, and malignant cells. These genetic profiles will tell us volumes about the nature and clinical outcomes of various cancers.

Many experts believe that by meeting this research challenge, the groundwork will be laid for medicine to embark on a new era in fighting cancer. No longer will most cancers be detected relatively late in their development or be classified imprecisely by their site of origin and

DRAFT

appearance under a microscope. Health professionals in the future will look inside of cells and collect its complete pattern of gene expression, or genetic fingerprint, much like a detective gathers fingerprints left at the scene of a crime. They will read the genetic fingerprint, looking for clues that tell them about the molecular nature of the tumor. These clues will indicate whether a tumor is likely to grow fast or slow and whether it will spread to other parts of the body, critical information that is not currently available to clinicians.

Cancer treatment, too, will be revolutionized. Whereas most treatments today are largely based on trial and error, health professionals will be able to target their treatments in each patient to the very genes and proteins that prompt cells to divide on their own. Based on the molecular profile of the tumor, health professionals will know whether the tumor will respond to treatment and decide on which therapies are likely to work in fighting the cancer.

Cancer Genome Anatomy Project: Overall Goals

To pursue this vision of the future, the NCI has developed a multi-faceted plan to advance developmental diagnostics. The first initiative in this area will be the Cancer Genome Anatomy Project (CGAP). Projected to begin in early 1997, the program's overall goals are to:

- Define the genetic differences between normal and cancer cells
- Define the impact of these differences on gene expression
- Define the protein pathways and networks within a cell that are affected by altered gene expression.

DRAFT

As NCI's first initiative in developmental diagnostics, the CGAP will build a framework for future work in this area. It will develop and implement technologies that monitor biological processes in the cell, establish appropriate clinical cell lines, train scientists interested in developmental diagnostics, and develop needed databases and analytical tools.

Cancer Genome Anatomy Project: Initial Programs

The first two initiative under the Cancer Genome Anatomy Project will be:

- Support the development of high-speed technologies that define the molecular characteristics of cancer. The initiative emphasizes the efficient detection of cancer-linked gene mutations, the development of genetic profiles in various tumor types, and the characterization of cancer-linked changes in protein pathways in the cell. The initiative will use a variety of mechanisms to ensure that researchers and clinicians alike have access to new diagnostic tools.
- Compile a list of all genes involved in the cancer process. Through the NIH's Frederick Cancer Research and Development Center, the NCI will establish a new program to coordinate the preparation of gene transcripts and the construction of needed cDNA libraries from normal and cancerous tissue. The NCI will make all of these resources widely available to researchers for sequencing and analysis. In addition, the NCI, in collaboration with the U.S. Department of Energy will support large-scale DNA sequencing to expedite the rate of gene discovery.

DRAFT

Although the initiative's main goals are to establish panels containing all genes expressed in tumor cells and to make them publicly available to researchers, it also will include three demonstration projects. These projects will characterize the patterns of gene expression in breast, prostate, and colon cancer.

#####

Jon - Shipley asked for
more with some ideas

Ernie

October 17, 1996

MEMO TO JON FOSTER, DAVID SHIPLEY, TIM NEWELL
FROM ERNIE MONIZ
RE: Possible S&T EVENT -- Human Genome Project

"Scientists and Engineers for Clinton-Gore" could help organize a newsworthy event that would tie in with next week's *Science* magazine's announcement of the first human "gene map" pinpointing the locations of 16,000 genes in human DNA. In addition, for the first time, this electronic gene map will be posted on the Internet, only a mouse click away for researchers, students, and families.

Appropriate sites in the following key battleground states would include high schools or universities linked to the Web, university hospitals, biomedical laboratories or companies. The best visual would be with young children clicking on the Web to pull up the electronic gene map on their computer screens.

Although 25 Federal departments and agencies fund R&D, 7 account for the vast majority of government R&D support. One-half of the Federal R&D spent in the United States is expended in six states -- California, New York, Michigan, Massachusetts, New Jersey and Pennsylvania. Add four more states -- Maryland, Texas, Illinois and Ohio -- and the proportion jumps to two-thirds of the national total.

Background

In the next century, "biomedical warfare" against new viruses such as AIDS, or old menaces such as tuberculosis, could supersede all other forms of combat. The ability to fight off major health threats will depend on our scientists' ability to supply our doctors with new "21st century medical bags." Scientists will increasingly help the medical community to select the most promising vaccines, drug treatments and new ways to fight disease. The intended result: doctors running up fewer blind alleys looking for cures. The opportunity at hand is to find real cures, enabling disease prevention instead of mere treatment of symptoms.

Previously, scientists have looked to nature for cures, but in the 21st century we will increasingly use high-performance computers to design drugs and vaccines. Using

supercomputing power to model drugs and their interactions with diseases, will enable scientists to better know what drugs to develop by predicting their ability to combat disease. The scientists have developed a database which provides a forum for scientists and doctors to exchange results and information.

Suggested theme

What the President could say...

"Now I'd like to tell you about some really exciting progress we're making in medicine. We have the best medical treatment in the world. But even here, most of what our fine doctors do is treat the symptoms of disease, they make us feel better. We have very little that actually cures disease or prevents it from occurring in the first place. It's time to move beyond aspirin and even antibiotics.

This is a very exciting time in biology because we are on the verge of entering a new era in medicine -- we can see what is possible on the horizon -- or, in the case of the Human Genome Project, what is on the computer monitor. Beginning tomorrow, a map of the human genome will be posted on the World Wide Web that will show the locations of 16,000 genes or about one-fifth of the entire set of human genes. The first rule of warfare is "know thine enemy." We need to understand disease at its most fundamental level in order to attack it efficiently. Having genetic information in hand gives us that critical intelligence so that we can mount an offensive attack, rather than having to play only defense.

This electronic gene map makes the information available not only to researchers who can put it to use, giving our doctors the medical weapons of the 21st century, but it also serves as a wonderful visual educational tool for our children. Every school that is wired into the Web will be able to call up the human genome map right in their classrooms. They will be able to click on a gene and learn everything that the scientists know about it, what its product does in the body, what disease might result if the gene is missing or defective, all in language that children from kindergarten through high school can understand. Then they can go home and explain it to their parents!"

Other Themes

-- Our nation has expended both human and financial resources to understand our universe and provide for our physical and economic security. It only seems fitting that the skills and knowledge developed for these endeavors be applied to understanding ourselves as well.

-- Let's give our doctors the tools for the 21st century. The human genome project will ultimately decipher the genetic information that is the basis of all life.

-- The human genome is the complete set of instructions for the development and function of the human body, and these instructions have a profound impact on how well and how long each individual will live.

-- The revolutionary understanding gained through this project will have profound effects on the quality of both medicine and our technological competitiveness, not in a century, but in our lifetime.

-- This project will generate huge quantities of data. To gain a perspective of the data-handling requirements, approximately one million pages of this size or a stack of pages 330 feet tall would be needed to simply print out the 3 billion base pairs comprising the human genome.

-- This scientific discovery and technological innovation will play central roles in increasing our productivity and economic growth. In the long run, it is the discovery of new ideas -- "better recipes," as distinct from merely more cooking in the traditional way with more of the same limited supply of ingredients -- that will reduce the cost to society because it's cheaper to prevent disease than just treat it. This is measurable in terms of dollars saved, and quality of life enhanced. Ultimately, these cost reductions will translate into some combinations of lower prices for consumers, higher wages for workers, and higher profits for investors. Over time these changes can lead to significant, cumulative increases in living standards.

-- This Administration has reoriented the Federal R&D effort from primarily defense-related investments toward investments in a broader set of national goals, including health, prosperity, environmental responsibility, and improved quality of life, in addition to national security.

#

#

Mary Beth 690-6133

Cancer — grants announcement —

— breast cancer —

— and cervical

Oct 2 — Breast Cancer Early
detection program Expansion

Went
through
Ann McGee

Grants went to
50 states, 102 million
Fed funding

Breast Cancer — proclamation

Communications Director.

Susan Dumenthal — women health centers.

Signed proc for 1

October 18, "Mammogram Awareness Day"

→ Reflect working

Ribbon of Hope — in Albuquerque now
breast cancer

Craig Gaudin

Clean house for all gov't agencies
Women's health info
Also on internet -
- news clippings -
- research -

Clean house - 1-800 number

- up in a week or two -
Susan Blumenthal

- [Nat Action Plan on Breast Cancer]

- public private

Susan Blumenthal Fran Visco

→ announce their web site. -

PORDS - signed breast cancer PDC -

no

~~Albuquerque~~ Albuquerque - Cancer

- Ellen Storel -

- balloon hat is called the ribbon

of hope

- Cancer survivors (their)

MAA

Mammography Event Oct 18 -

- National mammography awareness Day

- Something of substance w/ FDA -

- Melissa Scalfield -

Not in
Albuquerque
Late in

National Monography Day Oct-18

National Performance

Atlanta - Hammer award from ~~NPR~~ Review
to FDA Office in charge
of certifying mamography -

- Piedmont Center in Atlanta. -

= FDA's Office of Women's Health. -

~~Hammer Awards~~ -

NPR -

2 1/2 years - personally handled then out. first

600 issued over since March, 1993

- FDA Center certifying mamography shops. -

= VP has announced many (most of first year)

- No

(1-800-Sky Page)

Michael Messinger - Tuesday 632-1165

308-5861

Jerry Nikolaus 632-0391 - 8:00. -

- Vice President's Hammer Award -

teams of
Fed workers and
in some cases
state partners

- Linda Walker

Fax to 6-5709

6 pp

October 21, 1996

MEMO TO DAVID SHIPLEY

David, you'll recall last week we passed along some background information on human genome/internet/cancer for a possible event or mention in a speech. It's probably too late to get our oar in the water, but for what's it's worth, here's some information on a possible venue -- an internet conference in Philadelphia this week that expects 30,000 plus attendance.

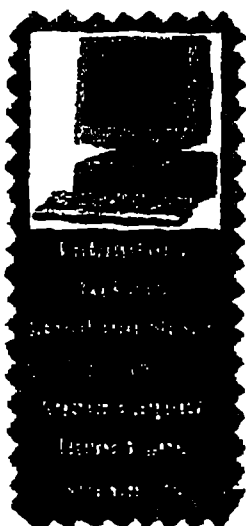

- Jeff Smith, OSTP
6-6047

cc:

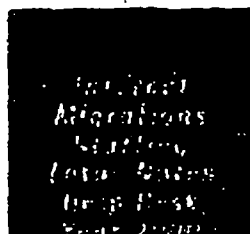
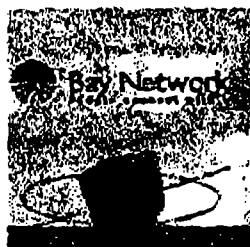
Elizabeth Dye - 67078 fax

1996 ITEC Internet Expo

Page 1 of 2



AMERISTAR
TECHNOLOGIES, INC.



BRINGING THE WORLD TO THE INTERNET

More than 28 regions are now participating in the Exposition, operating colorful online pavilions, and many more will open during the year. A central feature of this Exposition is that anyone, anywhere can open a pavilion -- and anyone, anywhere can visit all the fair has to offer. Visitors can explore the many international and theme pavilions or take a front seat at premiere online performances, for example:

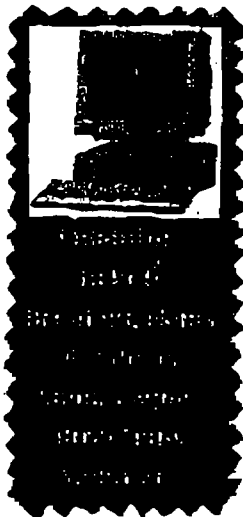
- **India Pavilion**
take in the Durga Puja Festival, Calcutta's most important religious observance
- **Lincoln Center/MIT Media Lab**
take your seat for the world premiere of "The Brain Opera" by composer/computer scientist Tod Machover
- **Global Schoolhouse**
roam this theme pavilion housing an Earthwatch Classroom, Creativity Cafe and a CyberFair for Schools
- **JFK Center for the Performing Arts**
check out the Young Artists Showcase
- **Reinventing Government Pavilion**
browse the Congressional Memory Project
- **Future of Media Pavilion**
visit the National Press Club or listen into Internet Talk Radio and World Radio Network

Post-It™ brand fax transmittal memo 7671		# of pages • 6
To <i>Enz Moril</i>	From <i>Gen Schuetz</i>	
Co. <i>OSTP</i>	Co. <i>AAES</i>	
Dept.	Phone <i>296-2237 x 207</i>	
Fax <i>456-6027</i>	Fax <i>296-1151</i>	

10/18/1996

1996 ITEC Internet Expo

Page 1 of 2



AMERISTAR
TECHNOLOGIES, INC.



When: Oct. 23-24 1996
Wednesday 10am - 6pm
Thursday 10am - 9pm

Where: Valley Forge Convention Center

Attendance: 31,000 (anticipated)
30,935 (1995 actual attendance)

Sponsors: Philadelphia Online
The Philadelphia Inquirer
Philadelphia Daily News
Eastern Technology Council
Ben Franklin Technology Center
Temple University Small Business Development Center
University City Science Center
West Chester University - CS/C & DB

Producer:

American Show Management,

A company with over 14 years' experience in producing shows.

The Internet World Expo comes to Philadelphia

Tens of thousands of visitors, from more than 50 countries have already flocked to the Internet 1996 World Exposition - a world's fair for the Information Age. The Exposition, which has opened its doors online at <http://park.org> - and the Internet Railroad, one of its key legacies, is coming to Philadelphia. On October 23-24, attendees at the ITEC Expo will have the opportunity to attend this virtual world exposition in a hands-on demonstration area. Modeled after historic world's fairs of the past, the Internet 1996 World Exposition will introduce people from all over the world to the marvels and potential uses of the Internet. In the tradition of past

OCT-18-96 FRI 18:05

AAES WASHINGTON, D.C.

FAX NO. 202 296 1151

P.03

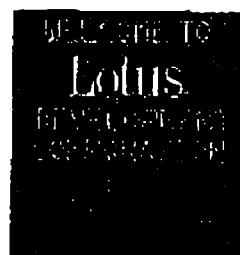
1996 ITEC Internet Expo

Page 2 of 2



world's fair legacies -- like the telephone and the Eiffel Tower, an important legacy from this year's fair will be the "Internet Railroad," a high-speed telecommunications backbone that will triple the Internet's global capacity. The Railroad will allow more people worldwide to access the Internet's resources with much faster connections.

The Philadelphia ITEC EXPO presents one of the largest, most exciting, action-packed high technology events to hit the Philadelphia area this year. Featured are the Internet World's fair; the Internet Lab and Theater sponsored by Voicenet; Microsoft's Windows NT Intranet Solutions Theater; New and Emerging Companies' Technology Pavilion, sponsored by Temple University SBDC; Medical Technology Area, sponsored by DVHIMSS and HFMA chapters and an Accounting Technology Pavilion, sponsored by IMA. Other distinguished sponsors are: The Eastern Technology Council, West Chester University-CS/C&DB, the Ben Franklin Technology Center, and the University City Science Center. In addition, for the first time in Philadelphia, ITEC EXPO is pleased to offer Electronic Commerce on the Web Seminar Series, featuring two tutorials and one general session on EC, Home Page Development and EDI Integration on the Web.



ASM Home	ASM Info	Advanta	ITEC Expos	TRE	etaCOM	Guesthook
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Philadelphia

Philadelphia ITEC Expo

October 23-24, 1996

10am - 5pm daily

Valley Forge Convention Center

Call 610-337-4000 for directions to the Center ... Click [here](#) for VIP passes!

In response to exhibitor requests, please note that no one under the age of 18 or student groups will be admitted to the ITEC Expo.

SHOW BACKGROUND

Returning for its fourth year, the Philadelphia ITEC Expo will feature over 200 top manufacturers and resellers, at both a local and national level. Each will be presenting their best solutions to today's technology issues. Don't miss this chance to see hundreds of solutions in one location!

ITEC EXPO SPONSORS

The Philadelphia ITEC Expo is sponsored by a number of companies and organizations, all of whom help build the event to meet the needs of all attendees. This year's key sponsors include:

Temple University Small Business Development Center, The Philadelphia Inquirer, Eastern Technology Council, West Chester University - CS/C & DB, Ben Franklin Technology Center, University City Science Center.

EXHIBITOR LIST

The first pass at our [exhibitor list](#) is now online! We're still finalizing many companies and booth locations, so check back here regularly for updates!

SEMINARS & CONFERENCES



The Philadelphia ITEC Expo will be presenting a tutorial/seminar series sponsored by the Electronic Commerce Resource Center. The series will focus on electronic commerce on the Web, as well as more generic EC/EDI issues. See all the information on the [ITEC/ECRC Tutorials & Seminars](#) page!

Check back here as the show date approaches for the final seminar schedule!

In addition to the ECRC conference series, the Philadelphia ITEC Expo will feature a wide range of seminars. At this point, probable topics include enterprise computing, networking, the Internet, intranets, data/telecommunications, Windows applications, multimedia, imaging & document management, and many others.

Philadelphia ITEC Expo

Page 2 of 3

TARGET AUDIENCE

Key decision makers from various industries, including:

- Manufacturing
- Banking and Financial
- Architecture
- Engineering
- Health Care
- Legal
- Education
- Government

PAVILIONS & FOCUS AREAS

The Philadelphia ITEC Expo will include a number of special features focused around particular technology areas. Some of the features at this year's event include:

- CIO Roundtable
- Microsoft Windows NT Intranet Solutions Theater - Sponsored by Microsoft
- Medical Focus Area - Sponsored by DVHMSS and HFMA
- Accounting Technology Pavilion - Sponsored by IMA
- CyberCafe - Sponsored by FASTNET
- VIP Lounge - Sponsored by SAP America, Inc.
- Multimedia Focus
- Internet "Test Drive" Lab
- Enterprise Computing/Client-Server Pavilion

INTERNET 1996 WORLD EXPOSITION AT ITEC

Each of the Fall 1996 ITEC shows has been selected as a destination site for the Internet 1996 World Exposition. The Philadelphia ITEC Expo has become a part of a global effort to educate users about the Information Superhighway. The show will be connected to other Exposition sites in Japan, the United Kingdom, and Berlin. Come and learn with ITEC and the Internet 1996 World Exposition!

ITEC EXPO PARTNERS

Philadelphia's program was developed by a distinguished Council of Advisors, under the leadership of Dr. Ken Geller. Dr. Keller has been with Drexel University since 1966, first as a professor of physics and then in a variety of administrative positions in research and technology development. As Assistant Vice President for Research and Technology Management, Dr. Geller has worked closely with government and industry, representing the university's interest in state-funded economic development programs like the Pennsylvania Ben Franklin Partnership (BFP) and the Delaware Valley Industrial Resource Center. As the University's manager of technology transfer, Dr. Geller was responsible for licensing university-owned technology for commercial development. Dr. Geller holds a PhD in nuclear physics from the University of Pennsylvania, with an undergraduate degree in physics from Brooklyn College.

The Philadelphia ITEC Expo also works with a number of local and national companies, associations, and non-profit organizations to insure that exhibitors and attendees have a successful event. We would like to thank the following for their assistance with this year's Expo:

Elizabeth -
F41 - this
is a cancer
center someone
recommended to
Doug for a POPS visit
This paper shouldn't
go to LCI b/c it
has "campaign"
written over it.

Let's Talk -
Debbie



Zima Graves and Field Inc.
123 Columbia Turnpike
Florham Park, NJ 07932
201/377-3300

POINTS TO SUPPORT A CLINTON CAMPAIGN VISITATION TO THE GARDEN STATE CANCER CENTER

The Garden State Cancer Center (GSCC), captures a driving theme of the Clinton campaign — building a bridge to the 21st century — and provides an excellent backdrop for President Clinton to address and expand on critical campaign issues.

1. GSCC is prime example of successful public-private partnership and fact it often "takes a village" to accomplish worthwhile things.

- Families can't cure cancer alone; it takes the collaborative effort of many:
 - \$10.5 million DOE start-up grant to help GSCC acquire new facility
 - Essex County \$2.4 million contribution of land
 - \$2.9 million from Essex County Improvement Authority bond offering.
 - Gifted scientists
 - Corporate and individual contributors
 - Collaborative partnerships with community hospitals
 - An additional \$41.9 million from various sources is needed to complete renovations to the GSCC.

2. GSCC is building a bridge to the future, echoing a powerful Democratic theme of hard work and hope

- Building on efforts of past researchers, invigorated by a young, gifted, scientific team and led by internationally renowned Dr. David Goldenberg, GSCC is working to close the gap between cancer research and cancer cure and deliver a future to our children free of some cancers and with hope for the cure of others.

- GSCC facility echoes same theme. With public-private funding, GSCC is renovating the 65-year old, former Essex County Isolation Hospital, once used to treat tuberculosis and smallpox patients, to meet healthcare needs of the future.

3. GSCC typifies Democratic vision of cost-conscious, humane, healthcare delivery system that supports entire family in time of crisis and is more equitable in accessibility.

- Nearly half of NJ cancer patients seek help outside the state at some time in their treatment. GSCC, as a regional cancer center, allows greater access to



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cutting edge cancer treatment while permitting patients and their families to stay at or closer to home during treatment. (Often only families with considerable resources can afford to travel to distant cancer centers, stay with loved ones during the course of treatment.)

4. Cancer — its pervasiveness, staggering costs and lagging investment in research — provides excellent entree to discuss Democratic healthcare agenda

- One in three women and one in two men will have cancer in their lifetimes — making visitation to GSCC easily understood platform for the President.
- Richard Nixon's so-called war on cancer is not won. Only one-tenth of one percent of each Federal dollar is spent on a disease that strikes 40% of Americans. (Hamilton Jordan op-ed piece in NYT.)
- Personal losses of both President and VP due to cancer and their pledges to fight this disease have already been interjected into the campaign.

5. NJ voters aware they suffer significantly higher cancer rate

- NJ ranks fourth (tied with Nevada) in cancer mortality rate. Selection of the GSCC as a campaign visitation site sends message to NJ voters that Clinton administration recognizes their concern.

6. GSCC location is in middle of a heavily populated, swing vote area

- Belleville is a middle-income, working class community within heavily blue collar Essex County. Opportunity to reach swing voters and, at same time, be shown a rousing welcome by VIP and party loyalists is certain.

Note: Belleville means beautiful or "pretty village," affording yet another opportunity to allude to the integral role of community in American life.

7. Connections

- Two-term NJ Democratic Governor, Brenda T. Byrne, is a friend of President Clinton, and served as governor while President Clinton was Governor of Arkansas. He is a member of the Garden State Cancer Center Foundation Board
- Tom Byrne, son of Brendan Byrne, is Chairman of the New Jersey State Democratic Committee.

NATIONAL
CANCER
INSTITUTE

Fax Transmittal

Office of Cancer Communications
Office of the Associate Director

Building 31, Room 10A31
Bethesda, Maryland 20892

301-496-6631
Fax 301-402-4945

Date 9/11/96To Elizabeth DyeFax Number 202-456-7028 7431From Dr. KlausnerCover Sheet plus 3 Pages Transmitted

Message

As discussed.NCI's statement.

A BRIDGE TO THE FUTURE OF CANCER TREATMENT

IMPACT OF CANCER ON SOCIETY

- More than any other disease, Americans fear cancer, a term that encompasses more than 100 different diseases. This year nearly 1.4 million people in the United States will be diagnosed with cancer, and more than 550,000 people will die of cancer--more than 1,500 people a day. One of every five deaths in the United States is from cancer.
- Twenty-five years ago, the United States declared war on cancer and enacted the National Cancer Act of 1971. It was clear then that cancer would not go away by itself, and that its terrible human toll could only get worse without a concerted national effort to control the disease.

IMPACT OF RESEARCH ON CANCER

- Since 1971, scientists have discovered the causes of many cancers and they have proven that cancer can be curable. Today, more than 10 million of our family members, friends, neighbors, and coworkers owe their lives to cancer research. And seven million of them are long-term survivors.
- Cancer survivors are alive today because 25 years of research in prevention, diagnosis, and treatment methods have given doctors better information and tools to deal with the diseases.
- America's youth have received the most benefit from this country's investment in cancer research. Scientists have been instrumental in developing better treatments. Thanks to the hard work and vision of these individuals, most cases of childhood leukemia are now curable. Death rates from children's cancers have declined by more than 62 percent. This was only a dream 25 years ago.
- Cancer research also made possible dramatic improvements in the survival rate of adults. The death rate for testicular cancer, for example, has declined 66 percent and now has a five-year survival rate of 95 percent. And Hodgkin's disease, which can strike young adults in the prime of their lives, was once one of the most feared cancers. Today, the majority of Hodgkin's disease patients can be successfully treated, and most of them are cured. The cancer death rates are falling for major cancers such as colon and rectum cancers, breast cancer, pancreas cancer, leukemia, stomach cancer, ovarian cancer, and cancer of the uterus.
- But most importantly for the future, research has identified the genes that make cancers grow, and the genes that prevent the growth of cancer cells. All of this new information provides a bridge to the 21st century.

LOOKING FORWARD TO THE 21ST CENTURY

Now, we begin to look forward to the 21st century, assured that the research of the 20th century is laying a solid foundation for our future. We can look forward to:

- **New technologies.** The National Cancer Institute is beginning a new initiative to allow us to finally know the nature of each cancer. If we know what a cancer is we can stop it before it starts. This initiative, called the Cancer Genome Anatomy Project, could lead to a new generation of diagnostic tools for all tumor types. It could lead to revolutionary approaches to early detection, accurate diagnosis, and appropriate choice of treatment for each type of cancer. If successful, this initiative could transform the practice of oncology and accelerate research on what causes cancer. The initiative will have two major thrusts. First, it will support the development of technologies that will enable high-speed analysis of genes and their products within any cell. Second, it will build a complete index of all genes that are expressed in tumors. This new initiative is possible because of the tremendous gains in knowledge of the past 25 years about why a cell divides or dies or becomes a cancer. By identifying every gene that contributes to cancer, and coupling this knowledge with the new technology, we will be able to determine the fingerprint of a tumor in just minutes. Through this initiative, the National Cancer Institute is building a bridge to the medicine of our future, a future that will let the doctor examine the tumor's fingerprint in much the same way that a detective studies the fingerprints and other evidence left at the scene of crime. Laboratory tests of the future will examine the fingerprint of the cancer, to see which genes, gene products, and interactions within the cell have led to the development of a cancer. With this knowledge, doctors will help patients select treatments designed to act against the character of a particular tumor. [Note: This initiative has not been announced outside of the scientific community.]
- **Better treatments.** The National Cancer Institute has undertaken two major initiatives to bring better cancer treatments to the people. The first, an Informatics Initiative, will create an information system that links the NCI, the Food and Drug Administration, pharmaceutical companies conducting new cancer treatment studies, all of the nation's cancer centers, and the thousands of hospitals and the nearly 10,000 doctors participating in cancer research into one information system. This Informatics system will speed up research by enhancing the consistency of study results across the country, provide instant access to the latest data, and support FDA's new drug approval process. This Informatics Initiative will also make information about the prevention, detection, and treatment of cancer available to all. It will link to computerized systems of NCI that describe in consumer-friendly language all cancer treatment studies under way, and provide detailed information for physicians on cancer studies as well as the latest standard treatment options for all cancers. The second, an Initiative to Develop Novel Drug Therapies, will capitalize on recent research advances to develop better treatments. Imagine a

virus that only grows in cancer cells. This virus would infect and kill tumor cells without harming normal cells. These and other creative potential cancer treatments have names like immunotoxins, antisense technologies, and oncolytic viruses. Science fiction? These approaches for the 21st century are already being studied in clinical research supported by the National Cancer Institute, and specifically target only a patient's cancer cells. This is in contrast to today's cancer treatments, which are like shotgun blasts, catching healthy cells in the crossfire. This fact accounts for the side effects of many cancer therapies. New drugs are already being tested in cancer patients. **[Note: Neither of these initiatives has been publicly announced. Both are known in the scientific community.]**

- **Greater Access To the Benefits of Research.** Cancer patients want access to the best, newest treatments available. As a result, the National Cancer Institute has established a model initiative that will give patients in managed care systems that kind of access. The initiative began with the Department of Defense, to refer military families into medical studies when that is the appropriate treatment choice for patients. Another agreement, with the Veterans Administration, will strengthen the information and treatment choices for patients who are veterans. The NCI will work to bring other private managed care systems under the initiative, and help bring the discoveries of medical research to all. **[Note: The DOD initiative was announced earlier this year, but received coverage only in the trade press. The VA agreement could be signed and announced in October.]**
- **Society Working Together.** The National Cancer Institute has spearheaded partnerships within all segments of our society to address the cancer problem and make the discoveries available to everyone. People from all sectors of society--teachers, businesses, government, scientists, doctors, nurses, patients, and advocacy organizations--will work together to confront issues like tobacco control, cancer care, government regulations that control environmental toxins, and many other societal issues. They will be brought together under a new initiative proposed and supported by the National Cancer Institute and carried out by the National Academy of Sciences. This initiative, known as the National Cancer Policy Board, will provide a forum where individuals from the diverse participants in the nation's cancer effort can debate policy and make recommendations for cancer policy affecting the nation. This Board will go beyond research and look at societal issues such as smoking control, and the conduct of cancer treatment studies in managed care settings. **[Note: This initiative has been announced in the scientific community, but not to the public.]**

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FACSIMILE COVER SHEET

Elizabeth - 222

To: Barbara Woolley

From: Martha Welsh

Date: 10-9-96

Fax Number: 202-456 6682

No. of pages (including cover page): 3

Comments: Please deliver immediately

Sender: msw Time: 2pm



October 9, 1996

TO: Barbara Woolley
FROM: Martha Bernard Welsh
SUBJECT: Photo Opportunity in Albuquerque relating to Breast Cancer Awareness
and Cancer Survivorship

As the President travels to Albuquerque this weekend for debate preparation, here is an opportunity for a dramatic photo you may want to consider. This could be the backdrop for an interest piece before the debate and even a health care/cancer prevention message.

In celebration of its 10th anniversary of service and support to the more than 10 million cancer survivors in the United States the National Coalition for Cancer Survivorship (NCCS) has commissioned a hot-air balloon named "The Ribbon of Hope" that is flying in the 25th Annual International Balloon Festival in Albuquerque through the weekend.

The balloon is flying the Ribbon of Hope - a yellow ribbon (the color of hope) signed by cancer survivors and those whose lives have been touched by cancer. It is to cancer survivors what the AIDS Quilt is to those affected by HIV and AIDS.

Approximately 10,000 people around the world have signed the Ribbon, including Mrs. Clinton and General H. Norman Schwarzkopf (see attached article).

Mrs. Dole is expected to sign the Ribbon on October 21 in New Jersey.

President Clinton is expected to sign the Ribbon before the election as part of the 25th Anniversary of the National Cancer Act.

Executive Director of the NCCS is **Ellen Stovall**, a 25 year cancer survivor, who also received a Presidential appointment to the National Cancer Advisory Board.

Please let me know if you need more information. I can be reached at 202-973-5850 or paged at 1-800-915-7232. Thank you very much.

Stretching a Ribbon of Hope Across America

by Anita Baumann

"There is no such thing as false hope."

"I hope everything turns out fine."

"Well, we can always hope."

"Hope does not equate with denial. True hope is based in reality."

As reflected in these statements overheard in conversations, general sessions, and proudly displayed on buttons, hope was in the air at the First National Congress on Cancer Survivorship. Hope is a cornerstone of cancer survivorship, and it is an attitude that NCCS fosters among our members and those we serve.

NCCS unveiled a vivid symbol of that important concept at the survivorship Congress: The Ribbon of Hope. The display—which is actually an arrangement of ribbons shaped like a radiant sun—symbolizes hope and new life. Cancer survivors and their supporters will affirm that message by signing the sunburst as it tours the nation.

That process got off to a strong start at the NCCS Congress as participants lined up to sign throughout the event. First Lady Hillary Rodham Clinton boosted the project with a signing at the White House attended by a delegation from NCCS. In so doing, Mrs. Clinton became the first person outside the NCCS Congress to sign the Ribbon of Hope.

The NCCS delegation included coalition President Betsy Clark, PhD; Deputy Executive Director Susan L. Scherr; Catherine Logan, executive director of People Living Through Cancer and an NCCS co-founder; Mary P. Lovato, director of A Gathering of Cancer Support; and Jack Sheahan, director of the Greater Washington Coalition for Cancer Survivorship.

During their 10-minute meeting with her, the delegation told Mrs. Clinton about the NCCS Congress and the coalition's work in the survivorship movement.

"Mrs. Clinton was very gracious," said Clark after the meeting. "She told us



First Lady Hillary Rodham Clinton met with NCCS delegation at the White House to sign the Ribbon of Hope. Here she inspects NCCS poster, "To Care." With her (l-r): NCCS President Betsy Clark, Deputy Director Susan Scherr and GWCCS President Jack Sheahan.

that the work we do is worthwhile and that she was personally glad that our group was there to help survivors. She mentioned that her mother-in-law had died of breast cancer and that she understood the need for groups like ours."

The "sunbeam" signed by the First Lady was later signed by Harold Freeman, MD, Chair of the President's Cancer Panel and director of surgery at Harlem Hospital; Richard Klausner, MD, director of the National Cancer Institute; the NCCS Board of Directors; and numerous Congress participants.

The Ribbon of Hope is the brainchild of artist John Feight, director of the Foundation for Hospital Art in Atlanta. Feight, who conducted last year's "Paint-In" at the ninth annual Assembly, created the display onsite at the Congress.

Throughout 1996, Feight will take the ribbon to hospitals around the nation, gathering cancer survivors' signatures at paint-ins and other special

events. In October, he will present it at NCCS' 10th anniversary celebration in Albuquerque, NM.

NCCS hopes to have the ribbon signed by people in every state, with the Congress ribbon representing the District of Columbia. A group in Canada has also expressed an interest in signing the ribbon.

After the Albuquerque meeting, the Ribbon of Hope will go on permanent display at a site to be determined.

"It will stand as a lasting legacy of hope to cancer survivors," says NCCS Executive Director Ellen Stovall. "It signifies that, even after the shock of a cancer diagnosis, a new rich life may be possible."

"The significance of the ribbon is compelling," says Clark. "The ribbon, as it travels throughout the country, and once it is fully formed, will call national attention to the survivorship movement in a highly visible, hope-filled way."

PODESTA

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MESSAGE

THIS TIME TREATMENT POSITIONS THE
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The Enemy Within

Though no "magic bullet" is at hand, cancer is gradually succumbing to a slow but steady dose of strategies

BY K. MADELEINE NASH

DEEP INSIDE DUSTIN FAGAN'S BRAIN, A COBWEBBY growth was spreading. Nothing, it seemed, could arrest the malignant tumor's terrible advance: not surgery, not radiation, not standard chemotherapy. So to save the nine-year-old's life, his doctors decided to kill him—nearly. They increased the dosage of an anticancer agent known as cyclophosphamide to levels that completely wiped out Dustin's bone marrow and thus destroyed his ability to generate new red and white blood cells. Then they revived their small patient by injecting him with healthy marrow that had been drawn in advance

MILESTONE: Cancer-free for almost four years, Dustin Fagan likes to play many sports



ANDREAS ALONSO FOR TIME

from his hipbone. The result: today Dustin is 12 and about to enter middle school in Pulaski, Virginia. For almost four years now, he has remained tumor-free.

Dustin's remarkable recovery—from medulloblastoma, one of the deadliest forms of childhood brain cancer—is more than a tribute to the skill of the cancer specialists, or oncologists, who treated him. It is also one of many small but significant mileposts that mark how far medical science has come in its fight against the cluster of diseases collectively known as cancer. The struggle has been long and hard and, unlike work in other medical fields, has produced few really dramatic breakthroughs. But patient by patient, tumor by tumor, doctors are beginning to gain ground. "We may not know how to cure most cancers yet," says Dr. Richard Klausner, director of the National Cancer Institute (NCI), "but we do know what we need to do to get there. And that's very exciting."

The cautious optimism that has begun to surface at major cancer-treatment centers is not grounded in any hard calculus. Despite some gains, cancer death rates remain unacceptably high (see chart), and the disease will kill 554,740 people in the U.S. this year. Rather, the optimism stems from an extraordinarily rich epoch of scientific discovery that has revealed the innermost secrets of malignant cells and suggested rational strategies for attacking them. "Until we

knew what was wrong with the cancer cell," says oncologist Dr. Bert Vogelstein of Johns Hopkins University, "we couldn't even think about ways of targeting treatment."

As doctors come to grips with cancer's complexity—and discard the dream of discovering a "magic bullet" capable of eradicating the disease forever—a succession of small, incremental improvements shows promise of pushing the death rate down. Already doctors have learned how to keep the disease at bay for months, and sometimes even to produce complete remissions that may last for years. "We're running a marathon, not a sprint," observes Dr. Eugenie Kleinerman, a pediatric oncologist at the M.D. Anderson Cancer Center in Houston. "What's important is not how fast we run the first two miles but when we cross the finish line."

Cancer, scientists now realize, is a genetic disease. It is caused by multiple mutations in the genes that control cell division, the process through which a cell makes a copy of itself by splitting in two. Some of these genes, known as oncogenes, stimulate cell division, while still others, called tumor-suppressor genes, damp it down. In their normal form, both types of genes work together, enabling the body to replace dead cells and repair damaged ones. But mutations in these genes—whether inherited or acquired through environmental insult—very quickly cause a cell to careen out

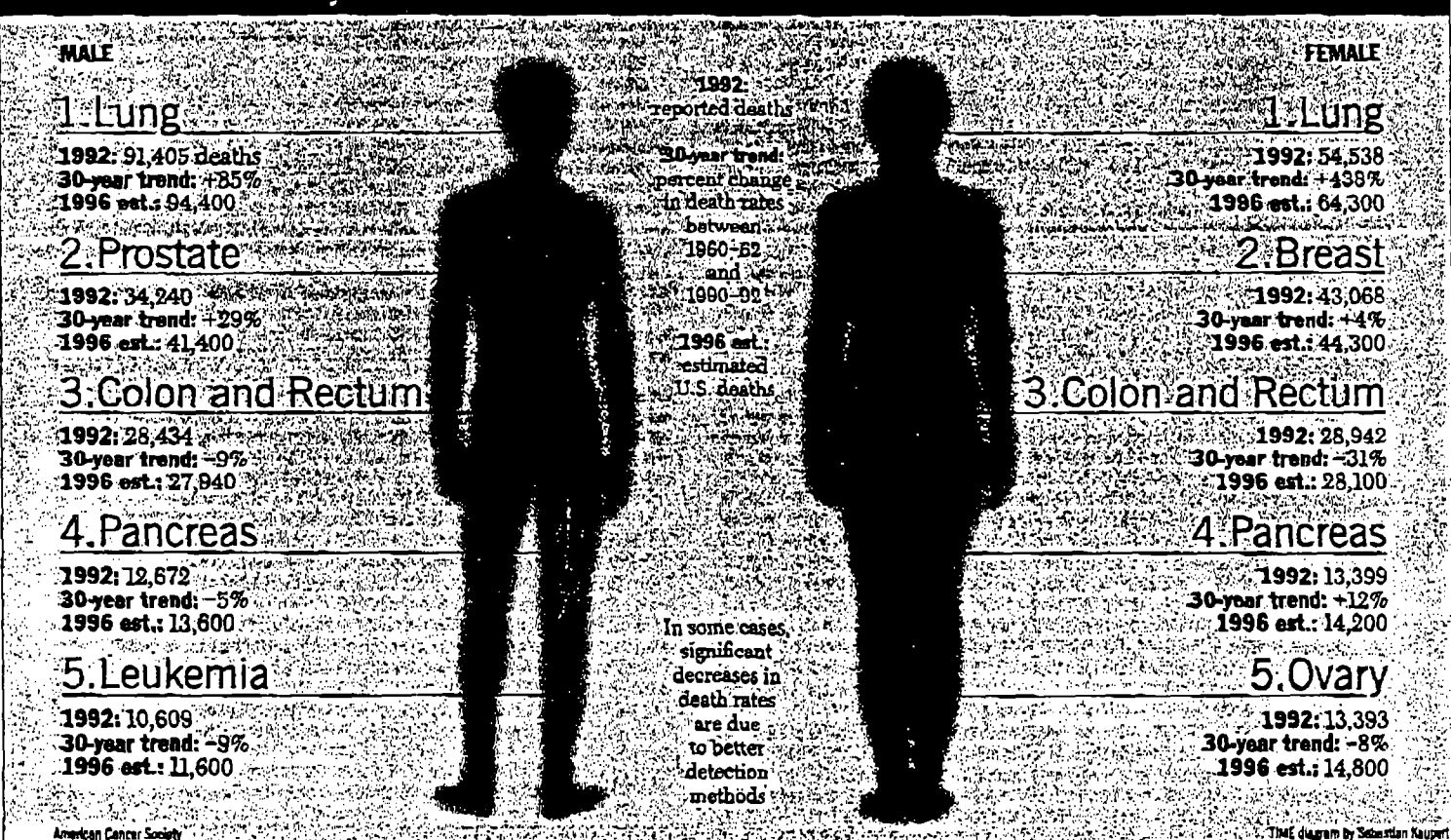
of control, like a car with a stuck accelerator pedal and no brakes.

In essence, cancer is an evolutionary drama played out in one part of the body or another—the lung, the breast, the brain. Over time, a single abnormal cell becomes two, then four, then eight, then 16. Early on, these cells develop a repertoire of "tricks" that confer a survival advantage. Among other things, the tricks ensure that mutation will pile on mutation by shucking off, or silencing, genes that ordinarily monitor replicating DNA for chemical errors. The malignant cells quickly become resistant to the poisons physicians prescribe to kill them. They also acquire the disturbing ability to stimulate the formation of nutrient-bearing blood vessels, thus spurring their own growth. Even if malignant cells grow rather slowly, they grow inexorably, eventually forming a deadly mass that invades surrounding tissue and spreads, or metastasizes, to far-flung locations.

Now the stunning laboratory insights into the biological basis of cancer that have accumulated over the past decade are heading into the clinic. Among the cutting-edge strategies that are giving physicians and patients alike reasons for hope:

Stopping the cell cycle. When a cell divides, normally or otherwise, it does so not all at once but in a series of carefully orchestrated steps. Each step provides oncologists with

America's Most Deadly Cancers



an opportunity to intervene in the process. In order to complete a successful division, for example, a cell must first faithfully copy its DNA. If a cell makes mistakes in this critical task, vigilant enzymes quickly call a halt to the process until repairs can be made. Sometimes, however, the DNA of a dividing cell is too badly damaged to be salvaged. At this point, these enzymes help activate a kamikaze circuit that compels the cell to commit suicide by destroying its own DNA.

Virtually all anticancer drugs interfere with cell division in some fashion. Cyclophosphamide, the compound that finally banished Dustin Fagan's cancer, belongs to a broad class of drugs that damage the DNA molecule by plastering it with sticky cross-links, thus triggering the suicide sequence. By contrast, the taxoids—including taxol, the compound isolated from the bark of the yew tree that was approved by the Food and Drug Administration as a weapon against ovarian cancer in 1992—cause the same suicidal result by deactivating a molecular machine that, just before cell division, separates the DNA in each chromosome into two separate strands. Still other drugs known as topoisomerase-1 inhibitors block a slightly earlier step in the DNA replication process, the uncoiling of the double-stranded DNA molecule.

Useful as they are, these drugs share the same serious drawback. Because they target all dividing cells, they also kill off normal tissue in the skin, hair and bone marrow. The next generation of anticancer agents, however, promises to be much more selective. By targeting oncogenes, for example, researchers hope to switch off the signals that prompt cancer cells to divide in the first place. Particularly promising is a class of drugs known as farnesyltransferase inhibitors, which have been shown to shrink tumors while sparing normal tissues. "Oncology is not a profession that inspires optimism," admits Dr. Allen Oliff, director of cancer research at Merck & Co. "But these days I'm almost Pollyannaish about finding safer, more effective cancer therapies."

Targeting toxins.

Not so long ago, doctors thought they had finally found that long-awaired magic bullet in the war against cancer. Their great hope bears the impressive name of monoclonal

antibodies, which are proteins that bind to—and attack—a particular target, usually another protein known as an antigen. But while natural antibodies go after antigens on the surface of viruses and bacteria, the artificial monoclonal antibodies are constructed to attack antigens that the immune system does not ordinarily recognize as dangerous, such as those displayed by tumor cells. Moreover, the antibodies (dubbed monoclonal because they are identical) can be made even more

deadly by loading them with radioactive iodine and other toxins. Infused into a patient's bloodstream by the millions, they become biological torpedoes that home in on clusters of malignant cells, blasting them with killer rays. Almost overnight, it seemed, cancer could become as curable as strep throat.

When that did not happen immediately, many clinicians gave up on monoclonal antibodies—prematurely, it turns out. "Monoclonal antibodies were always a fantastic idea," says Dr. Mark Kaminski, a University of Michigan oncologist. "But because we didn't see the results we had hoped for, enthusiasm waned. Now it's time to start believing again."

One source of the new hope is the experience of Patricia Haut, a former real estate broker from Auburn, Michigan. Eleven years ago, Haut, then 44, was found to have a slowly progressing but often fatal form of B-cell lymphoma, a disease that afflicts the very white blood cells that make antibodies in the first place. Like most patients, she initially responded to chemotherapy. But after each treatment, the cancer recurred. Then three years ago, as her remissions grew ominously shorter, Haut enrolled in an experimental trial of monoclonal-antibody therapy at

Michigan. Over the course of five weeks, she received four infusions of antibodies loaded with radioactive iodine. The result? The tumors in her groin, chest and abdomen disappeared, and to this day Haut remains cancer-free.

In a recently completed study, 19 out of 21 B-cell lymphoma patients treated at Michigan responded with partial to complete remissions.

Rousing the immune system. When viruses and bacteria invade the body, they are challenged by the white blood cells, which make up the body's immune system. Vaccines can strengthen the immune system so that it responds even more vigorously. So



ON TARGET: By using monoclonal antibodies to deliver toxins, Mark Kaminski has reported remarkable success in treating B-cell lymphoma

why can't physicians induce the immune system—through anticancer vaccines or other interventions—to attack tumors in the same fashion? "The problem," says Dr. Frank Hsu of Stanford University, "is that in attacking tumors, we're trying to kill cells that are derived from normal cells in our own bodies. That's just a lot harder than killing bacteria or a virus." But not, Hsu believes, impossible.

Early this year, a hint of progress came from a small clinical trial conducted by Hsu and his colleagues. First the researchers extracted specialized white blood cells—so-called dendritic cells—from patients with B-cell lymphoma. They "vaccinated" these cells by bathing them in an antigen found on the surface of tumors and then put the cells back into patients' bodies. The rationale for this elaborate procedure? Dendritic cells gobble up antigens and break them down into smaller fragments. Then, like bullfighters waving red flags, the cells display strips of antigen, inciting other white blood cells to attack and kill tissue bearing that particular biological marker. Of four patients treated

with dendritic-cell therapy by Hsu and his colleagues, two experienced complete remissions, while two others had their tumors substantially reduced in size.

Yet another strategy for jolting the immune system into action invokes the latent power of a different kind of white blood cell known as a macrophage. Both the lung and the liver, notes M.D. Anderson's Kleiner- man, are favored sites for the spread of cancer. As it turns out, these organs also contain large numbers of macrophages. But although macrophages sometimes attack tumors, they generally do so only after being alerted by a strong stimulus—a protein, say, that signals the presence of invading bacteria.

So Kleinerman and her colleagues took a bacterial protein and encapsulated it in fatty particles the size of red blood cells. They then injected these particles into children who had already been treated for bone cancer that had spread to their lungs. Out of a total of 16 patients, says Kleinerman, nearly a third have remained disease-free for the past three to six years. A much larger trial of this promising therapy is now under way.

Keeping tumors in check. Physicians have always focused on trying to eliminate cancer from the body. Many researchers, however, believe the time has come to add a strategy of containment. The idea, says Dr. Judah Folkman of Children's Hospital of Boston and Harvard Medical School, "is to treat cancer as a chronic disease." Of particular interest to Folkman and others are various compounds that stop or slow the process by which a tumor stimulates its own growth by creating its own blood supply. Indeed, until

that process, known as angiogenesis, takes place, a malignant growth may not even be particularly dangerous. It is the nourishing blood vessels formed through angiogenesis, researchers believe, that give cancer cells their scary ability to multiply and spread.

So far, scientists know of more than 20 compounds that block angiogenesis, and the results from animal tests are extremely encouraging. An immune-system stimulant called interleukin-12 has demonstrated an uncanny ability to make newly formed capillaries in mice melt away. Another anti-angiogenesis compound, angiostatin, discovered by Folkman's colleague Dr. Michael O'Reilly, makes colon, breast and prostate tumors shrink in mice. The rodents were given angiostatin for more than 50 days, the equivalent of five years for humans, and their tumors stayed small as long as they took the drug. At present, nine anti-angiogenesis compounds are being tested on human patients.

The hope, says Folkman, is that these compounds may be able to slow, or even halt, the growth of tiny cancerous clusters that are missed by radiation and conventional chemotherapy. If that happens, then the lives of patients, even those with widespread disease, might be significantly extended—particularly if more than one agent is used. For instance, the anti-angiogenesis compound TNP-470 appears to have much greater healing power when it is employed in combination with the agent that was used to treat Dustin Fagan, cy-

clophosphamide. In animal studies conducted at the Dana Farber Cancer Institute, each compound significantly slowed the growth of tumors. But when the two compounds were combined, they produced a complete cure in 42% of the mice.

For people with newly diagnosed cancer, this is one of the most exciting, and frustrating, times imaginable. Most patients today are stuck with standard treatment: surgery to remove the primary tumor, followed by radiation or chemo-

therapy to control metastasis. Yet here too progress is being made. A good example, says Dr. Edison Liu, the new chief of clinical science at NCI, is the adoption of higher-dose chemotherapy as the norm for breast-cancer treat-

ment. Doctors have switched not merely because new medicines that combat nausea, anemia and immune suppression have made the side effects more tolerable. They have also made the change because higher doses clearly help women whose tumors resist lower doses of the same drugs. Strikingly, the breast tumors of these patients showed high activity by an oncogene called ERBB2/neu, suggesting cancer genes themselves can be used as a clinical tool.

Currently, many women with metastatic breast cancer are opting to undergo a controversial procedure that bombards their bodies with extremely high doses of chemotherapy, then rescues them from certain death with a transplant of stem cells—the forebears of blood cells and platelets—gleaned from their own bone marrow or bloodstream. The trouble is, no one yet knows whether this expensive and risky procedure is worth the effort. While some patients—Dustin Fagan among them—appear to benefit from such aggressive treatments, others do not. The difference between patients who benefit and those who do not, many researchers now suspect, probably lies in the pattern of genetic mutation that characterizes their tumors.

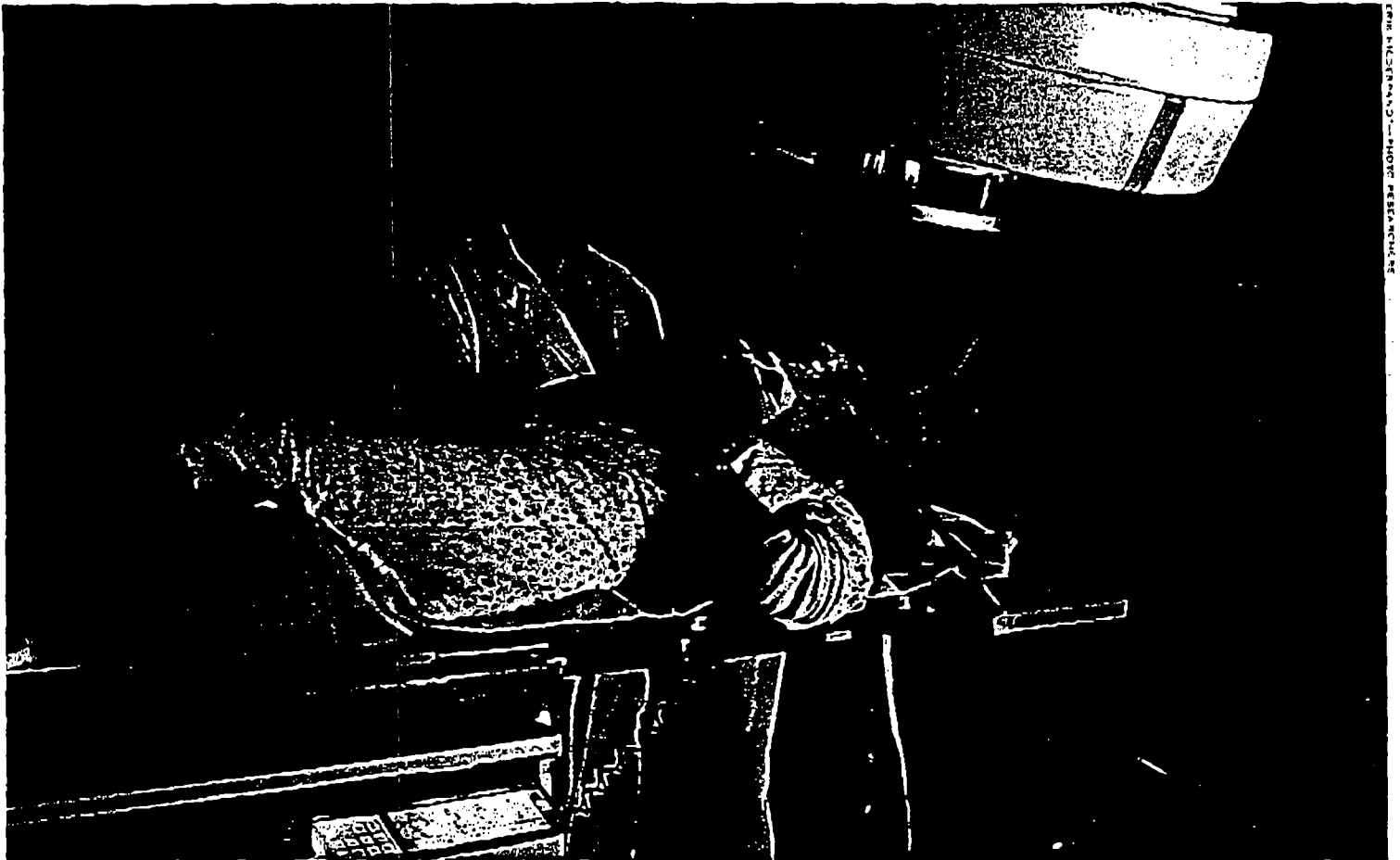
In the past, observes NCI director Klausner, physicians classified cancers by the organs they affected: brain cancer, breast cancer, liver cancer, prostate cancer. But these old-fashioned divisions are proving to be misleading. "Cancers should not be lumped together according to where they come from," declares Klausner, "but according to what they are." Because they are genetically unstable, many cancer cells end up jettisoning both copies of the tumor-suppressor gene p53. Still others contain mutant copies of this gene. The difference, it turns out, is highly important. Cells that have normal p53 genes tend to be exquisitely sensitive to chemotherapy, but those with mutant p53 genes are often extremely resistant.

This unexpected insight into p53's clinical role is already inspiring researchers to search out new therapies. Researchers at NCI, for example, are combing through a computer

Cancer is an evolutionary drama played out in the body's various parts



SICK GENES: In his lab at the National Institutes of Health, Richard Klausner searches for molecular clues to cancer, which occurs when the DNA inside the body's cells undergoes ominous change



AN OLD BUT TRUSTED THERAPY: As red lasers highlight the target areas on her body, a cancer patient prepares to undergo radiation treatment at an Albany, New York, medical center

database that contains the chemical profiles of some 350,000 potential anticancer compounds. To date they have identified 112 candidates that may work against cancers with mutant p53 genes.

At the same time, researchers in Vogelstein's lab at Johns Hopkins have come up with a blueprint for a "gene bomb" that selectively kills cells containing altered versions of p53. The bomb consists of a bacterial gene that converts a normally harmless substance into a toxic poison, but it is activated only by cells in which p53 has undergone significant mutation. In laboratory cultures, at least, the results look better than good. "It really is like a bomb," marvels Vogelstein. "It kills not only the cell in which it's activated but surrounding cells as well."

Will the gene bomb work similar magic for patients? Over the coming decade, many experimental anticancer agents that look so promising today will be discarded. Some will prove ineffective, others too toxic. But a select few will begin to make their way into clinical practice, not to substitute for conventional therapy, oncologists say, but to augment it. Every additional treatment, observes Duke University's Dr. Henry Friedman, the oncologist who treated Dustin Fagan, makes curing cancer more likely. By adding new therapeutic agents to the current mix, he observes, clinicians may be able to eliminate tiny clusters

of cancer cells that would otherwise later rebound to kill their patients. This year, for example, medical researchers are conducting a large clinical trial of a promising new vaccine against melanoma, the deadliest form of skin cancer. It will be judged not by its ability to shrink large tumors but by its success in prolonging survival among patients who have already received standard treatment.

What is the point of piling one treatment on top of another? Where cancer is concerned, as clinicians well know, one plus one often adds up to much more than two. Earlier this year, oncologists from the U.S. and Canada reported that adding chemotherapy to radiation significantly helped patients with advanced cancer of the nose and throat. Three years after treatment, an impressive 65% of patients who received the combination therapy were still alive, vs. only 24% of those who received radiation alone. Similarly, immune-system stimulants like the interferons and interleukins appear to increase their tumor-fighting power when used together. Twice as many patients with metastatic kidney cancer, a French team reported last May, experienced a notable

shrinkage of their tumors when interferon and interleukin were combined as when either agent was used alone.

In coming years, doctors hope to be able to combine therapeutic agents in increasingly effective ways. "There will never be a single cure for cancer," emphasizes the NCI's Klausner—and, in fact, many oncologists believe physicians should start focusing not just on curing cancer but also on ways of controlling it. Ideally, of course, doctors should not be treating cancer but dealing with the conditions that lead to it, such as premalignant polyps and lesions.

Even full-blown cancer no longer need look hopeless. If physicians can figure out ways of stopping a primary tumor from spreading, or of preventing small malignancies from growing large, they may yet work wonders. Cancer patients would still have a serious chronic disease but one that could be controlled—like diabetes, hypertension and atherosclerosis—for 10 years, 20 years, even longer. In the future, a diagnosis of cancer will still invoke dread. But if Klausner and others are on the right track, it will seem less and less like an automatic death sentence. —With reporting by Hannah Bloch/Washington

Doctors have kept the disease at bay for months and even produced remissions

Even full-blown cancer no longer need look hopeless. If physicians can figure out ways of stopping a primary tumor from spreading, or of preventing small malignancies from growing large, they may yet work wonders. Cancer patients would still have a serious chronic disease but one that could be controlled—like diabetes, hypertension and atherosclerosis—for 10 years, 20 years, even longer. In the future, a diagnosis of cancer will still invoke dread. But if Klausner and others are on the right track, it will seem less and less like an automatic death sentence. —With reporting by Hannah Bloch/Washington

October 11, 1996

Note to Elizabeth Drye:

Re: Your Request

We think that it would be great to do a Presidential event around the 25th Anniversary of Cancer Research. Our suggestion would be to focus on breast cancer, as October is Breast Cancer Awareness month. And since the President's Proclamation on Breast Cancer Awareness Month received little attention, this would be a second opportunity to get some good press.

If you are interested in highlighting breast cancer, it would make sense to schedule an event around National Mammography Day, October 18. One potential news hook of which we are aware is the presentation of the Vice President's Hammer Award to the FDA's Atlanta field office. The FDA office was nominated for the Hammer award for its workshop series which trained mammography personnel around the country on the new National Mammography Quality Standards Act (MQSA) (see attached). This Hammer award signifies what the agency is doing to fight breast cancer through early detection by ensuring that more women obtain mammograms in high quality facilities.

We would be happy to expand further on this idea and help you coordinate this or any other related event. Please let us know if you need any additional information.

Thank you.

Mary Beth Donohue



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

To: Amy Busch
From: Audrey Sheppard *A.S.*
Re: Hammer Award
Date: September 27, 1996

Food and Drug Administration
Rockville MD 20857

In 1995, FDA's Office of Women's Health funded Public Affairs Specialists in FDA's Atlanta office to design and administer five workshops around the country (in conjunction with field offices in the host cities) to familiarize mammography personnel such as radiologists and technologists with what the new mammography quality law would mean to them. This workshop series was nominated for a Hammer award, and apparently October 17 in Atlanta, the award is to be presented.

Our Office of Regulatory Affairs (ORA), which oversees the field staff, has been talking to the National Performance Review staff about the event, and who might make the presentation. As mentioned, the "rumor" of two days ago was that Mrs. Clinton will do so.

The date of October 17 was selected by FDA to coincide with Breast Cancer Awareness month and Mammography Day, and I believe this agency is hoping a high-ranking individual will be present at this event.

Please let me know if you need additional information.

*could be
Oct. 23rd
NPR - will be
making award
FLORES
↓
15 min.
Sharon Kopelman.*

Hammer Award Strategy

Background



The Hammer Award is Vice President Al Gore's special recognition to teams (not individuals) who have made significant contributions in support of the President's National Performance Review (NPR) principles. *Those principles are: putting customers first, cutting red tape, empowering employees and getting back to basics.* The Hammer Award is the Vice President's answer to yesterday's government's \$400.00 hammer. Fittingly, the award consists of a \$6.00 hammer, a little ribbon, and a card from Vice President Gore, all in an aluminum frame. The award recognizes new standards of excellence achieved by teams helping to reinvent government. Almost 600 Hammer Awards have been presented to teams comprised of federal employees, state and local employees, and citizens who are working to build a better government.

Nominations

The Vice President is always looking to celebrate the accomplishments of teams demonstrating extraordinary effort towards implementing the goals of the NPR. Accordingly, there is no limited, annual window of opportunity for nominations. Nominations are encouraged and accepted throughout the year.

Nominations originate from numerous sources. Departments and Agencies submit nominations to the NPR through their agency liaison, based on their own award and review processes. Federal Executive Boards/Federal Executive Associations nominate teams directly to NPR. State and local governments, private enterprises and other organizations nominate federal agencies with whom they are in partnership. Nominations submitted to the NPR must be shared with the nominated team's agency NPR liaison. Where this hasn't been done by the time the NPR receives it, the NPR will send a copy of the nomination to the NPR liaison.

The internal procedures used by the Departments and the FEB/FEA's vary with the policies and practices developed by each. Some Departments issue nation-wide requests for nominations which are then reviewed by the agency liaison and others at the Departmental level. FEB/FEA's have integrated nominations for Hammer Awards with their locally established, annual award programs, including Public Service Recognition Week awards. While each organization structures the nomination and review process as it deems fit, the final approval of all Hammer Awards is made by NPR staff.

Hammer Award ceremonies are organized by the nominating organization. At these ceremonies, the *team, not individuals*, receives the Hammer Award plaque. Individual team members receive a certificate signed by the Vice President and a Hammer lapel pin. The NPR provides the plaque, certificates and lapel pins.

For more information, contact: Jerry Nikolaus, (202) 632-0391, or Denise Clyburn, (202) 632-0181.



National Performance Review
750 Seventeenth Street N.W.
Washington, D.C. 20006
voice 202.632.0150
fax 202.632.0390

FAX COVER SHEET

To: Elizabeth Dye

Telephone Number: _____ Fax Number: 456-7028

From: Michael S. Messinger

Direct Telephone Number or ext.: 632-1165

Date: 10/11 Number of Pages Plus Cover Sheet: 3

Special Message or Comments:

Hope this is of help —
let me know what you need
from us —
Regards — Michael



VICE PRESIDENT GORE'S NATIONAL PERFORMANCE REVIEW

HAMMER AWARD NOMINATION

We are looking for teams of employees who have made extraordinary progress in reinventing government. Submit your nomination to your National Performance Review Agency Liaison, or local Federal Executive Board or Federal Executive Association. They will initially screen nominations and forward those that they recommend for Hammer Awards to the National Performance Review for final approval. They will notify you of the results. If you have questions, please call your Agency Liaison, FEB or FEA.

Name of Office/Group/Team: _____

Government Agency/Department: _____

Address: _____

Team Leader or Manager's Name: _____

Telephone Number: _____ Fax Number: _____

What process, function, or service has been reinvented? : _____

How has this group cut red tape or empowered employees to improve service to your customers? Are there tangible benefits to your customers and/or the government? _____

What has this group done that makes them truly outstanding? We are looking for those federal employees who have done extraordinary things to help build a government that costs less and works better. Please add any additional comments which you feel will support this nomination.

Please provide a short, plain English narrative that would tell any taxpayer why your reinvention is a success.

Name of person submitting this nomination: _____

Signature of that person: _____

Title of that person: _____

Telephone number: _____ Fax number: _____

Name of Agency/Department submitting this nomination: _____

Office Symbol: _____ Date _____

To facilitate the issuance of a news release should this nomination be approved, please prepare and attach a concise summary of the activity named in this nomination. The narrative should be less than one page in length and written in easily understood, layman's terms.

BREAST CANCER.



The President's Cancer Panel Special Commission on Breast Cancer

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute



BREAST CANCER:

A NATIONAL STRATEGY



A REPORT TO THE NATION

**The President's Cancer Panel
Special Commission on Breast Cancer**

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

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EXECUTIVE SUMMARY

Overview

Breast cancer is a large and growing public health problem in the United States. During the decade of the 1990s, it is estimated that nearly 2 million women will have been diagnosed with the disease and that 460,000 women will have died of it. Between 1950 and 1989, the incidence of breast cancer increased by 53 percent. The magnitude of this problem and its constant increase over time understandably result in considerable anxiety among all women.

Some improvements in breast cancer detection and treatment have occurred over the past few decades. Yet even these modest improvements are not uniformly applied throughout the population. Most current therapies (surgery, radiation therapy, and chemotherapy) are non-specific in their effects and frequently diminish quality of life. Although women diagnosed with early-stage breast cancer have a 5-year survival rate of 93 percent, there is no period of time after which a woman who has been treated for breast cancer can be assured that it will not recur. At this time, there are no proven methods of preventing breast cancer.

Advances in basic science have raised the realistic hope that more specific methods can be developed to treat or prevent breast cancer.

Breast cancer advocates – women with breast cancer, their families, friends, and supporters – demand that breast cancer become a national priority. There is a widespread sense of urgency that more can and must be done to address the problem of breast cancer in this country. There is growing public demand for even greater levels of funding of a national breast cancer program and an outcry for the development of cure and prevention.

Recommendations

The goals of the President's Cancer Panel Special Commission on Breast Cancer recommended breast cancer program are:

1. To make substantial progress in developing effective methods to cure and to prevent breast cancer, and
2. To make current and future proven methods of early detection, treatment, and prevention universally available.

The National Institutes of Health and other involved federal agencies must receive research funding of no less than \$500 million per year for this program until these goals are achieved.

Specific recommendations made by the commission are outlined below.

Causes and Prevention

- Research into breast cancer causes and prevention must receive high priority.
- Investigator-initiated inquiry should remain the mainstay of research funding.
- Genetic, hormonal, environmental, dietary, and other causes of breast cancer must be identified through basic and epidemiologic research; this knowledge is the foundation needed to develop effective preventive strategies.
- Knowledge gained through research must be translated into clinically effective methods of prevention, early detection, and treatment.

Earlier Detection and Diagnosis

- Early detection should be improved by further refining x-ray mammography, developing newer imaging methods using non-ionizing radiation, and identifying breast cancer biomarkers that can be detected in a blood test.
- Improved access to early detection must include prompt diagnostic work-up and treatment referral for patients in whom breast abnormalities are identified.

Treatment Strategies

- Women must be empowered to be active participants in their decisions about breast cancer screening and, if diagnosed with the disease, about their treatment options.
- Patients, their families, and breast cancer experts want and deserve less invasive, disfiguring, and toxic treatments than surgery, radiation, and chemotherapy.
- High priorities for new and more specific treatments include: therapy directed at hormones and hormone receptors, tumor growth factors or growth factor receptors; inhibitors of angiogenesis and metastasis; immunologic therapy; and gene therapy.
- Methods should be developed to overcome resistance to hormonal and chemotherapeutic agents.
- Diagnostic decisions, treatment options, and recommendations should be provided in an interdisciplinary setting.

Psychosocial Effects

- Current methods of psychosocial support should be available to all breast cancer patients and their families.
- More effective supportive care interventions for breast cancer patients and their families must be developed.

Access

- Current and future methods of early detection, treatment, and prevention should be universally available as soon as their efficacy is demonstrated.
- United States health care delivery system reforms must ensure the removal of financial barriers to access.

- Research is required to understand and remove the non-financial barriers to universal use of effective means of combating breast cancer.

Public Policy

- Federal regulations should limit the proliferation and use of unproven treatments, prognostic markers, prevention methods, and technologies, except within the confines of a well-defined clinical trial.
- Clinical testing of new detection, treatment, and prevention methods should be supported cooperatively by third-party payors, industry, academic centers, and the National Cancer Institute.
- Research costs for clinical trials should be carefully delineated and paid by industry or the National Cancer Institute, while patient care costs should be covered by third-party payors.
- The 1992 Mammography Quality Standards Act should be implemented immediately.
- Federal agencies should coordinate their breast cancer programs through an interagency breast cancer task force.

A Partnership of Breast Cancer Advocates and Breast Cancer Scientists

- This partnership must continue in a way that promotes the shared objective of finding effective prevention and cure of breast cancer.
- Breast cancer advocates should be integrated into decision-making regarding the optimal use of breast cancer research funding.

Information and Empowerment

- Women in the United States should be provided with accurate, up-to-date, and culturally sensitive information about the risks of breast cancer and how it is best detected.
- Women diagnosed with breast cancer should be provided with accurate, up-to-date, and culturally sensitive information about their treatment options.
- The National Cancer Institute should provide leadership in the development and distribution of culturally sensitive breast cancer educational materials and special materials for women with low levels of literacy.
- Women should be empowered both psychologically and financially to take responsibility for their own breast health, including adopting healthy lifestyles, practicing breast self-examination, following recommended guidelines for breast cancer screening, and immediately obtaining diagnostic and treatment services when breast abnormalities are observed.

Past investments in basic science and breast cancer research have brought us to a point where numerous opportunities exist to advance our ability to prevent and treat breast cancer. The enormity of the impact of breast cancer on the mental and physical well-being of women in the United States and their families requires that we as a society devote the resources needed to achieve the most rapid progress possible.

INTRODUCTION

Over the last decade, patients and their families have directed increasing national attention to breast cancer. Their input has stimulated breast cancer research, focusing on the need for prevention and cure. During the 1970s and 1980s, breast cancer incidence rose by 21 percent among women of all ages in the United States, and increased by 49 percent among women 65 and older. Even among women least likely to experience breast cancer—those under 50—incidence rose by 13 percent. National Cancer Institute funding for breast cancer has increased from \$92.7 million in 1991 to \$196.6 million in 1993. In addition, Congress appropriated \$210 million to the Department of Defense in Fiscal Year 1993 for a multi-year breast cancer research program. There is wide public demand for even greater levels of funding of a national breast cancer program and an outcry for effective prevention and cure.

In response to a request from the Vice President of the United States to the Chairman of the President's Cancer Panel, the President's Cancer Panel Special Commission on Breast Cancer was appointed by the Director of the National Cancer Institute in 1992. Its 19 members held 11 meetings over 14 months, hearing testimony from more than 190 scientists, clinicians, patient advocates, and experts in all aspects of breast cancer. This report contains the findings and recommendations of the Commission based on this comprehensive review.

Breast cancer is a large and growing public health problem in the United States. All women are at considerable risk for developing breast cancer during

most of their lives. It is estimated that during the 1990s nearly 2 million women in the United States will be diagnosed with the disease and that 460,000 women will die of it. Between 1950 and 1989, the incidence of breast cancer increased by 53 percent. Expanded use of screening mammography explains part of the recent rise in incidence, but the causes of the long-term increase are largely not known. The increasing magnitude of this problem has understandably resulted in considerable anxiety in the population, particularly among young women and especially regarding future generations of females.

Specific points about breast cancer should be recognized. The incidence of breast cancer rises continuously as women age: At age 30-34, the rate is 27 per 100,000; at 40-44, it is 127 per 100,000; at 50-54, it is 222 per 100,000; at 60-64, it is 343 per 100,000; and at 70-74, it is 434 per 100,000 women. Also, the natural history of the disease is prolonged. The time from the inception of breast cancer to its detection using current methods is estimated to be at least several years. The time following initial diagnosis and treatment to the development of recurrence and death is measured in years. Furthermore, there is no time period beyond which recurrence and death may not occur. If a cure is defined as elimination of any chance of recurrence and metastases, it is not correct at present to describe a "cure" of the disease. Nevertheless, most patients diagnosed with breast cancer live out the remainder of their lives without recurrence. As reported by the National Cancer Institute's Surveillance, Epidemiology, and End Results program, women diagnosed with early-stage

breast cancer have a 5-year survival rate of 93 percent, in contrast to 70 percent and 17 percent for those diagnosed with regional and distant metastases, respectively. Finally, the clinical course of breast cancer varies greatly among patients, suggesting that there is heterogeneity in the factors that affect both the occurrence and the natural history of the disease.

Breast cancer is now believed to result from a series of alterations (mutations) in the genes of the breast cells. Some such genetic changes may be inherited, but most are not. These alterations can result in an increased likelihood of additional genetic changes (genomic instability), uncontrolled cell growth (proliferation), invasion into adjacent tissues, and spread to other sites in the body (metastases). The causes of these genetic alterations are largely unknown. Ovarian hormones (estrogen and progesterone) clearly play an important role in the development of breast cancer. It appears likely that influences beginning very early in life and continuing throughout adulthood are important. At this time, there are no proven methods of preventing breast cancer.

Some improvements in breast cancer diagnosis and treatment have occurred over the past few decades. A major advance has been achieved through screening with mammography and clinical breast examination. Screening mammography can detect many cancers before they are clinically evident and can lead to a breast cancer mortality reduction of about 25 percent. However, the mortality benefit from mammography has been unequivocally demonstrated only in women aged 50–69. Possibly due to limitations in study design and implementation, the data for women aged 40–49 are inconclusive, and there is a paucity of information regarding the

effectiveness of screening women aged 70 and older, despite their high risk.

Breast-conserving treatment (consisting of excision of the cancer—commonly referred to as “lumpectomy” combined with breast irradiation) results in survival rates equivalent to those following mastectomy and provides important quality-of-life gains for many patients. In addition, new surgical techniques facilitate breast reconstruction in patients treated with mastectomy. Drug treatment, such as chemotherapy and Tamoxifen, given at the time of local therapy can decrease breast cancer mortality. While these improvements are important, the survival benefit of about 26 percent is relatively modest given the magnitude of the problem, and is achieved at a substantial cost in toxicity. Most current therapies (surgery, radiation therapy, and chemotherapy) are toxic to normal tissues and organs and thus frequently impact negatively on quality-of-life. Moreover, although the last decade has brought refinements in the available treatment modalities, no major treatment advances have been introduced, and the mortality rate has remained constant.

Even these modest improvements are not uniformly provided for all women. For many women, optimal early detection, diagnosis, and treatment measures are unavailable for financial reasons—they are unable to pay and have inadequate or no health insurance. These women represent a large and growing percentage of the population. Access is a particular problem for women who are low-income, minority, young, old, and living in rural areas. The inequities of this situation have become painfully manifest. Even well-insured women with adequate resources often do not receive the best of care, indicating the presence of significant non-financial barriers to optimal health services delivery.

The past decade has seen a major increase in understanding of the basic biological processes underlying both normal cell division and growth and the biology and genetics of cancer. This knowledge is beginning to be applied to breast cancer. Many excellent investigators have been supported in a broad spectrum of breast cancer research by the National Cancer Institute, the American Cancer Society, and other federal agencies and private organizations. This and other basic biomedical and cancer research have increased our understanding of many aspects of breast cancer and led to some promising new approaches for patients. However, more detailed information is needed about the biology and action of hormones on the normal breast, the genetic changes that lead to breast cancer, biologic factors that cause these genetic changes, and the means by which breast cancer cells grow and spread. It is reasonable to hope that this information will lead to new, more specific methods of earlier detection and diagnosis, treatment, and prevention.

In Fiscal Year 1993, the Department of Defense received an appropriation of

\$210 million to spend over 2 years on a breast cancer research program. The Commission notes the effort being made by the Army to ensure that this money is well spent, including an Institute of Medicine study commissioned by the Department of Defense to recommend funding priorities. The Institute of Medicine advised that most of the money be spent on investigator-initiated research projects, with some funds allocated to training, recruitment, and infrastructure enhancement.

There is a widespread sense of urgency that more can and should be done to address the problem of breast cancer in this country. This report provides our findings and recommendations. The Commission concludes that more and sustained resources are required to address breast cancer problems effectively. Specific areas and approaches that we believe are most likely to result in meaningful progress are emphasized. Our recommendation for support of breast cancer research at a level of no less than \$500 million per year is congruent with the funding level recommended in the Fiscal Year 1995 NCI bypass budget.

BREAST CANCER ETIOLOGY AND PREVENTION

Findings

- The ultimate goal of breast cancer research is prevention. To develop effective prevention strategies, basic and epidemiologic research must first identify risk factors that can be modified. Prevention studies can then determine the most useful approaches to reducing breast cancer risk by modifying such factors. Prevention trials can evaluate the relative effectiveness of modifying several risk factors and determine the impact of changing single risk factors.
- Today, the most promising areas of research for understanding breast cancer causes and developing optimal prevention methods include: genetics, hormones, diet, physical activity, environmental risk factors, premalignant and tumor markers, and, for secondary prevention, understanding the metastatic process.

Genetics and Tumor Markers

- There is both molecular and epidemiologic evidence that genetic changes are involved in the development of breast cancer, as has been observed for all cancers. Mutations in normal genes, loss of tumor suppressor genes, and altered expression of cellular proto-oncogenes may all be involved in converting a normal breast cell to a malignant one. Additional genetic changes altering expression of proteins on the tumor cell surface can increase or decrease tumor aggressiveness or metastasis. Knowledge of these genes and the proteins they encode potentially may be used to facilitate early detection and diagnosis and to identify high-risk women for prevention trials.

Hormones

- Being a woman is the major risk factor for breast cancer. Women develop breast cancer not only because they have breasts, but also because they have ovaries. Sex hormones, particularly the steroids made by the ovaries, have a central role in breast cancer. They increase the circulating level of two key ovarian hormones—estradiol and progesterone—and modify the levels of other hormones and locally acting growth factors. These changes alter the hormonal environment in the breast, increasing breast cancer risk.
- Other proxy indicators of hormonal activity support the concept that an altered hormonal environment is a major influence on breast cancer risk. Early age at menarche, late age at menopause, obesity in postmenopausal women, nulliparity, and older age at first full-term pregnancy are each associated with increases in risk.
- The effects of steroid hormone contraceptives and hormone replacement therapy have been studied extensively, but the findings have not been totally consistent. However, with each of these hormonal treatments, some elevation in breast cancer risks are noted for specific subgroups of women or in relation to particular characteristics of the hormonal regimen.

Diet

- Five-fold international differences in breast cancer incidence rates and major changes in rates among migrating populations indicate that non-heritable factors play a major role in disease development. Correlations between dietary factors and

breast cancer incidence rates internationally, as well as animal studies, suggest that nutritional factors strongly influence development of breast cancer. At this time, no dietary change has been proven to reduce breast cancer risk in humans.

□ Alcohol: A modest positive association between alcohol consumption and breast cancer risk has been shown in many case-control and cohort studies.

□ Vitamin A and precursors (carotenoids): Animal studies show reduced mammary carcinogenesis from high doses of vitamin A and related synthetic compounds; human case-control and cohort studies suggest a modest protective effect of pre-formed vitamin A and carotenoids.

□ Total energy intake: In animal models, restricting total energy intake profoundly and consistently reduces mammary carcinogenesis. Human epidemiologic data are consistent with an important effect of childhood and adolescent energy balance (caloric intake and energy expenditure) as rates of breast cancer are associated with height.

□ Plant constituents: In several studies, women with higher vegetable intake experienced lower rates of breast cancer. Epidemiologic evidence does not generally support a major role for dietary fiber in breast cancer prevention, although this was suggested in some laboratory studies.

□ Dietary fat: In some animal models, high-fat diets increase mammary tumors; polyunsaturated fats appear to have the strongest influence. Some human case-control studies show an association between fat intake and breast cancer risk, but little or no association has been shown in all recent, large, prospective studies, which are less subject to

methodologic biases. Protective effects of very low fat intake or alterations in dietary fat early in life cannot be excluded by available data.

□ Vitamin D: Women in latitudes with low sunlight exposure, and presumably lower vitamin D levels, appear to have higher breast cancer incidence rates, but more direct evidence for a protective effect of vitamin D is lacking.

□ Little is known about the influence of dietary factors on breast cancer prognosis.

Physical Activity

- A few studies have suggested that breast cancer risk is lower among female athletes and among women who have engaged in moderate physical activity.

Environment

- There have been few studies of environmental or occupational exposures as etiologic agents for breast cancer. Most conducted to date were severely flawed methodologically or based on small samples. Research on the effects of exposures to environmental and occupational agents must include assessment of known breast cancer risk factors.
- For none of the 30 known human chemical carcinogens is the human breast the primary site for the initiation of cancer. Exposure to high doses of ionizing radiation, such as that experienced by female atomic bomb survivors in Japan and women who had multiple fluoroscopic examinations for tuberculosis, is known to increase the risk of female breast cancer. Whether non-ionizing radiation from electromagnetic fields increases breast cancer risk is currently being studied.

Recommendations

Etiology

Genetics and Tumor Markers

- Evaluate the role of proto-oncogenes in normal breast tissue growth, differentiation, and reproduction.
- Identify genetic changes during the transformation from normal mammary tissue to premalignant to frankly malignant tissue.
- Evaluate the specific effects of point mutations or deletions of specific oncogenes, tumor suppressor genes, or chromosomal segments associated with breast cancer.
- Identify intermediate or premalignant events or markers of events that occur in the interval from the start of breast abnormalities to the detection of breast cancer. This will lead to earlier diagnosis, higher cure rates, and the development of rational preventive measures.
- Study new marker technologies for the identification of premalignant changes that could be targets for preventive interventions. As such technologies become available, they should be evaluated in multi-investigator or multi-institutional cooperative clinical research groups, which should establish quality control guidelines and design and conduct peer-reviewed clinical trials with adequate power to validate the sensitivity and specificity of new markers and tests.
- Enact federal regulations to limit the widespread sale and clinical use of markers of modifiable premalignant changes (when they become available) that are still experimental, and for which firm quality control guidelines and usefulness have not been established.

Hormones

- Study epithelial cell proliferation and hormonal control of the normal breast during the adolescent and adult menstrual cycle, during pregnancy and lactation, during systemic contraceptive use, and during hormone replacement therapy.
- Identify the genes in the normal breast and in breast cancers that are specifically regulated by endogenous hormones and growth factors, and by hormones in contraceptives and hormone replacement therapy.
- Conduct human research on “low-dose” hormonal contraceptive regimens, and compare the effects of estrogenic versus progestational components of systemic contraceptives on breast tissues.

Diet

- Study basic mechanisms of the preventive role of retinol and carotenoids.
- Define the dose-response relationships and the relative contributions of various forms of dietary vitamin A.
- Elucidate the mechanisms whereby energy restriction reduces mammary carcinogenesis.
- Investigate the relationship between specific types and amounts of dietary fat and protein and breast cancer incidence. Such studies should include a wider range of dietary intakes and examine diets beginning in childhood.
- Expand laboratory, clinical, and epidemiologic research on non-nutritive protective factors in vegetables and fruits, including screening the food supply for potential preventive agents.

- Study mechanisms by which moderate alcohol intake could increase the risk of breast cancer, with one focus being the relationship of alcohol consumption to hormone levels.
- Evaluate the interaction between dietary factors and markers of genetic predisposition as the latter become available.
- Investigate the possible relationship between vitamin D status and breast cancer risk.
- Conduct observational studies and clinical trials on the effect of dietary factors on breast cancer prognosis.

Environment

- Investigate the molecular nature of the carcinogenic process in breast epithelium to understand mechanisms by which environmental chemicals might influence mammary carcinogenesis.
- Conduct animal studies on mechanisms of species differences in susceptibility to chemically induced mammary cancers to increase understanding of human diversity in susceptibility.
- Study occupational exposures to chemical and other carcinogens and breast cancer risk in the context of other known risk factors.
- Investigate exposures to natural and synthetic estrogenic chemicals in the environment and their effects on breast cancer risk, particularly during prenatal, prepubertal, and pubertal periods. Such exposures must be evaluated in the framework of known breast cancer risk factors.
- Develop methodologies needed to study environmental risk factors: molecular

markers of exposure and susceptibility, improved methods of assessing dose-response relationships, and mechanisms of enzymatic transformations of precursor molecules to active carcinogens in humans.

- Determine the variable effects of individual and multiple etiologic factors on breast cancer risk by age at exposure.
- Continue studies of Japanese atomic bomb survivors, particularly women exposed *in utero* and during adolescence; evaluate the effects of hormonal, dietary, and genetic factors on susceptibility to breast cancer due to radiation exposure.

Prevention

- Develop approaches to modulate or eliminate the expression of specific oncogene products or abnormal genetic segments in premalignant breast tissue.
- Investigate hormonal chemoprevention intensively through basic, epidemiologic, and clinical studies. Research should focus on the development of pure antiestrogens and antiprogestins, the elucidation of hormonal regimens that mimic the protective effects of early pregnancy, work with retinoids and other vitamins, non-steroidal hormones and hormonal antagonists as systemic contraceptives, and non-hormonal contraceptive methods.
- Conduct observational studies and clinical trials on the effects of modifying multiple risk factors—for example, diet, physical activity, and hormones.
- Complete the Tamoxifen trial to determine whether it can prevent breast cancer among high-risk women.

SCREENING AND EARLY DETECTION AND THE DEVELOPMENT OF NEW TECHNOLOGIES FOR DETECTION AND DIAGNOSIS

Findings

- While prevention is the ultimate goal, earlier detection increases the likelihood of reducing mortality and should have a high research priority.
- Mammography in conjunction with breast physical examination has been shown to reduce mortality from breast cancer in women ages 50–69. Data regarding the benefit from mammography screening in women ages 40–49 are inconclusive, possibly due to limitations in study design or implementation.
- The technology of film-screen mammography has improved greatly over the past decade, but its sensitivity and specificity are still not adequate to detect all breast cancers at an early stage, especially in premenopausal women.
- Screening mammography is underutilized, especially by women aged 60 and older, who are most at risk. Racial and ethnic minorities and low-income women are also less likely to get mammograms.
- Failure of health care providers to recommend mammography is a major cause of poor utilization.
- The Mammography Quality Standards Act, designed to ensure high-quality mammography facilities across the country, was passed in 1992, but has not yet been implemented. The Food and Drug Administration is responsible for implementing this law, but instead is expending its efforts modifying it.
- Ultrasonography has limited use for breast cancer detection. Newer imaging

modalities such as positron emission tomography and magnetic resonance imaging are still under development and should be used only in the context of well-designed studies.

Recommendations

Practice and Outreach

- Immediately implement the Mammography Quality Standards Act to ensure that all women receive mammography of acceptable quality, and remove overlapping and conflicting standards. Current multiple certifications required at federal and state levels and from private organizations impose an excessive burden on mammography facilities, waste tax dollars, and increase costs.
- Promote utilization of screening mammography and clinical breast examination for groups of women who are currently being screened at disproportionately low rates (e.g., older women, rural women, women of lower socioeconomic status, and specific racial and ethnic populations, especially African American, Native American, Latino, and Asian women). This will require gathering additional information on barriers to screening and the information needs of these groups, and using existing information to develop effective educational materials and programs. Special attention should be given to conveying the message that increasing age is the major risk factor for developing breast cancer. These efforts should recognize the diversity of needs among and within specific groups and the necessity to develop materials, services, and interventions that address these specific needs.

- Educate and encourage physicians to recommend screening mammography actively.
- Provide screening and appropriate follow-up services for women, regardless of financial status or extent of insurance coverage.
- Help women assure their own breast health by providing financial and psychological support, enabling them to take responsibility for following recommended breast cancer screening guidelines and practicing breast self-examination.

Screening Research

- Conduct further studies to determine the mortality benefit of screening in women ages 40–49 and in women ages 70 and older, the optimal periodicity of screening in relation to age, and the relative utility of mammography and clinical breast examination. Investigators should first assess whether case-control studies could answer some of these questions as a less costly and more rapid approach than randomized controlled trials. Such studies should use state-of-the-art mammography and must be well designed and well executed. Consideration should be given to providing support for the ongoing trial in the United Kingdom to resolve questions related to screening women in their 40s.

- Develop a system designed to provide information about the practice of breast cancer screening in the United States.
- Assess the effects of co-morbid medical illnesses on breast cancer screening outcomes in women in different age groups.
- Determine the full range of breast cancer screening roles that nurses and physician extenders can play.

New Technologies Research

- Develop better technologies for detection and diagnosis. Such technology should detect breast cancer at its earliest stages, be highly sensitive and specific, non-invasive, and effective for women of all ages.
- Study the feasibility of earlier detection using computer-assisted mammography interpretation and techniques using digitization of mammographic images. Continue research into improving ultrasonography.
- Determine the comparative efficacy of stereotactic fine-needle and core biopsy and ultrasound-guided fine-needle and core biopsy with the goal of reducing the need for excisional biopsy.

IMPROVING THE OUTCOME FOR BREAST CANCER PATIENTS: TREATMENT AND QUALITY-OF-LIFE EFFECTS

Findings

- Despite some recent improvements in treatment, many thousands of women diagnosed with breast cancer die of the disease. No currently available treatment can be defined as curative.
- Since current treatments result in modest improvements in survival, assessing the effects of treatment on quality of life is important to inform patients adequately about treatment options. Quality-of-life issues include functional status, psychological well-being, social (work and home) functioning, sexuality and fertility, and spiritual well-being. Quality of life is influenced by personal factors (e.g., developmental stage and social support), clinical factors (e.g., stage of disease and type of treatment), and demographic factors (e.g., ethnicity and geographic location). The effects of treatment on long-term quality of life are not adequately known at this time.
- Adjustment to breast cancer is an ongoing process. While some patients do well following diagnosis and treatment, many experience adjustment difficulties in succeeding years. Fear is an overriding issue for women who have had a diagnosis of breast cancer.
- Treatment recommendations are best made in a clinical setting that includes experts in the various disciplines. Patients should be empowered to participate actively in making treatment decisions.

Recommendations

Treatment

- Exploit advances in molecular biology to find a cure for breast cancer. In particular, new and more specific therapeutic strategies should be developed, including: therapy directed at tumor growth factors or growth factor receptors; inhibitors of angiogenesis and metastases; gene therapy; and immunologic therapy, including vaccines. Innovative research should be encouraged.
- Identify cell surface factors associated with the ability of tumors to invade and metastasize; develop strategies to modulate the expression of such factors. Explain the predilection of metastatic cells to home to some but not other target organs.
- Improve current treatment strategies to make them more effective—identify mechanisms of resistance to hormonal and chemotherapy, develop ways to avoid or overcome resistance, evaluate dose intensification of chemotherapy in primary and metastatic breast cancer, evaluate pre-operative chemotherapy effectiveness, and optimize the long-term results of breast-conserving treatment and breast reconstructive surgery.
- Determine prognostic and predictive factors (or markers) for systemic therapy in order to select patients who are likely to benefit. However, it is necessary to regulate the clinical use of breast cancer markers that are still experimental. Markers should be made available outside the confines of a clinical trial only.

when they have been adequately validated and when firm quality control guidelines for their use have been established.

- Continue drug development research to discover new, more active agents.
- Ensure adequate funding for clinical investigations of new treatments and provide positive inducements for physicians and patients to participate in studies of promising new approaches. In particular, continue support of single institution pilot studies and of cooperative group randomized clinical trials.
- Define the natural history of ductal carcinoma *in situ* and other proliferative breast lesions, including factors strongly associated with progression to invasive breast cancer.

Quality-of-Life

- Evaluate the frequency, severity, and persistence of adverse physical changes caused by treatment and develop strategies to deal with these changes. In particular, evaluate treatment effects on fertility in premenopausal patients, and on sexual function in women of all ages. Strategies to treat menopausal symptoms and arm edema, as well as improved breast

implants or other methods of reconstruction, must be developed.

- Include quality-of-life measures in clinical trials of new treatment and prevention regimens and approaches.
- Develop guidelines for psychosocial evaluation and support over time of women diagnosed with breast cancer and those at risk for the disease; develop and test effective interventions to improve psychosocial adjustment. Specifically, studies should involve patients of all ages, women at high risk for developing breast cancer, and patients with recurrent disease. Research also should include the effects of diagnosis and treatment on patients' families and social functioning.
- Develop better strategies for supportive care of end-stage breast cancer patients and ensure availability of these services to patients and their families.
- Conduct clinical trials to provide information on the effects on survival and quality of survival of systemic hormonal contraceptives, pregnancy, and hormone replacement therapy at menopause in breast cancer survivors, including women in whom treatment of premenopausal breast cancer induced premature menopause.

INFRASTRUCTURE, EDUCATION, AND TRAINING

Findings

- Breast cancer research requires resources such as repositories, registries, and specialized research centers which must operate for many years. It is difficult to obtain stable, long-term funding to establish and maintain such resources outside an hypothesis-driven research proposal.
 - Advances in understanding the biology and genetics of breast cancer are not likely to be immediately applicable to improved prevention and treatment methods. A new generation of trained, basic, translational and clinical investigators is needed to ensure that the knowledge gained from basic research leads to human benefit, specifically the prevention and cure of breast cancer.
 - It is essential to ensure that clinical studies of prevention, detection, diagnosis, and treatment include women of diverse ethnic and sociocultural backgrounds. Culturally acceptable study design and recruitment of women from varied ethnic and racial groups are facilitated by the participation of investigators sensitive to sociocultural issues and who also come from diverse backgrounds.
- (Specialized Programs of Research Excellence), the National Cancer Institute's Surveillance, Epidemiology, and End Results program, and other high-quality cancer registries capable of providing data to monitor long-term trends in breast cancer, relevant animal models and cell lines, and repositories for biological specimens.
 - Develop an information-sharing network for breast cancer researchers.
 - Fund training grants specifically targeted to the next generation of investigators in all aspects of breast cancer research.
 - Train investigators in translational research and in clinical trials to facilitate the development of improved prevention, detection, and treatment strategies.
 - Emphasize during research training the role of ethnic and sociocultural diversity in risk of breast cancer, as well as the need to develop acceptable and sensitive strategies for research on prevention, early detection, diagnosis, and treatment for diverse population groups.
 - Train future clinical investigators in both translational and clinical trials research. These investigators need broad training in the biology, genetics, and clinical manifestations of breast cancer, and in epidemiology and biostatistics.
 - Utilize tumor boards in institutions that treat breast cancer to ensure optimal care through proper and timely input from various cancer specialists and to help train young physicians.

Recommendations

- The preponderance of research funding should be directed to investigator-initiated inquiry. A major emphasis should be placed on supporting innovative and imaginative research.
- Expand or create specialized research resources: breast cancer SPOREs

- Ensure that oncologists (medical, surgical, radiation, and nursing) receive interdisciplinary training to improve the quality of breast cancer care.
- Train clinicians of diverse ethnic heritage in breast cancer care.
- Promote continuing education programs for all professional and technical personnel dealing with breast cancer patients to ensure that advances in care are translated to practice.
- Ensure that medical school, residency, and fellowship training programs and training for advanced nursing practice include education on the need for regular breast examinations, including mammography and clinical breast examination, and on the performance of a thorough clinical examination of the breast.
- Encourage health care providers to educate patients about breast cancer, including treatment and rehabilitation options.

PUBLIC COMMUNICATION

Findings

- Information appropriate for and appealing to the mass media and information necessary for public education differs substantially. A fundamental principle of communicating with the public about breast cancer issues is to distinguish between information that is newsworthy and that which is needed for educational purposes. News media professionals generally consider it their responsibility to report news accurately, but not to serve as public educators. Therefore, channels other than the media are required for education.
- There is a discrepancy between the media attention given to breast cancer and its importance as a public health problem. While the media do give some attention to breast cancer, more resources could be expended by the media to present breast cancer-related issues to the public. For example, newspapers, television stations, and radio stations send reporters to international conferences on AIDS, but are very unlikely to send anyone to scientific meetings concerned with breast cancer. To some extent, this discrepancy is attributable to advocacy groups. It is clear that news media respond to activism. The more assertive breast cancer advocacy groups are, the more attention breast cancer will receive from the press.

- A significant segment of the U.S. population has a low level of literacy. It is essential to present educational materials and media messages in diverse formats so that all target audiences are reached. In some situations, it may be best to present both news and education via audio and visual channels (radio and television).

Recommendations

- Support a national work group on low literacy and cancer information and education.
- Make publicly funded public information and educational materials understandable to individuals at all literacy levels.
- Encourage breast cancer scientists, clinicians, and advocates to collaborate to determine the most effective methods for presenting clear messages to the public which neither understate nor overstate specific issues or overall progress in breast cancer research and care.
- Emphasize coordination of public information efforts between components of the National Institutes of Health and with other federal agencies, such as the Centers for Disease Control and Prevention.
- Work with news media to promote accurate, responsible, and adequate coverage of breast cancer issues.

PATIENT ADVOCACY

Findings

- Breast cancer is a public health problem involving multiple constituencies. It must be a high priority for all concerned with the health of women. Improving breast cancer research, prevention, detection, and treatment is a shared responsibility of consumers, health care providers, biotechnology and pharmaceutical industries, health educators and researchers, public health agencies, legislators, third-party payors, the National Cancer Institute, and other government agencies.
- Over the past decade, patients and their families have promoted breast cancer as a national priority and have focused attention on the need for a cure and for prevention.
- Service, patient support, and advocacy organizations exist for women, including underserved and minority women, at local, state, regional, and national levels. These organizations are valuable resources for many women and are influential in shaping public policy. Voluntary organizations fund and operate breast cancer screening programs, often targeted to underserved and minority women, and provide outreach and support to women during and following treatment for breast cancer. Some fund breast cancer research. Patient organizations provide psychosocial support; advocate for individual patients within the health care system and with payors; urge specific research emphases; and work at local, state, and national levels for policies and legislation on many breast cancer issues. Unfortunately, many minority and low-income women do not feel that most existing organizations represent them,

although there are some exceptions. Improved communication between patient advocacy groups and voluntary and government organizations would be beneficial to all.

- Breast cancer advocates want more participation in decision-making concerned with research and the optimal use of breast cancer research funding.

Recommendations

- Encourage patient advocates and voluntary organizations to work cooperatively to achieve legislation that provides funding, research, treatment, education, and support for women with breast cancer.
- Support voluntary and advocacy organizations' work to ensure access to care for all women and fund community-based programs to bring breast cancer information, education, and interventions to affected groups where they live and work.
- Ensure that health care reform implementation in each state reflects breast cancer issues specific to that population and geographic area.
- Educate physicians about the medical and psychosocial aspects of breast cancer and women's needs for screening, diagnosis, treatment, and continuing care. Physicians must include the woman as a partner in arriving at a diagnosis and choosing the most suitable care.
- Integrate breast cancer advocates into decision-making regarding the optimal use of breast cancer research funding.

- Encourage efforts by patient advocate organizations and other voluntary and educational groups to ensure that women are fully informed and educated about their own breast health, including adopting healthy lifestyles, practicing monthly breast self-examination, following recommended guidelines for early detection, and obtaining immediate diagnostic and treatment services when an abnormality is observed.



PUBLIC POLICY

Findings

National and State Legislation

- Recent breast cancer research funding increases have provided a large infusion of support for this area of biomedical investigation and raised the priority level of breast cancer within biomedical research. However, increased National Cancer Institute support for research on breast and other specific cancers without the addition of sufficient funds has required redirection of resources from other areas of cancer research. A sustained level of increased funding should include additions to the budget to strengthen breast cancer research specifically, and cancer research generally.
- In addition to federal legislation pertaining to aspects of breast cancer detection and treatment, states have enacted laws to provide quality assurance for mammography, ensure that treatment options are presented to women diagnosed with breast cancer, mandate payment for some off-label uses of chemotherapeutic drugs, and improve access to mammography by requiring insurance companies and Medicaid programs to cover breast cancer screening.
- Impending health care reform is projected to improve access to breast cancer screening, education, treatment, and supportive care. The main principles expected to govern these reforms include security in health care coverage, eliminating exclusions for pre-existing conditions; provider of quality of care and accountability; cost controls; and comprehensiveness of care.

Payment Policies

- Payment policy for all aspects of breast cancer care has a major health, psychosocial, and economic impact on women. Current problems in payment for breast cancer care include inadequate insurance coverage of screening mammography and breast clinical exam; no reimbursement for preventive interventions; limited or no payment for routine care associated with clinical trials; no reimbursement for drugs that have been approved by the Food and Drug Administration for cancers other than breast cancer, but not for breast cancer (off-label use); lack of reimbursement for physical and psychological rehabilitative services; lack of coverage for prostheses, wigs, transportation, or other indirect treatment or rehabilitation costs; and no reimbursement for reconstructive surgery following mastectomy.
- The ability to purchase health insurance, enroll in a group policy, or obtain publicly funded care is critical for access to care. Exclusion of pre-existing conditions leaves women previously diagnosed with breast cancer without coverage in the event of a recurrence. Women who have been diagnosed with breast cancer cannot change jobs because future treatment for breast cancer would be excluded from coverage. Women with no coverage or inadequate insurance often experience delays in diagnosis and treatment.
- Affordability of care and of health insurance is an important issue. In small companies, breast cancer patients may be discriminated against and feel guilty if the costs of their care lead to a large insurance premium increase for their co-

workers. Increased premiums and patients' out-of-pocket costs for breast cancer care can affect family resources and cause the breast cancer survivor to feel guilty.

- There is a very specific problem with regard to reimbursement for mammography. While the current guidelines of the National Cancer Institute, the American Cancer Society, and other professional organizations recommend annual mammograms for women 50 and older, Medicare provides reimbursement every other year for women 65 and older and does not provide any coverage for breast clinical examination.

Recommendations

National Legislation

- New funds should be appropriated to support the President's Cancer Panel Special Commission on Breast Cancer's recommended program at a level no less than \$500 million per year until breast cancer prevention and cure are achieved. This research effort should be under the leadership of the National Cancer Institute.

State Legislation

- Support state legislation to provide quality assurance for mammography and insurance coverage for screening, diagnostic tests, treatment, and patient care costs of clinical trials.

Payment Policies

- Decisions about health care coverage in this country should involve all members of

our society and take into consideration the society as a whole, government responsibilities, and the concerns of business.

- Increase access to affordable health care coverage by:
 - eliminating pre-existing condition clauses;
 - providing a universal health care package regardless of financial status or job or career changes; and
 - utilizing and adequately reimbursing primary care physicians and other providers such as nurse-practitioners and physician assistants.
- Provide comprehensive coverage for reasonable costs of screening and diagnostic tests, treatment, rehabilitation, and psychosocial services by:
 - consensus development of practice guidelines; and
 - covering treatment known to be effective and listed in the three compendia (*AMA Drug Evaluations*, *United States Pharmacopeia*, *Hospital Formulary*) whether or not FDA-approved specifically for breast cancer.
- Encourage and support breast cancer clinical research by:
 - providing coverage of standard health care costs incurred in peer-reviewed clinical trials;
 - providing coverage of interventions not yet proven to have medical benefit only in the peer-reviewed clinical trial setting; and
 - providing incentives to industry and the private sector to support treatment costs of clinical trials.

SPECIAL ISSUES FOR MINORITY AND UNDERSERVED WOMEN

Findings

- Minority and underserved women are heterogeneous, encompassing diverse ethnic groups (e.g., Native Americans, African Americans, Latinas, and Asian Americans); rural women; women with low literacy; women with inadequate health care, health insurance, or financial resources; women with disabilities from other illnesses or injuries; and women 65 and older, who often do not receive breast cancer screening or obtain state-of-the-art treatment.
- Diversity must be a key word in breast cancer research, prevention, diagnosis, treatment, and supportive and continuing care. No subgroup of women is homogeneous: white women in the United States are considered as a single, homogeneous entity, yet they have diverse demographic, socioeconomic, and ethnic backgrounds which influence their risk of breast cancer and their potential for access to the full range of appropriate care from prevention and early detection to rehabilitation. Similarly, other ethnic groups, such as Latino, African American, and Asian women are treated as if they all were similar. Diversity within these groups in culture, tradition, language, education, and other factors associated with breast cancer risk and access to optimal care must be considered in developing culturally sensitive programs.
- Access to breast cancer education, early detection, treatment, and rehabilitation is often restricted among women having one or more of the characteristics described above. Breast cancer research rarely includes women from many of

these populations and fails to encompass their issues in developing strategies for optimal care.

Recommendations

- Where scientifically appropriate, structure clinical trials to reflect the racial and ethnic population diversity.
- Build partnerships with underserved communities to encourage their involvement and self-advocacy in health care. Hospitals, clinics, health departments, and other providers should be encouraged to assist the underserved in navigating the health care system. Such strategies will increase early detection and reduce costly use of emergency rooms.
- Precede design of outreach and research projects in minority populations with consultation and interaction with community leaders where the project will take place. Provide adequate funding for long-term efforts.
- Conduct behavioral/social research on culturally sensitive approaches to current and future primary prevention strategies and ways to increase access to and utilization of early detection techniques and state-of-the-art treatment.
- Reduce geographic barriers to optimal education, early detection, treatment, and rehabilitation, particularly in rural areas.
- Investigate the psychosocial impact of breast cancer on women and their families and differences related to diversity by ethnicity, urban/suburban/rural residence, and socioeconomic status.

- Conduct studies to determine risk factor prevalence across diverse ethnic, socioeconomic, and cultural (e.g., urban/suburban/rural) populations.
- Make available breast cancer incidence and mortality data for all major ethnic groups: African American, Latino, Native American, Chinese, Japanese, Native Hawaiian, etc. The U.S. Census Bureau should provide intercensal population estimates for these groups. The National Cancer Institute's Surveillance, Epidemiology, and End Results program should provide the incidence data, while the mortality information should be provided by the National Center for Health Statistics.
- Target public information and media channels for providing breast cancer education to specific ethnic communities by: focusing on their media outlets, emphasizing radio advertisements and print media, and developing diverse programming that takes into account differences within an ethnic group in acculturation, literacy, language, and traditional cultural practices and beliefs.
- Remove linguistic and cultural barriers to screening, treatment, and rehabilitation.

APPENDIX A: PRESIDENT'S CANCER PANEL SPECIAL COMMISSION ON BREAST CANCER MEMBERSHIP ROSTER

Chairman

Nancy G. Brinker

Founding Chairman
Susan G. Komen Breast Cancer Foundation
Dallas, Texas

Dorit D. Adler, M.D., M.P.H.

Associate Professor of Radiology
Associate Director
Division of Breast Imaging
University of Michigan Medical Center

Karen H. Antman, M.D.

Chief, Division of Medical Oncology
Columbia Presbyterian Medical Center
New York, New York

Zora K. Brown

Founder and Chairman
Cancer Awareness Program Services
Washington, D.C.

Pelayo Correa, M.D.

Professor of Pathology
Louisiana State University Medical Center

Gerald D. Dodd, M.D.

Radiologist and Professor of Radiology
The University of Texas M.D. Anderson
Cancer Center

Karen Hassey Dow, R.N., Ph.D.

Nurse Researcher
Beth Israel Hospital
Cambridge, Massachusetts

Harmon J. Eyre, M.D.

Deputy Exec. V.P. for Medical Affairs and
Research
American Cancer Society
Atlanta, Georgia

Jay R. Harris, M.D.

Clinical and Educational Director
Professor in Radiation Oncology
Shields Warren Radiation Laboratory
Joint Center for Radiation Therapy
Harvard Medical School

Kathryn B. Horwitz, Ph.D.

Professor of Medicine and Pathology
University of Colorado
Health Sciences Center

Barbara S. Hulka, M.D., M.P.H.

Kenan Professor and Chair
Department of Epidemiology
School of Public Health
University of North Carolina

Mary-Claire King, Ph.D.

Professor of Epidemiology
School of Public Health
University of California-Berkeley

Sherry L. Lansing

Chairman and CEO
Paramount Motion Picture Group
Los Angeles, California

Sam Shapiro

Professor Emeritus
Health Services Research and
Development Center
School of Hygiene and Public Health
The Johns Hopkins University

S. Eva Singletary, M.D.

Chief
Breast Surgical Section
Department of General Surgery
The University of Texas M.D. Anderson
Cancer Center

G. Marie Swanson, Ph.D., M.P.H.

Professor of Medicine
Director, Cancer Center
Michigan State University

Reed V. Tuckson, M.D.

President
Charles R. Drew University of Medicine
and Science
Los Angeles, California

Frances M. Visco, Esq.

President
National Breast Cancer Coalition
Philadelphia, Pennsylvania

Walter C. Willett, M.D., M.P.H., Dr.P.H.

Nutrition Department
Harvard School of Public Health

Executive Secretary

Iris J. Schneider

Assistant Director for Program Operations
and Planning
National Cancer Institute



APPENDIX B: MEETINGS OF THE PRESIDENT'S CANCER PANEL SPECIAL COMMISSION ON BREAST CANCER

May 28, 1992

Overview of Breast Cancer Research

July 8, 1992

Issues in Basic Research

September 23, 1992

Radiation and Toxic Exposures as
Risk Factors

Dietary Influences on Risk and
Implications for Prevention

October 23, 1992

Patient Advocacy and Voluntary
Organizations

November 12, 1992

Hormonal Factors

January 11-12 1993

Treatment, Rehabilitation, and Quality
of Life

February 23, 1993

New Product Development for
Breast Cancer Prevention, Treatment,
Detection, and Diagnosis

March 18-19, 1993

Screening and Early Detection

Development of New Technologies for
Detection and Diagnosis

April 29, 1993

Possible Environmental Influences on
Breast Cancer

Health Care Delivery and the Role of
the Payors

June 25, 1993

Information Dissemination and the
Role of the Media

July 21, 1993

Public Policy and Legislation

Copies of meeting agendas, transcripts,
and meeting summaries available by
writing to:

**President's Cancer Panel Special
Commission on Breast Cancer**

Attention: Nora Winfrey
National Cancer Institute
Building 31, Room 4A34
Bethesda, MD 20892

APPENDIX C: PRESIDENT'S CANCER PANEL MEMBERS

Harold P. Freeman, M.D.

Chairman
Director of Surgery
Harlem Hospital Center
1991 to 1994

Henry C. Pitot, M.D., Ph.D.

Professor of Oncology and Pathology
McArdle Laboratory
University of Wisconsin
1992 to 1995

Nancy G. Brinker

Founder
Susan G. Komen Breast Cancer
Foundation
1992 to 1993

Frances M. Visco, Esq.

President
National Breast Cancer Coalition
1993 to 1996

NATIONAL
CANCER
INSTITUTE

October 1993



Memorandum

Date September 24, 1996

From Joe Harford, Ph.D.
Associate Director for Special Projects, NCI

Subject Technical Review of Proposal for National Cancer Policy Board

To Elizabeth Drye, Domestic Policy Council, Office of Policy Development
The White House (By Fax @ 202-456-7028)

Pursuant to our telephone conversation, I am sending you the following materials:

1. A "For Response to Inquiries" description of the Office of Cancer Survivorship (OCS) that contains some information re. Dr. Anna T. Meadows who has been named by Dr. Klausner to head the Office (2 pages).
2. A more detailed biographic sketch of Dr. Meadows (1 page).
3. A description of the Children's Hospital of Pennsylvania in Philadelphia (CHOP) (2 pages). This institution has grants from the NCI, and it is the current home institution of Dr. Meadows. Note that CHOP boasts the first follow-up program for long-term survivors of childhood cancer.
4. A description of the University of Pennsylvania Cancer Center in Philadelphia (1 page).
5. A description of the Fox Chase Cancer Center in Philadelphia (1 page).
6. Description of a conference in Albuquerque, NM on Oct. 3-6 sponsored by the National Coalition for Cancer Survivorship (NCCS) in partnership with People Living Through Cancer (PLTC) (1 page). Dr. Klausner is scheduled to address this conference.
7. A narrative from 1987 describing the "Legislative History of the National Cancer Institute" with a description of the National Cancer Act of 1971, the twenty-fifth anniversary of which we are celebrating this year (1 page). I include with this document a bullet-point version of this history that is up-to-date (3 pages).
8. A draft of a press release concerning the formation of the National Cancer Policy Board (NCPB) within the National Academy of Sciences, the establishment of which is occurring at the request of Dr. Klausner in his role as coordinator of the National Cancer Program pursuant to the National Cancer Act of 1971 (3 pages).

Note that we are in the process of preparing additional material containing facts and figures relevant to the subject of cancer survivorship. I will forward these to you as they become available.

In Honor of the 10th Anniversary of the
National Coalition for Cancer Survivorship...

OF, BY, AND FOR CANCER SURVIVORS

A Conference in Partnership with
People Living Through Cancer (PLTC)

Albuquerque, New Mexico, October 3-6, 1996

The National Coalition for Cancer Survivorship teams with People Living Through Cancer, the Albuquerque grassroots cancer support organization from which NCCS grew, to highlight valuable links between the national cancer survivorship movement and regional and local organizations.

The program includes information-packed workshops and plenary sessions around Resources for Action and Resources for Living and showcases successful cancer peer support, information access, and networking opportunities. Plus the Conference celebrates NCCS' 10 years of service to the survivorship movement with display of the NCCS Ribbon of Hope™—a huge sunburst of gold ribbons signed throughout the past year in honor of people touched by cancer—a Paintfest presented by the Foundation for Hospital Art, NCCS awards, exhibits, and a special morning excursion to witness the International Balloon Fiesta.

Space is limited! Register today!

ABOUT YOUR CO-HOSTS

The National Coalition for Cancer Survivorship (NCCS), founded by a small number of cancer survivors and supporters in 1986, has grown in 10 years into the largest network of independent organizations and institutions representing people with all types of cancer. NCCS helps cancer survivors find answers to their questions and attain a better quality of life following diagnosis by linking them to direct service and peer support organizations; addressing professional, legal, and health dilemmas; and participating in and shaping public policy on health care and cancer survivorship research.

People Living Through Cancer (PLTC), a grassroots organization founded in 1983 by cancer survivors, sponsors a variety of support groups, including an innovative support network serving Santo Domingo and other pueblos in New Mexico. PLTC also offers one-to-one support, New Mexico's largest lending library of cancer related material for healthcare consumers, and a Telephone LifeLine program. NCCS has its roots in PLTC, which generously provided a home base for NCCS during the coalition's formative years.

SCHEDULE OF EVENTS *(subject to change)*

THURSDAY, OCTOBER 3

3-7pm Registration
7pm Welcome Reception: a multimedia retrospective on the survivorship movement

FRIDAY, OCTOBER 4: RESOURCES FOR ACTION

8-9am Continental Breakfast
Registration
8am-5pm Exhibits
9-10:30am Opening Session: a panel of cancer survivors and leaders of the survivorship movement assesses the state of the movement today and trends for the future.
10:45-11:45am Networking Groups: exploring today's vital issues.
Poster Presentations
12-1pm The New NCCS Almanac: A special luncheon presenting the expanded, updated version of *A Cancer Survivor's Almanac: Charting Your Journey*.
1:30-4:30pm Information Fair: The new wave of cancer information resources
Book Fair: over 100 titles of the best of survivorship literature, plus other special items
6-9pm NCCS Town Hall Meeting: with buffet reception

SATURDAY, OCTOBER 5: RESOURCES FOR LIVING

7-8am NCCS Annual Business Meeting & Continental Breakfast
7-8:30am Book Fair
7:30am Registration
8am-5pm Exhibits
8:30-10:15am Keynote Address: Michael Lerner, PhD
10:45am-12:15pm Workshops: Your choice of 10 sessions reflecting the theme of Choices—in healing, mainstream medicine, complementary therapies, pain management, and end-of-life issues.
12:15-1:30pm Networking Luncheon
1:30pm NCCS Public Policy Meeting
1:30-3pm Afternoon Workshops: Some morning workshops to be repeated, plus new selections
1:30-4:30pm Paintfest
3:30-4:15pm Closing Ceremony
5:30-9pm Celebratory dinner at the Indian Pueblo Cultural Center with music, museum tours, 50% shopping discount

SUNDAY, OCTOBER 6

5:30am Buses depart for 25th Anniversary Albuquerque International Balloon Fiesta, most-photographed sports event in the world
7:30am Mass Ascension: 850 hot-air balloons go sky-high
11am Buses arrive back at hotel

PROFILE: Michael Lerner

Although securely anchored in mainstream medicine, Michael Lerner, PhD, explores complementary and mainstream therapies without bias. His *Choices in Healing* won widespread acclaim as a balanced inquiry into traditional and nontraditional approaches. Lerner is president of Commonweal, a health and environmental research institute that he founded in 1976 in Bolinas, California.

Item # 8

National Cancer Policy Board To Be Formed

This year, nearly 1-1/2 million people will be diagnosed with cancer. Up to 40 percent of us will eventually be diagnosed with this disease over our lifetime. The impact of the many different diseases we call cancer on our society is enormous. Today, there are over 10 million cancer survivors in the U.S. Hundreds of organizations representing Federal and state governments, academic institutions, professional societies, patient and advocate organizations, private organizations and others have responded to the enormous challenges of cancer. The National Cancer Program represents the sum of all of these activities. To articulate the differing viewpoints of all of the stakeholders in this Nation's commitment to reduce the burden of cancer, the National Cancer Institute (NCI), the President's Cancer Panel, and the National Cancer Advisory Board, have requested that the National Academy of Sciences form a National Cancer Policy Board (NCPB). The governing boards of the Academy's National Research Council (NRC) and Institute of Medicine (IOM) approved the formation of the Board in July. The NCPB would bring together representatives of the diverse participants in the Nation's cancer effort, which encompasses both Federal and non-Federal activities aimed at reducing the burden of cancer in the United States. These would include members of the cancer research community, cancer care providers, relevant professional organizations, and patient advocacy groups. While the National Cancer Act of 1971 designated the Director of the NCI as coordinator of the National Cancer Program, it is clear that the issues and questions related to cancer policy exceed the scope and authority of any single organizational entity.

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In describing this new endeavor, the NCI Director, Dr. Richard Klausner states, "We believe that the issues that the National Cancer Program needs to confront vis-à-vis major societal issues, requires some forum that can produce useful advice, guidelines, or recommendations independent of the constraints of a particular Federal agency, any particular advocacy group, or any particular set of interests within the National Cancer Program." The NCPB will provide this forum in which various sectors of the society can discuss overarching issues related to the Nation's cancer effort in a neutral and independent environment. The Board will survey current and possible outcomes of the Nation's cancer effort and deliberate on issues of broad national significance related to the movement of cancer research findings to implementation at all levels of society.

Dr. Klausner describes the new NCPB as "... a roof under which all of us can gather to deal with issues such as standards of care, cancer control policy issues, insurance and privacy issues, payment for clinical trials, standards of clinical trials, manpower needs, informational and educational needs, environmental/occupational policy in cancer, smoking policy, etc."

While the NCI will provide core support for the formation of the NCPB, the Academy will also solicit support from other Federal agencies with an interest in cancer issues, as well as from foundations and other organizations. The Board will consist of approximately 20 individuals who collectively represent the diversity of interests in the Nation's endeavors to eradicate cancer. Board members will have various relevant expertise and will have distinguished themselves through their prior contributions. The Academy will seek nominations for Board membership and ideas for topics the Board

October 11, 1996

NOTE TO DON BAER

FROM: Elizabeth Drye

SUBJECT: Breast Cancer Activities

As you know, The President just quietly signed a proclamation declaring October National Breast Cancer Awareness Month (attached). October 18th is Mammography Awareness Day. HHS (Melissa Skolfield's shop) suggested two very small news hooks we could use in a breast cancer event:

1. The National Action Plan on Breast Cancer -- an innovative public-private partnership developing a national strategy for prevention, education, and care -- is ready to announce its web site.
2. The National Performance Review is ready to present the Vice President's Hammer Award to FDA's Atlanta field office for its efforts to improve mammography quality. FDA has trained mammography personnel around the country on the new National Mammography Quality Standards Act (MQSA). The Hammer Award would highlight our efforts to fight breast cancer through early detection by ensuring that more women obtain mammogram in high quality facilities, and could be announced on Mammography Awareness Day. (The President has never presented a Vice President's Hammer Award. The VP has personally presented over 100 of the 600 granted to date.)

Also, FYI, the "Ribbon of Hope" (the cancer analog to the AIDS quilt) will be in Albuquerque, NM, this weekend. The National Coalition for Cancer Survivorship (NCCS) has commissioned a yellow hot-air balloon, "The Ribbon of Hope," to fly the actual ribbon in the 25th Annual International Balloon Festival. The First Lady has signed the ribbon; Mrs. Dole is expected to sign it on 10/21 in NJ. Attached is a recent memo from Porter/Novelli to Public Liason suggesting the President sign the ribbon at this event.

Please let me know if you'd like to pursue any of these ideas or those we previously discussed (earlier memo attached for reference). I can be reached through White House Signal all weekend.

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should address from the broad range of groups that comprise the Nation's cancer constituency. Once established, the NCPB will operate under the existing policies of the NRC and IOM which include independent, carefully reviewed studies on topics deemed to be in the Nation's interests. The NCPB will publish the outcomes of these studies and thereby advise the Nation regarding cancer policy issues.

Item #3

First in Pediatric Care

The Children's Hospital of Philadelphia has been a pioneer of pediatric medicine, responsible for clinical innovations such as:

- the first pediatric day surgery unit in the U.S.
- the first neonatal surgical and pediatric intensive care unit in the nation
- the first pediatric bone marrow transplantation program in the Delaware Valley
- the first multidisciplinary home-care program in the U.S. For children who need mechanical ventilators to survive
- the first designated Pediatric Regional Resource Trauma Center (Level I) in eastern Pennsylvania
- the first follow-up program for long-term survivors of childhood cancer
- the first clinic in the nation for the treatment of childhood speech defects
- the first pediatric MRI in Philadelphia, used to create high-resolution images of soft body tissue

Item #7

Legislative History of the National Cancer Institute

Mary C. Knipmeyer¹

On August 5th, 1937, President Franklin D. Roosevelt signed into law the National Cancer Institute Act (P.L. 244) establishing the National Cancer Institute. The law mandated the new Institute "to provide for, foster, and aid in coordinating research relating to cancer." In 1944, the Public Health Service Act consolidated much of the Nation's health efforts, including designating the National Cancer Institute as part of the National Institutes of Health.

The next major legislative step in the Federal effort to fight cancer occurred with the signing of the National Cancer Act (P.L. 92-218) on December 23, 1971 by President Richard Nixon. This legislation was enacted following the report of the National Panel of Consultants on the Conquest of Cancer appointed by Senator Ralph Yarborough. The Act found a middle ground between those who thought the National Cancer Institute should be an independent agency and those who thought it belonged within the National Institutes of Health. The 1971 legislation met the concerns of both perspectives by enlarging the authorities and responsibilities of the Institute Director and initiating a National Cancer Program. Special authorities included appointment of the Director by the President, the development of an annual By Pass Budget, special peer review and training authorities, and the authority to hire expert consultants to enter into contracts and to award construction projects. It also established a 5-member President's Cancer Panel, charged with reporting to the President any delays or blockages in the rapid execution of the National Cancer Program. The National Cancer Advisory Board also was established with 18 Presidentially appointed members in addition to 5 ex-officio members. The first cancer centers were authorized by this new law, which called for 15 new research, training, and demonstration cancer centers. The Act also established cancer control programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer. An Information Dissemination Program for the collection, analysis, and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer was established as well as the International Cancer Research Data Bank.

Three years after signing the original Act, President Nixon signed the National Cancer Act Amendments of 1974 (P.L. 93-352). This law included new provisions for disseminating information on nutrition as related to the treatment or causation of cancer as well as a peer review system of grant applications and contract projects.

The next significant set of amendments to the National Cancer Act came in 1978 when the Act was amended to emphasize education and demonstration programs in cancer treatment and prevention. The amendments (P.L. 95-622) also stipulated that the National Cancer Institute devote more resources to prevention, focusing particularly on environmental, dietary, and occupational cancer causes.

In 1985, the Health Research Extension Act (P.L. 99-158) recodified the portion of the Public Health Service Act related to the National Institutes of Health. The special authorities of the National Cancer Institute were maintained with the clear intent of continuing to provide for an expedited cancer research program. The mission of the National Cancer Institute continues to be to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer. The 1985 law placed additional emphasis on the continuing care of cancer patients and their families.

The legislative history of the National Cancer Institute reflects the Nation's continuing commitment to the goal of eradicating cancer through a multifaceted national research program and the desire of the Congress to provide the authority and flexibility needed to facilitate its achievement.

¹Legislative Analyst/Congressional Liaison, Office of the Director, National Cancer Institute.

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Legislative History of the
National Cancer Institute and the National Cancer Program

HIGHLIGHTS

August 5, 1937

National Cancer Institute Act of 1937 [P.L. 244]

- o Established the National Cancer Institute within the Public Health Service
- o Sec. 2 (b) directs the Surgeon General, through the Institute, "To promote the coordination of researches conducted by the Institute and similar researches conducted by other agencies, organizations, and individuals;"
- o Established the National Advisory Cancer Council

December 23, 1971

National Cancer Act of 1971 [P.L. 92-218]

- o Outgrowth of the report of the National Panel of Consultants on the Conquest of Cancer (the Yarborough Commission)
- o Elevated and expanded certain authorities of the National Cancer Institute director, including appointment by the President and preparation and submission of the annual budget estimate (Bypass Budget) directly to the President
- o Established the President's Cancer Panel and the National Cancer Advisory Board
- o Initiated the National Cancer Program under Sec. 407 of the PHS Act as follows: "(a) The Director of the National Cancer Institute shall coordinate all of the activities of the National Institutes of Health relating to cancer with the National Cancer Program. (b) In carrying out the National Cancer Program, the Director of the National Cancer Institute shall: (1) With the advice of the National Cancer Advisory Board, plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the National Cancer Institute, related programs of the other research institutes, and other Federal and non-Federal programs."
- o Authorized the first cancer centers
- o Established cancer control programs as necessary for cooperation with State and other health agencies
- o Established an information dissemination program
- o Established the International Cancer Research Data Bank (ICRDB)

Item # 7

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

July 23, 1974

National Cancer Amendments of 1974 [P.L. 93-352]

- o Broadened authority to collect, analyze and disseminate "information" (replaced "data")
- o Authorized award of construction grants for new construction or alteration/renovation of basic research laboratory facilities
- o Authorized expanded information dissemination activities for scientists, health professionals and the general public

November 9, 1978

Community Mental Health Center Extension Act of 1978 and Biomedical Research and Research Training Amendments of 1978 [P.L. 95-622]

- o Recodified the 1971 Act; reorganized and consolidated duties and functions of the NCI Director (in the process, the language regarding the scope of the National Cancer Program as including other Federal and non-Federal programs was dropped)
- o Called for an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens
- o Reduced minimum number of President's Cancer Panel meetings from 12 to 4 per year
- o Expanded the mission of cancer centers to include basic research and prevention
- o Expanded and strengthened the cancer control mandate to emphasize the importance of education and demonstration programs initiated within local communities and hospitals
- o Added several ex-officio members to the NCAB, reflecting the importance of environmental and occupational carcinogenesis research and required that five of the appointed members be knowledgeable in environmental carcinogenesis

Item # 7

Legislative History of the
National Cancer Institute and the National Cancer Program
(continued)

November 20, 1985

Health Research Extension Act [P.L. 99-158]

- o Established the position of Associate Director for Prevention
- o Added to NCI's mission and cancer control activities research on continuing care of cancer patients and their families
- o Consolidated cancer communications activities and highlighted the ICRDB

November 4, 1988

Health Omnibus Programs Extension of 1988 [P.L. 100-607]

- o Added rehabilitation research to NCI's mission
- o Further expanded NCI's information dissemination programs

June 10, 1993

The NIH Revitalization Amendments of 1993 [P.L. 103-43]

- o Requires intensified and expanded research programs in breast/women's cancers and prostate cancer
- o Mandates a set-aside of NCI's appropriation for cancer control activities (FY94-7%; FY95-9%; FY96-10%)
- o Mandates a case control study of elevated breast cancer rates on Long Island; requires study of potential environmental risk factors and establishment of a geographic information system

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In describing this new endeavor, the NCI Director, Dr. Richard Klausner states, "We believe that the issues that the National Cancer Program needs to confront vis-à-vis major societal issues, requires some forum that can produce useful advice, guidelines, or recommendations independent of the constraints of a particular Federal agency, any particular advocacy group, or any particular set of interests within the National Cancer Program." The NCPB will provide this forum in which various sectors of the society can discuss overarching issues related to the Nation's cancer effort in a neutral and independent environment. The Board will survey current and possible outcomes of the Nation's cancer effort and deliberate on issues of broad national significance related to the movement of cancer research findings to implementation at all levels of society.

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While the NCI will provide core support for the formation of the NCPB, the Academy will also solicit support from other Federal agencies with an interest in cancer issues, as well as from foundations and other organizations. The Board will consist of approximately 20 individuals who collectively represent the diversity of interests in the Nation's endeavors to eradicate cancer. Board members will have various relevant expertise and will have distinguished themselves through their prior contributions. The Academy will seek nominations for Board membership and ideas for topics the Board

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The Blue Sheet 1996; 39(28): 2-3

July 10, 1996

SECTION: CANCER POLICY

LENGTH: 798 words

TITLE: NATIONAL ACADEMY OF SCIENCES TO ESTABLISH NATIONAL CANCER
COUNCIL WITH NCI SUPPORT

TEXT:

A National Cancer Council to facilitate and coordinate cancer policy will be established under the administration of the National Academy of Sciences (NAS), National Cancer Institute Director Richard Klausner informed the House Appropriations/HHS Subcommittee recently.

Klausner told the subcommittee: "In working with the President's Cancer Panel, we have developed a plan to create a National Cancer Council, a group that will represent a full range of public and private sectors including research, the voluntary organizations, the pharmaceutical industry, insurance and health care providers, professional organizations and the public."

The statement came in a written response to an information request by the subcommittee and was included in the official record of hearings on a FY 1997 spending bill reported out by the full Appropriations panel.

Klausner added that the council "will bring together all constituents with interest in the outcome of a national cancer effort, as well as other sectors with an interest in the health and welfare of the nation."

The NCI director noted that "we have formulated a mission charge to the council and identified a key aspect of the council's operation, namely that it must operate in a way that it is as free of institutional biases as possible."

An "appropriate venue for the council," Klausner added, "is the National Academy of Sciences and we are now working with the Academy leadership to develop a plan to implement the Council as an academy round table."

Klausner asserted that "this mechanism will catalyze and enable communication between the sectors and be the ideal setting for discussion of such critical issues as cancer screening, pain management, information dissemination, and achieving state-of-the-art detection and treatment."

"We believe that coordination across all sectors is vital to the success of the National Cancer Program," the NCI director maintained.

The Klausner statement is in response to a written question from HHS Subcommittee Chair John Porter (R-Ill.).

In the document, Porter stated: "Last year the subcommittee expressed concerns about lack of coordination of cancer research activities across all sectors, public and private. What steps have you taken to re-establish coordination of cancer research activities?"

The council has been under development for several months among members of NAS, NCI and cancer advisory boards. A draft mission statement and proposed structure were circulated among NAS and NCI officials within the last month.

Cancer Council To Review Broad Policy Issues

The proposed council will be considered later in July by the Governing Board of the National Research Council (NRC), a component of the academy. NCI terms of contractual support and membership selection would take place shortly after the NRC board's expected approval.

According to NIH officials, current plans are for the council to be a permanent body within NAS. The group would work to develop specific policy questions and possibly commission separate academy committees to answer them.

One of the advantages of such a group over existing NIH panels such as the National Cancer Advisory Board is a broader scope. NCAB and other NCI panels are useful in dealing with cancer research issues, but are less well-equipped to handle broad policy issues, according to an NIH official.

Part of the impetus for establishing the group is a desire to impart a consistent message on cancer issues. One official involved with the project pointed to the controversy about mammography screening for breast cancer among women 40 to 49 years of age.

After initially recommending routine screening for this age group, NCI recently reversed its position, stating that not enough information is available in order to make a firm recommendation. However, more recent data indicate that more frequent screening may be effective in diagnosing breast cancer in that age group (see related story, p. 8).

Another factor driving the development of the council is concern about impartiality of non-governmental cancer groups. For example, one official raised questions about the role of the National Comprehensive Cancer Network in setting cancer policy. NCCN, a group of 14 major cancer centers, recently issued treatment guidelines on eight different types of cancer ("The Blue Sheet" March 13, p. 11).

Similar questions have been raised about the objectivity of guidelines produced by professional societies. The Agency for Health Care Policy and Research has announced that it will cease producing guidelines itself and instead provide the "scientific foundation" for professional societies and health care providers and insurers to develop their own guidelines ("The Blue Sheet" May 1, p. 3).

THE **CANCER** LETTER

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National Academy Of Sciences To Form Cancer Policy Board At NCI's Request

Responding to a request by NCI, the National Academy of Sciences plans to form an independent board that would provide advice on cancer policy issues.

The Institute asked the Academy to form the board in response to a Congressional recommendation, NCI Director Richard Klausner said.

The House Appropriations Committee last year asked NCI to re-establish coordination of the National Cancer Program, the program of federal and non-federal efforts in cancer research, treatment and control
(Continued to page 2)

In Brief

Emory Univ. Receives \$295 Million Endowment; Winship Cancer Center To Get Half Of Income

EMORY UNIVERSITY'S Robert W. Woodruff Health Sciences Center received an endowment consisting of \$295 million in Coca-Cola Co. stock from the Woodruff family foundations, university officials said. At least half of the income generated by the endowment will go to the Winship Cancer Center. Next year alone, the cancer center's share of the proceeds will be at least \$1.8 million, said **Howard Ozer**, director of the cancer center. "Obviously, we want to make Emory the very best in the country," said Ozer. "Recruitment of basic and clinical investigators who are at the very top of national reputation is our primary goal." The gift was made jointly by the Woodruff Foundation, the Joseph P. Whitehead Foundation and the Lettie Pate Evans Foundation. . . . **FOUR MEDICAL SCIENTISTS** were named recipients of the 9th annual City of Medicine Awards presented in Durham, NC. The winners are **Alfred Knudson**, geneticist at Fox Chase Cancer Center; **Kenneth Olden**, director, National Institute of Environmental Health Sciences; **Joan Steitz**, scientist at Yale University; and **Eng Tan**, director of the W.M. Keck Autoimmune Disease Center, Scripps Research Institute. Each receives \$5,000 and a crystal sculpture. The awards are given annually by the City of Medicine, a program based in Durham. . . . **SAM SOROF**, 74, a protein biochemist at Fox Chase Cancer Center, died Aug. 4 at his home in Huntingdon Valley, PA. He had lymphoma for more than 16 years. Sorof joined Fox Chase in 1952 following a postdoctoral fellowship at NCI. His work dealt with the interaction of cancer-causing chemicals and their target proteins in liver cancer cells from rats. He is survived by his wife, Phyllis; a son, Jonathan, of Houston; a daughter, Lauren, of New York City; and a sister, Marsha,
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Policy Board Needed To Tackle Difficult Issues, Klausner Says

(Continued from page 1)

as originally envisioned by the National Cancer Act of 1971 (**The Cancer Letter**, Aug. 4, 1995).

Members of the two top advisory committees to NCI have said repeatedly that their committees, the President's Cancer Panel and the National Cancer Advisory Board, are unsuited for conducting expert studies of national cancer policy issues. Since the advisory groups are not independent, their recommendations are sometimes viewed as politically or institutionally motivated.

The new entity, proposed to be called the National Cancer Policy Board, would bring together representatives from federal agencies, academia, cancer care providers, professional organizations, and patient advocacy groups.

The new board will operate under the auspices of the Academy, Klausner said at the Aug. 7 meeting of the NCI Board of Scientific Advisors.

"We believe that the issues that the National Cancer Program needs to confront vis-à-vis major societal issues, require some forum that can produce some useful advice, guidelines, or recommendations, independent of the constraints of a particular federal agency, a particular advocacy group, or a particular set of interests in the National Cancer Program," Klausner said to the BSA.



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"[The Academy board] will be widely representative of all the stakeholders in the National Cancer Program," Klausner said. "It will be independent, establish its own agenda, as a neutral forum in which issues—especially policy issues that are of import to the National Cancer Program—can be discussed, and where recommendations can be made.

"This will bring us together to address pressing issues that are otherwise difficult to address for structural reasons, for political reasons, for institutional reasons, within any one of the organizations that make up the National Cancer Program," Klausner said.

"This will be a roof under which all of us can gather as individuals to deal with issues such as standards of care, cancer control policy issues, insurance and privacy issues, payment for clinical trials, standards of clinical trials, manpower needs, informational, educational needs, environmental/occupational policy in cancer, smoking policy, etc.," Klausner said.

NCI Contract Would Fund Board's Formation

The governing boards of the Academy's National Research Council and the Institute of Medicine approved the formation of the board on July 18, according to an NAS spokesman.

The NRC and the IOM regularly convene both standing committees and short-term study groups for federal agencies, said Robert Cook-Deegan, a senior program officer in the IOM.

Examples include the Space Studies Board, Transportation Research Board, the Government-University-Industry Research Roundtable, and the Board on Radiation Research Effects.

NCI plans to issue a contract to the Academy for the board's formation, most likely for a three-year period, said Cook-Deegan, who has been assigned to provide staff support for the new board.

Other federal agencies with interests in cancer issues could be asked to help support the board, Cook-Deegan said. The board would also seek support from foundations and other organizations.

Under the Academy's rules, funding by for-profit companies could not exceed 49 percent of the board's budget, he said.

Approximately 20 board members would be selected by the IOM and the NRC, Cook-Deegan said. Soon after the contract is issued, the Academy would

publicly solicit nominations, as well as ideas for topics the board should address, he said.

Idea Grew From NCAB Subcommittee Report

The idea for an independent cancer policy board functioning outside NCI stems from the 1994 report of the National Cancer Advisory Board's Subcommittee to Evaluate the National Cancer Program, said Paul Calabresi, chairman of the subcommittee and a member of the President's Cancer Panel.

The report was issued prior to Klausner's appointment as NCI director in August 1995, but Klausner expressed support for the findings, Calabresi said.

According to the report, "Cancer at a Crossroads," better coordination of the work of federal agencies, non-profit groups, and private organizations is necessary to reduce the burden of cancer (**The Cancer Letter**, Oct. 7, 1994).

The report did not say who should coordinate the cancer program. Subcommittee members said further study was necessary. Although the Cancer Act originally envisioned the NCI director to act as the coordinator of the entire cancer program, bureaucratic and political constraints make that impossible, Calabresi said.

"It was clear to us that no one person could coordinate the National Cancer Program," Calabresi said to **The Cancer Letter**. Similarly, NCI's existing advisory groups, because they are within the Institute, do not have the authority to speak for the entire cancer program, he said.

"We've seen many flaws over the past several years in our attempts to deal with issues such as screening mammography, gene testing, or clinical trials," said Calabresi, who served on the NCAB prior to his appointment to the Cancer Panel.

The President's Cancer Panel, comprised of three members appointed by the President, has a budget that supports only four one-day meetings per year, Calabresi said. The panel is charged with alerting the President to obstacles in cancer research, treatment and control.

"The Cancer Panel has a limited scope in both funding and people, and the NCAB has a different mission of overseeing NCI," Calabresi said. "We thought there should be another body, and Dr. Klausner's suggestion was that this be outside of government. The model that came to mind was the

National Academy of Sciences."

The policy board would have a broad base of expertise, as well as financial support, to study the complicated issues that confront the cancer program, Calabresi said. "We would hope that once these studies are done, they would be filtered through the Cancer Panel and the NCAB," he said.

"It's an exciting venture, its a new direction," Calabresi said.

Stronger Voice For Cancer Program

John Durant, executive vice president of the American Society for Clinical Oncology, and a former NCAB member, said the policy board would give the cancer program a stronger, more authoritative voice.

"This is a creative, clever idea," Durant said to **The Cancer Letter**. "This group will have the full weight and power of the National Academy. The public and the Congress is highly likely to pay attention and do something with an opinion rendered by the National Academy. Dr. Klausner has made another good step in a series of good steps."

Durant said the President's Cancer Panel has not been an effective voice because its authority depends on the panel members' ties to the White House.

What's more, NCI should not render opinions on national cancer policy issues because the Institute's mission is cancer research, Durant said. "NCI has gotten into the position of making pronouncements about the best forms of cancer care, which has obscured its mission of sponsoring the best research," he said. "When the Institute has gotten into disputations over its pronouncements, it has not been good for the cancer community."

"I think [the policy board] will be able to generate more clout, and help get the Cancer Institute out of the middle of some circumstances where it never belonged in the first place," Durant said.

The American Cancer Society, too, is a supporter of the creation of the policy board, said Harmon Eyre, ACS executive vice president for research and cancer

Two-Week Publishing Break Scheduled For Cancer Letter

Publication of **The Cancer Letter** will be suspended for the next two weeks while the staff takes its annual summer break.

The next issue of **The Cancer Letter**, Vol. 22, No. 34, will be dated Sept. 6.

control. "We have expressed our support to Dr. Klausner for this concept, with the hope that this will have a positive impact on the National Cancer Program and facilitate communication and coordination among the different entities, federal, state, private, and not-for-profit voluntary agencies," Eyre said to **The Cancer Letter**.

"The National Cancer Act, when it was passed, dictated that the NCI director is the coordinator of the National Cancer Program, but it has become clear that the NCI director can't tell the Department of Defense what to do in cancer, can't tell the Centers for Disease Control what to do in cancer, and can't tell the Health Care Financing Administration what to do in cancer," Eyre said. "The role of the President's Cancer Panel, in my judgment, has varied. If the chairman has not been intimately connected with the President, it has had less authority.

"The policy board, depending upon its membership, has the potential for being widely accepted," Eyre said.

Prostate Cancer Advocates Consider Coalition Modeled On Breast Cancer Movement

Jane Reese-Coulbourne is still surprised by the standing ovation she received at a recent meeting of the leaders of prostate cancer advocacy groups.

"I'd given that speech many times," said Reese-Coulbourne, executive vice president of the National Breast Cancer Coalition. "I walked in and said, here is what we did. I had pictures. I told anecdotes. I gave them a feel for how it could be."

While breast cancer advocates were constructing what could be the most effective organization in cancer politics, men with prostate cancer remained politically dormant. Now, five years after the formation of NBCC, prostate cancer survivors are finding inspiration in the breast cancer movement. More importantly, the men are adopting NBCC strategies.

The aim of the meeting, Reese-Coulbourne addressed July 20 was the formation of an umbrella group tentatively called the "National Prostate Cancer Coalition."

On Aug. 18, a steering committee of prostate cancer advocates is scheduled to meet again, to devise the structure of the coalition, map out its political strategy, and to determine how to unite the disparate

political factions in prostate cancer.

As much as the men would like to follow the breast cancer model, it is apparent that at least in embryonic stage, the prostate cancer coalition is very different from NBCC.

The breast cancer coalition emerged as a grassroots organization of women who first became politicized at protests against the Vietnam war and in the women's movement.

The prostate cancer group, by contrast, is being started under an unrestricted educational grant from Zeneca Pharmaceuticals and with the organizational help from the American Foundation for Urologic Disease, a patient-oriented group founded 10 years ago by the American Urological Association.

Zeneca's products include Zoladex, a hormonal treatment for prostate cancer.

Since prostate cancer usually afflicts an older population, prostate cancer activists would be a generation older—and carrying a very different cultural baggage—than their counterparts at NBCC.

Wisdom of Solomon

"We were brought up with that John Wayne mentality that illness is a sign of weakness, so you didn't admit to it," said Robert Samuels, a retired banker and civil rights activist who has emerged as a likely leader of the prostate cancer coalition.

Samuels, who founded a prostate cancer education service in Tampa, said he did not seek to lead the emerging coalition when he departed for a "preliminary task force meeting" near Dallas last month.

Now, Samuels is considering his impending role of forming a coalition and keeping it together.

"It's going to require the wisdom of Solomon to try to get us all focused on the same objective," said Samuels, chairman of the interim steering committee for the emerging group.

Indeed, the politics of prostate cancer unfold on a dizzying number of fronts:

National umbrella groups of prostate cancer organizations are competing for constituencies among support groups that have sprung up all over the US. Advocates of PSA testing are locked in battle with those who express reservations about the test and how it should be interpreted. Urologists are competing with radiotherapists and oncologists. Debates rage over the value of radical prostatectomy. Believers in cryosurgery and radiotherapy are

Item #3

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

Founded in 1855 as the nation's first pediatric hospital, the Children's Hospital of Philadelphia is committed to improving the health of today's children through its clinical care programs, and the health of tomorrow's children through its basic and clinical research programs and training of the next generation of pediatric health care professionals.

Children's Hospital provides comprehensive care, both inpatient and outpatient, for children from birth through age 19. With 304 beds, 20 percent of which are allocated to intensive care, the Hospital admits over 15,000 inpatients and handles over 200,000 emergency and outpatient visits annually.

Critically ill children and those suffering from unusual or hard-to-diagnose diseases are sent here from the Delaware Valley, the nation and the world, for such services as: the only pediatric trauma service in eastern Pennsylvania; one of the largest pediatric oncology services in the nation; a Comprehensive Sickle Cell Centers infant intensive care for premature newborns; liver, heart and bone marrow transplantation; and cardiovascular surgery for children with rare or complicated heart defects. Because of such specialized programs, Children's Hospital placed second among all pediatric hospitals in the United States in the 1995 physicians' rating of America's best hospitals in U.S. News and World Report.

Children's Hospital takes pride in its role as the community caregiver for the disadvantaged children of West and South Philadelphia. As a result of this commitment, the Hospital last year absorbed more than \$31 million in uncompensated care expenses.

The advancement of pediatrics through research and education is also central to the mission of the Children's Hospital of Philadelphia. In May of 1995, the Hospital dedicated its state-of-the-art research facility. The 13-story Leonard and Madlyn Abramson Pediatric Research Center houses the Joseph Stokes, Jr., Research Institute which receives \$30 million annually in research funding.

Research undertaken at the Hospital has resulted in many advances in the prevention, diagnosis and treatment of childhood disease, including the development of the following: the first closed incubator for newborn; the cardiac balloon catheter technique for curing specific congenial heart defects in infants; and vaccines against rubella and mumps.

Each year Children's Hospital's graduate medical training programs train more than 150 pediatric professionals in 26 different subspecialties who then go on to careers in academic medicine, medial research or community practice. The Hospital is also a pediatric training ground for medical students from the University of Pennsylvania School of Medicine, clinical and research fellows from universities worldwide and for nursing students from eight schools of nursing.

For more information please contact (215)590-4100

Item #3

First in Pediatric Care

The Children's Hospital of Philadelphia has been a pioneer of pediatric medicine, responsible for clinical innovations such as:

- the first pediatric day surgery unit in the U.S.
- the first neonatal surgical and pediatric intensive care unit in the nation
- the first pediatric bone marrow transplantation program in the Delaware Valley
- the first multidisciplinary home-care program in the U.S. For children who need mechanical ventilators to survive
- the first designated Pediatric Regional Resource Trauma Center (Level I) in eastern Pennsylvania
- the first follow-up program for long-term survivors of childhood cancer
- the first clinic in the nation for the treatment of childhood speech defects
- the first pediatric MRI in Philadelphia, used to create high-resolution images of soft body tissue

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ABOUT THE UNIVERSITY OF PENNSYLVANIA CANCER CENTER

The University of Pennsylvania Cancer Center is a national leader in cancer research, patient care, education and training of health care professionals in cancer, and community education and outreach. The preeminent position of the Cancer Center is reflected in its designation by the National Cancer Institute as one of only ~~25~~ cancer centers in the country approved and designated as a Comprehensive Cancer Center.

The University of Pennsylvania Cancer Center takes seriously its commitment to serve as a regional and national leader in developing and offering innovative cancer treatments that improve the chance for recovery while preserving the quality of life. The Cancer Center is equally committed to understanding the underlying causes of cancer through basic, translational, clinical and cancer control research, and to educating health care professionals, patients, families and our community. This commitment reflects the Cancer Center's goal of reducing the incidence and mortality of cancer in our region and throughout the country. As an NCI-designated Comprehensive Cancer Center, the University of Pennsylvania Cancer Center is able to meet the desire of community hospitals to have a relationship with a national leader in cancer research and treatment.

As an institute of the University of Pennsylvania, our Cancer Center benefits substantially from the vast clinical, educational and research resources available through the University of Pennsylvania. Cancer treatment is enhanced because patients experiencing non-cancer-related problems can receive comprehensive care by full-time Penn faculty who practice at the University of Pennsylvania Medical Center. Cancer Center members have access to the substantial research capabilities throughout the Penn campus. Thus, by being part of one of the nation's leading academic medical centers, the University of Pennsylvania Cancer Center's ability to provide the latest cancer treatments, conduct leading-edge research, educate health care professionals, and serve the needs of our community are clearly enhanced.

Mission of the Center

Throughout its ²³ year history, the University of Pennsylvania Cancer Center has provided the organizational framework required to promote and enhance interdisciplinary cancer research, education and patient care.

The University of Pennsylvania Cancer Center was initially founded in 1973 as the focus for cancer-related research and education at the University of Pennsylvania. At that time, the Cancer Center's original research mission was defined through six primary objectives, including:

- Development of basic science and clinical research programs.
- Recruitment of faculty with expertise in cancer.
- Development of interdepartmental and interdisciplinary

educational programs in cancer.

- Development of cancer prevention and control research programs.
- Development of NCI-funded Shared Resource facilities that provide cancer researchers with advanced technology needed to conduct innovative research.
- Provision of technical services that facilitate innovative cancer research.
- Development of new cancer research space.

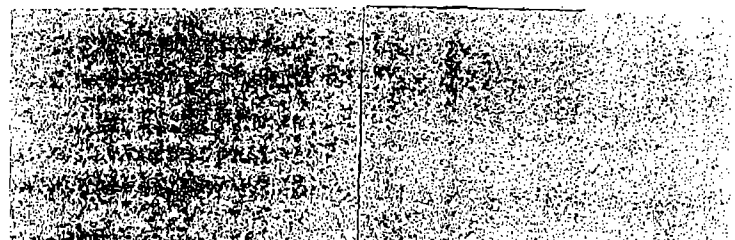
In 1990, the Cancer Center's mission was officially expanded to include a strong clinical initiative. This patient care mission is achieved through the following objectives:

- Expand the range of cancer-related services and interdisciplinary cancer programs.
- Improve patient and referring physician access.
- Enhance the image of the Cancer Center.
- Increase the level of clinical cancer activities.
- Increase clinical research, emphasizing translational research opportunities.
- Expand community outreach activities.

The mission and priorities of the University of Pennsylvania Cancer Center are in concert with those of community hospitals in our region. The development and maintenance of a strong network of select community hospitals meets the Cancer Center's research, clinical, community outreach, education and training responsibilities. At the same time, a well-organized, integrated collaborative relationship with an NCI-designated Comprehensive Cancer Center provides invaluable access to the community hospital and its physicians, and the opportunity to participate directly in innovative clinical, research and educational programs. Most importantly, such cooperative efforts enable the University of Pennsylvania Cancer Center and the Cancer Network hospital to enhance their collective ability to serve the multiple needs of our community.

Designation as a Comprehensive Cancer Center by the National Cancer Institute

The University of Pennsylvania Cancer Center has been continuously funded by the Centers' Program of the National Cancer Institute since its inception in the early 1970s. The Cancer Center is formally approved and designated as a Comprehensive Cancer Center by the National Cancer Institute, a status enjoyed by only 26 cancer centers. This designation is in recognition of the Cancer Center's excellence in cancer research, patient care, community service and outreach, cancer information services, and the education and training of health care professionals.



Item #5

FACT SHEET

CONTACT: Eric Rosenthal
(215) 728-2700

Fox Chase Cancer Center

Fox Chase Cancer Center is one of 27 National Cancer Institute-designated comprehensive cancer centers in the nation. Fox Chase's activities include basic, clinical and prevention research; detection and treatment of cancer; and community outreach programs. In 1974 Fox Chase was formed by the union of American Oncologic Hospital (the nation's first cancer hospital, established in 1904) and the Institute for Cancer Research (founded in 1927). Today it has more than 1800 employees and an annual budget of \$127 million. Research is conducted in more than 75 laboratories by a staff of more than 300 physicians and scientists who hold M.D.s, Ph.D.s or both.

Fox Chase's 100-bed hospital is one of the few facilities in the country devoted entirely to cancer care. More than 130 clinical trials of new prevention, diagnostic and treatment techniques are under way at any one time. Almost 1,000 new patients a year participate in clinical trials. Annual hospital admissions average about 3,400 a year and outpatient visits to physicians exceed 37,000 a year. Combining research in many disciplines with patient care enables Fox Chase to translate new research findings into medical applications that may become models for improved comprehensive cancer care.

Fox Chase is structured around three divisions: medical science, basic science and population science. Medical science is committed to providing excellent patient care and conducting a broad-based program of clinical research. The division of basic science is renowned worldwide for its work in understanding both normal and abnormal cell growth and development. The goal of the division of population science is to identify people at high risk for cancer and to develop strategies to reduce these risks through programs of prevention and early detection.

Fox Chase is also involved in developing trials to test new agents that may prevent cancer in high-risk individuals, and is an active participant in the national trials to prevent breast cancer and prostate cancer. For women at high risk for breast or ovarian cancer, Fox Chase offers the Margaret Dyson Family Risk Assessment Program providing state-of-the-art medical care, cancer genetic counseling and education.

In 1986 Fox Chase established partnerships with community hospitals in the region. Fox Chase Network now includes 19 hospitals throughout the Philadelphia area and as far as Pittsburgh, Pa. and central and southern New Jersey. This program has been successful in raising the quality of cancer care in the community and increasing the number of patients enrolled in clinical trials. In 1995 the center was a founding member of the National Comprehensive Cancer Network, an alliance of 15 of the nation's best cancer centers. In 1996 Fox Chase announced the formation of the Oncology Physician Network, an organization of medical oncologists in Pennsylvania, New Jersey and Delaware sharing common practice philosophies and contracting needs.

Fox Chase operates the NCI's regional Cancer Information Service (1-800-4-CANCER) serving eastern Pennsylvania, New Jersey and Delaware. The regional Cancer Information Service receives more than 35,000 calls and conducts more than 1,900 cancer-related data-bank searches for patients and physicians each year, and maintains an active outreach program.

Fox Chase investigators have received numerous awards and honors including a Nobel Prize for medicine; membership in the National Academy of Sciences; General Motors Cancer Research Foundation Prizes; American Cancer Society Medals of Honor; and induction into the National Inventors Hall of Fame. The president of Fox Chase, Dr. Robert C. Young, is past president of the American Society of Clinical Oncology, one of the world's largest oncology societies.

FOX CHASE
CANCER CENTER

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