

Withdrawal/Redaction Sheet

Clinton Library

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

25th Anniversary of National Cancer Act

2014-0046-S

rc1445

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
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- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- 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)]

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Cancer
25th
Aniv.



FAX

Date: 10/25Number of pages including cover sheet: 2

To:

ELIZABETH DRYE

Phone:

Fax: 202-456-7028

CC:

From:

/ Ellen Stovall o Judie Blanchard

o Susan Scherr o Deborah Ash

o Terry Campbell o Sally McElroy

o Donna Doneski o Sonja Tyler

Phone: 301-650-9127

Fax: 301-565-9670

REMARKS:☐ Urgent☐ For your review☐ Reply ASAP☐ Please Comment☒ Per our Conversation☐ Per your request

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BIOGRAPHICAL SKETCH

ELLEN L. STOVALL

Ellen Stovall is Executive Director of the National Coalition for Cancer Survivorship (NCCS)—the largest network of individuals, organizations, and institutions, advocating on issues that affect people with all types of cancer. Prior to her appointment as Executive Director of NCCS in May 1992, she volunteered for over 20 years with organizations in the Washington, DC community as a spokesperson and advocate for quality of life issues that affect people with cancer and their families. Ms. Stovall is a 25-year cancer survivor, having recovered from two bouts with Hodgkin's Disease. She was diagnosed with cancer in December 1971, the year President Richard M. Nixon signed the National Cancer Act. She is a frequent panelist and requested speaker on a variety of issues related to cancer survivorship and quality health care.

Ms. Stovall represents NCCS's positions and policies to a variety of groups who have an interest in broadening access to quality health care for people with cancer. In December 1995, Ms. Stovall was made a member of the Board of Trustees of the Foundation for Accountability (FACCT), a purchaser and consumer driven organization that evaluates, endorses, and promotes a common set of patient-oriented measures of health care quality focused on the outcomes of care. She also serves on advisory panels, working groups, and committees of the National Cancer Institute (NCI), the American Society of Clinical Oncology (ASCO), the Association of Community Cancer Centers (ACCC), the Southwest Oncology Group (SWOG), and the United States Pharmacopeial Convention, Inc.

Recognizing a need for the voice of cancer survivors to be heard during the national debate over health care reform, a group known as the Cancer Leadership Council (CLC) was convened in 1993 under her direction. Organized to develop a consensus statement on health care reform that spoke from the cancer patient's perspective, the CLC continues to meet regularly and develops positions on health policy matters of consequence to people with cancer. In addition to the National Coalition for Cancer Survivorship (NCCS), CLC members include Cancer Care, Inc.; Candlelighters Childhood Cancer Foundation; National Alliance of Breast Cancer Organizations (NABCO); Y-ME National Breast Cancer Organization (Y-ME); Susan G. Komen Foundation; North American Brain Tumor Coalition; and the US-TOO International Prostate Cancer Support Organization (US-TOO).

Item #1

For Response to Inquiries

**NATIONAL
CANCER
INSTITUTE**Office of Cancer
CommunicationsBuilding 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

Mtg
Scheduled
for
November

(more)

Statement

Withdrawal/Redaction Marker

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Item # 1

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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.

[001] Born in (b)(6) Meadows is a 1969 graduate of the Medical College of 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.

#

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 (dial 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.

Item #6

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.

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.

Item #7

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)

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

THE WHITE HOUSE
WASHINGTON

September 18, 1996

MEMORANDUM FOR: CAROL RASCO
BRUCE REED ✓
DON BAER ✓
DOUG SOSNIK
ALEXIS HERMAN
KAREN HANCOX
BILL CURRY

FROM: Elizabeth Drye
Debbie Fine

SUBJECT: Proposal for POTUS to Visit Cancer Center

Please
see
me.
Don

This year marks the 25th Anniversary of the National Cancer Act, which gave the National Cancer Institute a mandate to pursue new scientific leads in research and apply the results to improve methods of cancer detection, treatment, prevention and control.

Several groups in the private sector have formed a coalition to raise public awareness about the importance of cancer research in honor of this Anniversary. This coalition and the National Cancer Institute have both approached us to request a Presidential event commemorating the Act's 25th anniversary in the next couple of months. Tony Podesta has been representing the private sector coalition, which consists of the American Cancer Society, National Breast Cancer Coalition, American Nurses Association, survivors, researchers and others.

Below for your consideration is a potential Presidential event on the road or in DC in the near future. If you think it's worth pursuing, we will draft a formal scheduling proposal. We would like to get back to Tony Podesta by next week if possible with a sense of whether or not this is a possibility.

SUGGESTED PROPOSAL

1. The President could visit one of the major cancer centers, which are located all over the country. There he could make remarks to patients, researchers, cancer center employees, and cancer survivors on his accomplishments and agenda for the future. Prior to remarks, the President could also tour the facility and/or sign the National Coalition of Cancer Survivors' "Ribbon of Hope." (The

"Ribbon of Hope" is similar to the AIDS quilt in its symbolism; it travels all over the country for people to sign as an expression of hope and concern. At the outset of its tour approximately one year ago, the First Lady signed it. It is due to be put on display in Albuquerque at the annual meeting of the National Coalition of Cancer Survivors October 4-6.)

2. Podesta also suggested the President deliver remarks at the Nina Hyde Breast Cancer dinner on the evening of September 24th in Washington D.C.

SUGGESTED MESSAGE

- In the 25 years since passage of the Cancer Control Act, we have made dramatic gains. Death rates from children's cancers have declined by almost two-thirds. Today, 10 million Americans owe their lives directly to cancer research.
- But cancer still kills one out of every five Americans. This year nearly 1.4 million people in the U.S. will be diagnosed with cancer, and more than 550,000 people will die of cancer--more than 1,500 people a day. Research offers tremendous promise to improve survival rates.
- President Clinton has a strong record of support for cancer research and other cancer initiatives. Review record of accomplishment, specifically touching on FDA's cancer initiative, breast cancer research, the tobacco initiative (smoking is the cause of over 30% of cancer deaths), etc.
- Under President Clinton's leadership, the Administration is continuing to build on that record with several initiatives that will help us as we move into the 21st century. See attached for specific potential announcements of NCI activities.

COURSE OF ACTION

1. **Would you support consideration of an event commemorating the 25th Anniversary of the Cancer Control Act?**

_____ YES _____ NO

cc: Jennifer Klein
Barbara Woolley

POTENTIAL CANCER INITIATIVES FOR POTUS TO HIGHLIGHT/ANNOUNCE

NCI has initiatives underway to:

1. **Identify the keys to each cancer.** NCI's **Cancer Genome Anatomy Project** will speed cancer detection and improve treatment by helping doctors quickly identify specific cancer genes within tumors. Under the project, NCI is building a complete index of genes expressed as tumors and is investing in developing technologies that can identify these genes in minutes.

Status: NCI has announced to scientific community.

2. **Speed the approval and use of new treatments.** NCI's **Informatics Initiative** will link NCI, the FDA, and public and private research centers throughout the nation to provide instant access to the latest data and support FDA's new drug approval process.

Status: NCI has not formally announced; known to scientific community.

3. **Develop novel, targeted drug therapies.** NCI is supporting the development of cancer cell-specific viruses and other novel therapies that carefully target cancer cells and better spare healthy cells.

Status: NCI has not formally announced; known to scientific community.

4. **Expand veterans' access to clinical trials of cutting-edge therapies.** NCI has crafted an agreement with the VA to increase veterans' participation in and speed completion of clinical trials. NCI announced a similar arrangement for DoD beneficiaries earlier this year. NCI will work to bring private insurers into the initiative.

Status: VA agreement is ready and has not been announced.

5. **Build collaboration.** NCI has catalyzed and will help underwrite the creation of the National Cancer Policy Board. Modeled on the National Academy of Sciences, the board will bring together many sectors of society -- including business, government, doctors, and advocacy groups -- to debate cancer policy issues affecting the nation (e.g. tobacco control and regulation of environmental toxins).

Status: NCI has announced to scientific community.

The National Cancer Act of 1971 -- Summary

NATIONAL CANCER PROGRAM

This section redefines the role of the National Cancer Institute, calling upon it to create an "expanded, intensified, and coordinated cancer research program," working with the NIH and other related agencies. The NCI is also charged with creating an international cancer research data bank to store and disseminate all known cancer research data collected anywhere around the world. It is given the task of supporting research in other countries which could be expected to benefit the American people, and it is also encouraged to create international ventures.

In addition, the President's Cancer Panel is defined by this section. This panel is composed of three people appointed by the President to appraise the National Cancer Program. Two serve three-year terms, one serves for a two-year term, and one is designated by the President as Chairman. All three are paid for their working time, and they are required to meet at least twelve times a year and report to the President.

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

This section provides for the establishment by the NCI of fifteen new centers for clinical research and training related to cancer. Agreements can be reached with private or nonprofit agencies to help the establishment and operation of these centers.

CANCER CONTROL PROGRAMS

\$90 million were allocated by this section to be spent in 1971-1974 to help the National Cancer Institute establish programs for cooperation with state and other health agencies in the prevention, diagnosis, and treatment of cancer.

AUTHORITY OF DIRECTOR

Authorized the director of the NCI to hire consultants, maintain cancer centers, and use the facilities and resources of the government.

SCIENTIFIC REVIEW: REPORTS

Director of the NCI is ordered to establish for appropriate scientific review over all programs which he oversees and submit a report to the President.

NATIONAL CANCER ADVISORY BOARD

This section establishes a National Cancer Advisory Board of twenty-three members, six ex-officio members and eighteen appointed by the president for six-year terms. This board superseded the existing National Advisory Cancer Council and was instructed to meet at least five four times a year. The Board's role is to investigate the activities of the National Cancer Program and report yearly to the President. Members not employed by the government are compensated for the time they work.

AUTHORIZATION OF APPROPRIATIONS

Additional appropriations (other than the appropriation listed above) total \$1.5 billion for 1971-74. The director of the NIH and the NCI are authorized under this act to approved grants for cancer research and training.

National Cancer Act Amendments of 1974

EXTENSION OF CANCER PROGRAM

This amendment extends the National Cancer Act, providing \$210.5 million in funding for 1974-77 under "Cancer Control Programs," and \$2.18 billion in funding for other project of the Cancer Institute. Amendments also clarify the type of review the director is reacquired to conduct.

BIOMEDICAL RESEARCH

Additionally, this amendment establishes the President's Biomedical Research Panel, composed of the Chairman of the President's Cancer Panel and six Presidential appointees. The panel is paid for their work, is allowed to hire staff, and is charged with reviewing the biomedical and behavioral research supported by the NIH and the National Institute of Mental Health.

Dec. 22

Dec. 23

NATIONAL CANCER ACT

P.L. 92-218

PRESIDENT'S ECONOMIC REPORT—JOINT ECONOMIC COMMITTEE REPORT—FILING TIME

PUBLIC LAW 92-216; 85 STAT. 778

[S. J. Res. 184]

Joint Resolution extending the dates for transmission of the Economic Report and the report of the Joint Economic Committee.

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That:

(a) Notwithstanding the provisions of section 3 of the Act of February 20, 1946, as amended (15 U.S.C. 1022), the President shall transmit to the Congress not later than February 15, 1972, the Economic Report; and (b) notwithstanding the provisions of clause (3) of section 5(b) of the Act of February 20, 1946 (15 U.S.C. 1024(b)), the Joint Economic Committee shall file its report on the President's Economic Report with the House of Representatives and the Senate not later than March 10, 1972.

Approved December 22, 1971.

NINETY-SECOND CONGRESS, SECOND SESSION— CONVENING DATE

PUBLIC LAW 92-217; 85 STAT. 778

[S. J. Res. 186]

Joint Resolution to provide for the beginning of the second session of the Ninety-second Congress.

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That:

The second regular session of the Ninety-second Congress shall begin at noon on Tuesday, January 18, 1972.

Approved December 22, 1971.

THE NATIONAL CANCER ACT OF 1971

For Legislative History of Act, see p. 2337

PUBLIC LAW 92-218; 85 STAT. 778

[S. 1828]

An Act to amend the Public Health Service Act so as to strengthen the National Cancer Institute and the National Institutes of Health in order more effectively to carry out the national effort against cancer.

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

SHORT TITLE

Section 1. This Act may be cited as "The National Cancer Act of 1971".

FINDINGS AND DECLARATION OF PURPOSE

Sec. 2. (a) The Congress finds and declares—

(1) that the incidence of cancer is increasing and cancer is the disease which is the major health concern of Americans today;

(2) that new scientific leads, if comprehensively and energetically exploited, may significantly advance the time when more adequate preventive and therapeutic capabilities are available to cope with cancer;

(3) that cancer is a leading cause of death in the United States;

(4) that the present state of our understanding of cancer is a consequence of broad advances across the full scope of the biomedical sciences;

(5) that a great opportunity is offered as a result of recent advances in the knowledge of this dread disease to conduct energetically a national program against cancer;

(6) that in order to provide for the most effective attack on cancer it is important to use all of the biomedical resources of the National Institutes of Health; and

(7) that the programs of the research institutes which comprise the National Institutes of Health have made it possible to bring into being the most productive scientific community centered upon health and disease that the world has ever known.

(b) It is the purpose of this Act to enlarge the authorities of the National Cancer Institute and the National Institutes of Health in order to advance the national effort against cancer.

NATIONAL CANCER PROGRAM

Sec. 3. (a) Part A of title IV of the Public Health Service Act is amended by adding after section 406 the following new sections:

"NATIONAL CANCER PROGRAM

"Sec. 407. (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.

"(2) Expeditiously utilize existing research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise.

"(3) Encourage concerns, where for such research

"(4) Collect, prevention, diagnosis, establishment of collect, catalog results of cancer use of any persons

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"(3) Encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research.

"(4) Collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country.

"(5) Establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials.

"(6) Support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States.

"(7) Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and allied health professions personnel, for participation in clinical and basic research and treatment programs relating to cancer, including where appropriate the use of training stipends, fellowships, and career awards.

"(8) Call special meetings of the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

"(9)(A) Prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the National Cancer Institute.

"(c)(1) There is established the President's Cancer Panel (hereinafter in this section referred to as the 'Panel') which shall be composed of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two of the members of the Panel shall be distinguished scientists or physicians.

"(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) in the case of two of the members first appointed, one shall be appointed for a term of one year and one shall be appointed for a term of two years, as designated by the President at the time of appointment, and (ii) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

"(B) The President shall designate one of the members to serve as Chairman for a term of one year.

“(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel, and shall be allowed travel expenses (including a per diem allowance) under section 5703(b) of title 5, United States Code.

"(3) The Panel shall meet at the call of the Chairman, but not less often than twelve times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chairman shall make such transcript available to the public.

“(4) The Panel shall monitor the development and execution of the National Cancer Program under this section, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct. At the request of the President, it shall submit for his consideration a list of names of persons for consideration for appointment as Director of the National Cancer Institute.

"NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

"Sec. 408. (a) The Director of the National Cancer Institute is authorized to provide for the establishment of fifteen new centers for clinical research, training, and demonstration of advanced diagnostic and treatment methods relating to cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

“(b) The Director of the National Cancer Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited

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"CANCER CONTROL PROGRAMS

"Sec. 409. (a) The Director of the National Cancer Institute shall establish programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer.

"(b) There are authorized to be appropriated to carry out this section \$20,000,000 for the fiscal year ending June 30, 1972, \$30,000,000 for the fiscal year ending June 30, 1973, and \$40,000,000 for the fiscal year ending June 30, 1974.

"AUTHORITY OF DIRECTOR

"Sec. 410. The Director of the National Cancer Institute (after consultation with the National Cancer Advisory Board), in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act, is authorized—

"(1) if authorized by the National Cancer Advisory Board, to obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than fifty experts or consultants who have scientific or professional qualifications;

"(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; to acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Cancer Institute for a period not to exceed ten years;

"(3) to appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

"(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

"(5) to accept voluntary and uncompensated services;

"(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

"(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution; and

"(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the National Cancer Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

"SCIENTIFIC REVIEW; REPORTS

"Sec. 410A. (a) The Director of the National Cancer Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

"(b) The Director of the National Cancer Institute shall, as soon as practicable after the end of each calendar year, prepare in consultation with the National Cancer Advisory Board and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding calendar year and a plan for the Program during the next five years.

"NATIONAL CANCER ADVISORY BOARD

"Sec. 410B. (a) There is established in the National Cancer Institute a National Cancer Advisory Board (hereinafter in this section referred to as the 'Board') to be composed of twenty-three members as follows:

"(1) The Secretary, the Director of the Office of Science and Technology, the Director of the National Institutes of Health,

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the chief medical officer of the Veterans' Administration (or his designee), and a medical officer designated by the Secretary of Defense shall be ex officio members of the Board.

"(2) Eighteen members appointed by the President.

Not more than twelve of the appointed members of the Board shall be scientists or physicians and not more than eight of the appointed members shall be representatives from the general public. The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto. Each appointed member of the Board shall be appointed from among persons who by virtue of their training, experience, and background are especially qualified to appraise the programs of the National Cancer Institute.

"(b)(1) Appointed members shall be appointed for six-year terms, except that of the members first appointed six shall be appointed for a term of two years, and six shall be appointed for a term of four years, as designated by the President at the time of appointment.

"(2) Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve only for the remainder of such term. Appointed members shall be eligible for reappointment and may serve after the expiration of their terms until their successors have taken office.

"(3) A vacancy in the Board shall not affect its activities, and twelve members thereof shall constitute a quorum.

"(4) The Board shall supersede the existing National Advisory Cancer Council, and the appointed members of the Council serving on the effective date of this section shall serve as additional members of the Board for the duration of their terms then existing, or for such shorter time as the President may prescribe.

"(c) The President shall designate one of the appointed members to serve as Chairman for a term of two years.

"(d) The Board shall meet at the call of the Director of the National Cancer Institute or the Chairman, but not less often than four times a year and shall advise and assist the Director of the National Cancer Institute with respect to the National Cancer Program.

"(e) The Director of the National Cancer Institute shall designate a member of the staff of the Institute to act as Executive Secretary of the Board.

"(f) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the Board deems advisable to investigate programs and activities of the National Cancer Program.

"(g) The Board shall submit a report to the President for transmittal to the Congress not later than January 31 of each year on the progress of the National Cancer Program toward the accomplishment of its objectives.

"(h) Members of the Board who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Board compensation at rates not to exceed the daily equivalent of the annual rate in effect for GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for person in the Government service employed intermittently.

"(i) The Director of the National Cancer Institute shall make available to the Board such staff, information, and other assistance as it may require to carry out its activities.

"AUTHORIZATION OF APPROPRIATIONS

"Sec. 410C. For the purpose of carrying out this part (other than section 409), there are authorized to be appropriated \$400,000,000 for the fiscal year ending June 30, 1972; \$500,000,000 for the fiscal year ending June 30, 1973; and \$600,000,000 for the fiscal year ending June 30, 1974."

(b) (1) Section 402 of the Public Health Service Act ^{72a} is amended by adding at the end thereof the following:

"(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act for cancer research or training—

"(1) in amounts not to exceed \$35,000 after appropriate review for scientific merit but without the review and recommendation by the National Cancer Advisory Board prescribed by section 403(c), and

"(2) in amounts exceeding \$35,000 after appropriate review for scientific merit and recommendation for approval by such Board as prescribed by section 403(c)."

(2) Section 402 of such Act ^{72b} is further amended—

(A) by inserting "(a)" immediately after "Sec. 402."; and

(B) by redesignating paragraphs (a), (b), (c), (d), (e), (f), and (g) as paragraphs (1), (2), (3), (4), (5), (6), and (7), respectively.

(3) Section 403(c) of such Act ^{72c} is amended by striking out "In carrying out" and inserting in lieu thereof "Except as provided in section 402(b), in carrying out".

REPORT TO CONGRESS

Sec. 4. (a) The President shall carry out a review of all administrative processes under which the National Cancer Program, established under part A of title IV of the Public Health Service

^{72a.} 42 U.S.C.A. § 282(b) (1), (2).
^{72b.} 42 U.S.C.A. § 282(a) (1) to (7).

^{72c.} 42 U.S.C.A. § 283(c).

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^{72d.} 42 U.S.C.A. § 218(c)
^{72e.} 42 U.S.C.A. § 241(c)
^{72f.} 42 U.S.C.A. § 241(i)
^{72g.} 42 U.S.C.A. § 282.

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Act, will operate, including the processes of advisory council and peer group reviews, in order to assure the most expeditious accomplishment of the objectives of the Program. Within one year of the date of enactment of this Act the President shall submit a report to Congress of the findings of such review and the actions taken to facilitate the conduct of the Program, together with recommendations for any needed legislative changes.

(b) The President shall request of the Congress without delay such additional appropriations (including increased authorizations) as are required to pursue immediately any development in the National Cancer Program requiring prompt and expeditious support and for which regularly appropriated funds are not available.

PRESIDENTIAL APPOINTMENTS

Sec. 5. Title IV of the Public Health Service Act is amended by adding after part F the following new part:

"PART G—ADMINISTRATIVE PROVISIONS

"DIRECTORS OF INSTITUTES

"Sec. 454. The Director of the National Institutes of Health and the Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407(b) (9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health."

CONFORMING AMENDMENTS

Sec. 6. (a) (1) Section 217 of the Public Health Service Act ^{72d} is amended (A) by striking out "National Advisory Cancer Council," each place it occurs in subsection (a), and (B) by striking out "cancer," in subsections (a) and (b) of such section.

(2) Sections 301(d), ^{72e} 301(i), ^{72f} 402, ^{72g} and 403(c) ^{72h} of such Act are each amended by striking out "National Advisory Cancer Council" and inserting in lieu thereof "National Cancer Advisory Board".

(3) Section 403(b) of such Act ⁷²ⁱ is amended by striking out "National Cancer Advisory Council" and inserting in lieu thereof "National Cancer Advisory Board".

(4) Section 404 of such Act ^{72j} is amended—

(A) by striking out "council" in the matter preceding paragraph (a) and inserting in lieu thereof "National Cancer Advisory Board", and

(B) by striking out "COUNCIL" in the section heading and inserting in lieu thereof "BOARD".

^{72d.} 42 U.S.C.A. § 218(a), (b).

^{72e.} 42 U.S.C.A. § 241(d).

^{72f.} 42 U.S.C.A. § 241(i).

^{72g.} 42 U.S.C.A. § 282.

^{72h.} 42 U.S.C.A. § 283(c).

^{72i.} 42 U.S.C.A. § 283(b).

^{72j.} 42 U.S.C.A. § 284.

EFFECTIVE DATE

Sec. 7. (a) This Act and the amendments made by this Act shall take effect sixty days after the date of enactment of this Act or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

(b) The first sentence of section 454 of the Public Health Service Act (added by section 5 of this Act) shall apply only with respect to appointments made after the effective date of this Act (as prescribed by subsection (a)).

(c) Notwithstanding the provisions of subsection (a), members of the National Cancer Advisory Board (authorized under section 410B of the Public Health Service Act, as added by this Act) may be appointed, in the manner provided for in such section, at any time after the date of enactment of this Act. Such officers shall be compensated from the date they first take office, at the rates provided for in such section 410B.

Approved December 23, 1971.

FISHERMEN'S PROTECTIVE ACT—AMENDMENT

For Legislative History of Act, see p. 2409

PUBLIC LAW 92-219; 85 STAT. 786

[H. R. 3304]

An Act to amend the Fishermen's Protective Act of 1967 to enhance the effectiveness of international fishery conservation programs.

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

The Fishermen's Protective Act of 1967 (68 Stat. 883, as amended; 82 Stat. 729), is amended by inserting at the end thereof the following new section:

"Sec. 8. (a) When the Secretary of Commerce determines that nationals of a foreign country, directly or indirectly, are conducting fishing operations in a manner or under circumstances which diminish the effectiveness of an international fishery conservation program, the Secretary of Commerce shall certify such fact to the President. Upon receipt of such certification, the President may direct the Secretary of the Treasury to prohibit the bringing or the importation into the United States of fish products of the offending country for such duration as he determines appropriate and to the extent that such prohibition is sanctioned by the General Agreement on Tariffs and Trade.

“(b) Within sixty days following certification by the Secretary of Commerce, the President shall notify the Congress of any action taken by him pursuant to such certification. In the event the President fails to direct the Secretary of the Treasury to prohibit the importation of fish products of the offending country, or if such prohibition does not cover all fish products of the offending country, the President shall inform the Congress of the reasons therefore.

“(c) It shall be the duty of the Secretary of the United States to be imported into the United States by the Secretary of the United States.”

“(d) (1) Any person who violates this section may be fined not more than \$25,000 for each violation.”

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“(3) All provisions of law relating to the seizure, forfeiture, and condemnation of property, and the disposition of the proceeds thereof, and the remission of fines and penalties, and the remission of seizures and forfeitures, and the remission of fines and penalties under the provisions of law are applicable to the property of the United States.”

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NATIONAL CANCER ACT AMENDMENTS OF 1974

For Legislative History of Act, see p. 3730

PUBLIC LAW 93-352; 88 STAT. 358

[S. 2893]

An Act to amend the Public Health Service Act to improve the national cancer program and to authorize appropriations for such program for the next three fiscal years.

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

TITLE I—EXTENSION OF CANCER PROGRAM

Sec. 101. This title may be cited as the "National Cancer Act Amendments of 1974".

Sec. 102. Section 402(b) of the Public Health Service Act ⁹⁶ is amended—

(1) by striking out "in amounts not to exceed \$35,000" in paragraph (1) and inserting in lieu thereof "if the direct costs of such research and training do not exceed \$35,000, but only"; and

(2) by striking out "in amounts exceeding \$35,000" in paragraph (2) and inserting in lieu thereof "if the direct costs of such research and training exceed \$35,000, but only".

Sec. 103. Section 407(b)(4) of the Public Health Service Act ⁹⁷ is amended by striking out "all data" and inserting in lieu thereof "information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer)".

Sec. 104. Section 407(b)(7) of the Public Health Service Act ⁹⁸ is amended by striking out "where appropriate".

Sec. 105. Section 407(b)(9)(A) of the Public Health Service Act ⁹⁹ is amended by inserting "(including an estimate of the number and type of personnel needed for the National Cancer Program)" after "budget estimate".

Sec. 106. Section 408(a) of the Public Health Service Act ¹ is amended by striking out "fifteen".

Sec. 107. (a) Subsection (a) of section 409 of the Public Health Service Act ² is amended by inserting before the period at the end thereof a comma and the following: "including programs to provide appropriate trials of programs of routine exfoliative cytology tests conducted for the diagnosis of uterine cancer".

(b) Subsection (b) of such section ³ is amended by striking out "and" before "\$40,000,000" and by inserting before the period at the end thereof a comma and the following: "\$53,500,000 for the fiscal year ending June 30, 1975, \$68,500,000 for the fiscal year ending June 30, 1976, and \$88,500,000 for the fiscal year ending June 30, 1977".

Sec. 108. Section 410 of the Public Health Service Act ⁴ is amended—

(1) by striking out "fifty" in paragraph (1) and inserting in lieu thereof "one hundred";

(2) by striking out "and" at the end of paragraph (7);

(3) by striking out the period at the end of paragraph (8) and inserting in lieu thereof "; and";

(4) by adding after paragraph (8) the following new paragraph:

"(9) to award grants for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program."; and

96. 42 U.S.C.A. § 282(b).

97. 42 U.S.C.A. § 286a(b)(4).

98. 42 U.S.C.A. § 286a(b)(7).

99. 42 U.S.C.A. § 286a(b)(9)(A).

1. 42 U.S.C.A. § 286b(a).

2. 42 U.S.C.A. § 286c(a).

3. 42 U.S.C.A. § 286c(b).

4. 42 U.S.C.A. § 286d.

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July 23

NATIONAL CANCER ACT

P.L. 93-352

(5) by inserting "(a)" after "410." and by adding after paragraph (9) the following new subsection:

"(b)(1) The Director of the National Cancer Institute shall provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer.

"(2) The Director of the National Cancer Institute shall include in the annual report required by section 410A(b) a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the National Cancer Program."

Sec. 109. Section 410C of the Public Health Service Act⁵ is amended by striking out "and" before "\$600,000,000" and by inserting before the period at the end thereof a semicolon and the following: "\$750,000,000 for the fiscal year ending June 30, 1975; \$830,000,000 for the fiscal year ending June 30, 1976; and \$985,000,000 for the fiscal year ending June 30, 1977".

Sec. 110. The part H of the Public Health Service Act⁶ relating to the appointment of the Directors of the National Institutes of Health and the National Cancer Institute is redesignated as part I, section 461 of such part is redesignated as section 471, and such part is amended by adding at the end the following new section:

"PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS"

"Sec. 472. (a) The Secretary, after consultation with the Director of the National Institutes of Health, and, where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse, shall by regulation require appropriate scientific peer review of—

"(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research; and

"(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute on Alcohol Abuse and Alcoholism, or the National Institute on Drug Abuse.

"(b) Regulations promulgated under subsection (a) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—

"(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research, and

"(2) by peer review groups performing such review on or before such date.

"(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States."

Sec. 111. Section 301(h) of the Public Health Service Act⁷ is amended by striking out "during the fiscal year ending June 30, 1968, and each of the eight succeeding fiscal years".

Sec. 112. (a) The first sentence of section 471 of the Public Health Service Act (as so redesignated by section 110)⁸ is amended to read as follows: "The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate; and the Director of the National Cancer Institute shall be appointed by the President."

(b) The amendment made by subsection (a) shall apply with respect to appointments to the office of Director of the National Institutes of Health made after the date of the enactment of this Act.

5. 42 U.S.C.A. § 286g.
6. 42 U.S.C.A. § 289l.

7. 42 U.S.C.A. § 241(h).
8. 42 U.S.C.A. § 289l.

Sec. 113. Section 601 of the Medical Facilities Construction and Modernization Amendments of 1970⁹ is amended by striking out "ending prior to July 1, 1974,".

TITLE II—BIOMEDICAL RESEARCH

Sec. 201. (a)(1) There is established the President's Biomedical Research Panel (hereinafter in this section referred to as the "Panel") which shall be composed of (A) the Chairman of the President's Cancer Panel (established under section 407(c) of the Public Health Service Act); and (B) six members appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to carry out the duties of the Panel. At least five of the members of the Panel shall be distinguished scientists or physicians. The appointed members of the Panel shall be appointed for the life of the Panel.

(2) The President shall designate one of the appointed members to serve as Chairman of the Panel.

(3) Appointed members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Panel; and while away from their homes or regular places of business in the performance of services for the Panel, all members of the Panel shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) of title 5 of the United States Code.

(4) The Panel may appoint and fix the pay of such personnel as it deems necessary to carry out its duties.

(b) The Panel shall—

(1) review and assess,

(2) identify and make recommendations with respect to policy issues concerning the subject and content of, and

(3) identify and make recommendations with respect to policy issues concerning the organization and operation of,

biomedical and behavioral research conducted and supported under programs of the National Institutes of Health and the National Institute of Mental Health.

(c)(1) Not later than the expiration of the 15-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office, the Panel shall submit simultaneously to the President and to the Congress a comprehensive report of (A) its findings made on the basis of the review and assessment conducted under clause (1) of subsection (b), and (B) the policy issues identified under clauses (2) and (3) of such subsection and the Panel's recommendations with respect to such issues.

(2) The Panel shall terminate upon the expiration of the 18-month period beginning on the first day of the first month that follows the date on which all of the appointed members of the Panel have taken office.

Approved July 23, 1974.

9. 42 U.S.C.A. § 201 note.

③ Patient Representation

① Oncology Advisory Cmt.

June 13-14 - met about 3 diff drugs. 3 X
3 diff reps.

② Other Cmt's - —

even Mtg has examined cancer
drug - has been patient rep

- Since then - a

④ IND's exemptions.

14 prior to

21 following ^{March 29} announcement.

Increased by 50% the number of IND's
we're requiring - ↓ paperwork for doctors.

that that I would suggest to the editors and the other opinionmakers here: that from time to time, maybe once a month, that message might come through.

NOTE: The President spoke at 2:56 p.m. in the Holiday Inn.

On the same day, the White House released a list of participants at the briefing.

223 Statement on the Death of Louis Armstrong. *July 6, 1971*

MRS. NIXON and I share the sorrow of millions of Americans at the death of Louis Armstrong. One of the architects of an American art form, a free and individual spirit, and an artist of worldwide fame, his great talents and magnificent spirit added richness and pleasure to all our lives.

NOTE: Mr. Armstrong, 71, died of a heart attack in his home in Corona, Queens, N.Y. He achieved worldwide fame as a jazz musician and trumpet player.

The statement was made available to the press on board Air Force One en route to San Clemente, Calif.

On July 9, 1971, Leonard Garment, Special Consultant to the President, represented the President at funeral services in New York City.

224 Statement Following Senate Approval of the Conquest of Cancer Bill. *July 7, 1971*

THE SENATE deserves the thanks of all Americans for its prompt bipartisan action today in passing the conquest of cancer act introduced by Senator Dominick and cosponsored by 67 Senators of both parties. This measure represents an important part of the "total national commitment" to an intensive campaign to find a cure for cancer that I called for in my State of the Union Message and in my special message to the Congress on a national health strategy. Another essential part of that commitment was the additional \$100 million I asked for cancer research. The Congress has already met that request, and I signed the bill on May 25.

But money alone will not be enough. The way we organize our work in this field is also extremely important. It was for that reason that on May 11, I proposed legislation to establish the cancer cure program that would be independently budgeted, with its Director responsible directly to the President.

Now that the Senate has acted on this program, I urge prompt agreement by the House of Representatives so that we can swiftly lengthen our strides against the dreaded ravages of cancer, bringing new hope to all Americans—and indeed bringing new hope to the world.

NOTE: The statement was released at San Clemente, Calif.

- Dr. Joe Hartford

- List - Philadeh

- Anna Meador's Bio

- Description of her current institution
children's hospital of Phil.

- Fox Chase -

- Univ of PA -

- Office of ^{Cancer} ~~Cancer~~ Survivorship -

- 2 page press release draft -

- mentioned in news -

- No official press relief -
2 page

- National Cancer Act. -

- 1937 - National Cancer Institute Act of 1937.

- Declaration of the war on cancer

- Fact that Director became a

direct Presidential appointee

- bypass budget

- ~~funding~~ Defined national cancer

{ program as being all activities
in gov't

Declaring a war on cancer — President Nixon did with that Act. —

- made cancer one of the nation's top priorities, December of 1971 —

Mandated expanded ~~coord~~ ^{plan and} develop NCI & related programs of other research Institutes, and other including

expanded,
intensified,
coordinated
research program. —

NAS — National Cancer Policy Board in Conjunction w/IDM, NRC —

- has been approved by all relevant

- NCI contract → funds for it will be drawn from NCI. —

Academy → Funded through federal sponsors. —

- Coordinating national cancer program — will include issues outside NCI

- Impact of Managed health care on research

- Confidentiality and genetic testing

- In the process of identifying someone to chair that. —

sponsorship of new Board from Public
and private organizations.

— Not more than 49% . —

— Not Cancer Advisory Board —

Initiated by Dr. Klausner

— brought on board President's Cancer Panel —

~~Eight~~ White reports —

— Marleen Wilson at NCI - Exec Sec of

President's Cancer Panel. —

— Three people - Meet 3-4 times year. —

President's Cancer Panel chart seen

1/21/88

e-mail
Chris

Burzynski is going to see The Pope!
Washington Times article tomorrow

FDA oncology initiative

① 2 Drugs) ① 5/14/96 Taxotere

Refractory (difficult to treat)
breast cancer

② 6/14/96
Camptosar - refractory
colorectal cancer

Approved on accelerated approval using
as an endpoint tumor shrinkage.

Since, March announcement, approved
two drugs on tumor shrinkage.

② Expanded Access Provision

Contacted 25 countries so far

14 responses

41 drugs that are not approved
in U.S.

- couple approvable / about to be approved
- 9 - no longer marketing - have advanced to another product
- 22 drugs that may

Rough Timeline → Appointment of Chair

Secured by Nov. 1

→ Appt. board by Dec. 15

- First mtg. of board by Jan 15.

- Public forum on Nat Cancer Policy
by March 1,

- National Transportation Board. —

- In response to oral request from NCI,
IOM commenced to set up Policy Board.

- Brings all stakeholders to the

- National Reading Advisory Board

THE WHITE HOUSE
WASHINGTON

OFFICE OF THE FIRST LADY

TO Elizabeth Dye

FROM Jennifer Klein

FAX # 6-7028

PHONE # _____

OF PAGES (including cover) _____

COMMENTS - Other pending ANNIVERS

PODESTA
associates, inc.

MEMORANDUM

Date: August 1, 1996
To: Debbie Fine
Cc: Elizabeth Drye, Jennifer Klein, Barbara Woolley
From: Tony Podesta
Subject: Cancer Research Event for the President

Cancer touches almost every American family.

The good news: Ten million Americans owe their lives directly to cancer research, according to the National Cancer Institute. Put another way, one out of every 10 Americans has a family member who is alive because of advances in the prevention, diagnosis, and treatment of cancer.

The bad news: More than 40 percent of us will develop cancer, and more than 20 percent of us will die of it. Soon cancer will surpass heart disease as the leading cause of death in the U.S.

The President has a strong record of support for cancer research and other cancer initiatives.

During his Administration, funding for the National Cancer Institute has totalled more than \$8 billion. The Institute's new director, Rick Klausner, is an energetic and highly respected leader in this field. Earlier this year the President announced (and won wide support for) a Reinventing Government initiative to enhance patient access to new cancer treatments under review by the FDA. (A description is attached.)

There is an opportunity this fall to announce new initiatives that will remind voters of what has been accomplished, and identify the President as a leader in the war against cancer.

- This is the 25th anniversary of the National Cancer Act, which gave the National Cancer Institute a mandate to comprehensively and energetically exploit new scientific leads in research and apply the results to improve methods of cancer detection, treatment, prevention and control.

- The NCI is establishing an **Office of Cancer Survivorship**. This new emphasis on cancer *survival* is an indicator of the progress that has been made through research over the last 25 years. The purpose of the new Office is to explore the research issues and consequences of cancer survivorship, involving scientific disciplines ranging from those involved with genetics and clinical trials to behavioral research and the quality of life. Survivorship issues for children and adults will be addressed -- including long-term and late side effects -- the physical/medical and psychosocial aspects of cancer survival. The new Office's programs will take advantage of existing programs and develop new research initiatives.
- Coordination of cancer research activities across all sectors, public and private, is vital to the success of the National Cancer Program. In working with the President's Cancer Panel, NCI Director Richard Klausner has developed a plan to create a **National Cancer Council**, a group that will represent a full range of public and private sector constituents with interest in the outcome of a national cancer effort, including researchers, voluntary organizations, the pharmaceutical industry, insurance and health care providers, professional organizations, and the public. The purpose is to identify ways to improve detection and treatment of cancer and share information more widely by working together and coordinating activities without any single institution's bias. For this reason, the National Academy of Sciences has been asked to implement the Council as an academy roundtable. This mechanism will catalyze and enable communication between the sectors on such critical issues as cancer screening, pain management, information dissemination, and achieving state-of-the-art detection and treatment.

We recommend that the President announce these initiatives and associate himself with the pioneering medical research in this field at an event at one of the nation's major cancer centers.

The cancer community is very well organized and has joined together to mark the 25th anniversary of the National Cancer Act with a series of public events. A presidential event could be structured and sited according to your guidance. Some suggestions follow:

WHAT: A short speech to a large group of researchers, cancer center employees, patients, families, and invited cancer survivors who have benefited from the results of research.

This could be preceded by a briefing and tour of the research facility, a visit with patients and/or survivors, or other media opportunity.

WHERE: Major cancer centers are located in virtually every state. A list is attached. Some examples of suitable sites in politically important states include:

- Fox Chase Cancer Center, Philadelphia, PA.
- University of Chicago Cancer Research Center, Chicago, IL.
- Barbara Ann Karmanos Cancer Institute, Detroit, MI.
- Kenneth Norris Jr. Comprehensive Cancer Center (or) Jonsson Comprehensive Cancer Center, Los Angeles, CA.

Attachment 1:**Remarks by Dr. David Kessler on White House cancer initiative, 3/29/96**

The four initiatives that the President announced today have a single significant meaning: American cancer patients from now on will have faster and easier access to more promising therapies. Here in a nutshell is the importance of each of the President's and the FDA's four proposals.

First, for patients with refractory, hard-to-treat cancer, instead of requiring evidence of clinical benefits, such as survival, FDA will rely on objective evidence of partial response, such as tumor shrinkage, as an initial basis for approval. This will allow us to rely on smaller, shorter studies for the initial approval of cancer drugs.

This accelerated procedure, which will be followed up by further studies on clinical safety and effectiveness in larger groups of patients, should and will simplify and speed up the evaluation and approval of drugs for advanced stages of solid tumors. Use of similar approaches to drug evaluation and review in our experience with AIDS therapies has been a powerful stimulus to the development of new and important agents, especially for people who need them most.

The second proposal, we will expedite the availability of promising medications that have been approved in certain other countries. If there is a promising drug approved in a foreign market, we will invite the manufacturer to submit to us the same information that made possible the approval abroad and whenever possible use it as a basis for making such therapy available under our expanded access programs to critically ill patients in this country.

Third, we will include representatives of cancer patients in FDA's cancer advisory committees and thereby make sure that their views are heard when it comes to recommending approval or nonapproval of cancer drugs.

And, fourth, we will eliminate unnecessary paperwork that used to delay or discourage cancer research by noncommercial, clinical investigators.

Two important points about these initiatives are of importance. First, they are designed to accomplish their aims without lowering FDA's high standards of drug safety and effectiveness, or reducing the amount of information available to patients and physicians. And second, they are not to be seen as one-time measures, but rather as part of a continuing FDA and administration effort to improve the quality and availability of drugs for all people with serious and life-threatening diseases.

Attachment 2:**NCI-Designated Cancer Centers*****Comprehensive Cancer Centers***

University of Alabama Comprehensive
Cancer Center
Birmingham, Alabama

University of Arizona Cancer Center
Tucson, Arizona

Jonsson Comprehensive Cancer Center
University of California at Los Angeles
Los Angeles, California

Norris Comprehensive Cancer Center
University of Southern California
Los Angeles, California

Yale University Comprehensive Cancer
Center
New Haven, Connecticut

Lombardi Cancer Research Center
Georgetown University Medical Center
Washington, D.C.

Sylvester Comprehensive Cancer Center
University of Miami Medical School
Miami, Florida

Johns Hopkins Oncology Center
Baltimore, Maryland

Dana-Farber Cancer Institute
Boston, Massachusetts

Barbara Ann Karmanos Cancer Institute
Detroit, Michigan 48201

University of Michigan Comprehensive
Cancer Center
Ann Arbor, Michigan

Norris Cotton Cancer Center
Dartmouth-Hitchcock Medical Center
Lebanon, New Hampshire

Roswell Park Cancer Institute
Buffalo, New York

Memorial Sloan-Kettering Cancer Center
New York, New York

Kaplan Comprehensive Cancer Center
New York University Medical Center
New York, New York

UNC Lineberger Comprehensive Cancer
Center
University of North Carolina School of
Medicine
Chapel Hill, North Carolina

Duke Comprehensive Cancer Center
Durham, North Carolina

Comprehensive Cancer Center of Wake
Forest University at the Bowman
Gray School of Medicine
Winston-Salem, North Carolina

Ohio State University Comprehensive
Cancer Center
Columbus, Ohio

Fox Chase Cancer Center
Philadelphia, Pennsylvania

University of Pennsylvania Cancer
Center
Philadelphia, Pennsylvania

University of Pittsburgh Cancer Institute
Pittsburgh, Pennsylvania

The University of Texas M.D. Anderson
Cancer Center
Houston, Texas

San Antonio Cancer Institute
San Antonio, Texas

Vermont Regional Cancer Center
University of Vermont College of
Medicine
Burlington, Vermont

Fred Hutchinson Cancer Research Center
Seattle, Washington

University of Wisconsin Comprehensive
Cancer Center
Madison, Wisconsin

Clinical Cancer Centers

University of California at San Diego
Cancer Center
San Diego, California

Irvine Clinical Cancer Center
University of California at Irvine
Orange, CA

City of Hope National Medical Center
Beckman Research Institute
Duarte, California

University of Colorado Cancer Center
Denver, Colorado

University of Chicago Cancer Research
Center
Chicago, Illinois

Robert H. Lurie Cancer Center
Northwestern University
Chicago, Illinois

Mayo Cancer Center
Rochester, Minnesota
Albert Einstein College of Medicine
Montefiore Medical Center
Department of Oncology
Bronx, New York

Columbia-Presbyterian Cancer Center
College of Physicians & Surgeons
Columbia University
New York, New York

University of Rochester Cancer Center
Rochester, New York

Ireland Cancer Center at Case Western
Reserve University
University Hospitals of Cleveland
Cleveland, Ohio

St. Jude Children's Research Hospital
Memphis, Tennessee

Huntsman Cancer Institute - Utah Cancer
Center
University of Utah Health Sciences
Center
Salt Lake City, Utah

Massey Cancer Center
Medical College of Virginia
Virginia Commonwealth University
Richmond, Virginia

Consortium Cancer Centers

Drew-Meharry-Morehouse Consortium Cancer Center
Nashville, Tennessee

Basic Science Cancer Centers

La Jolla Cancer Research Foundation
La Jolla, California

Armand Hammer Center for Cancer
Biology
Salk Institute
San Diego, California

Purdue Cancer Center
Purdue University
West Lafayette, Indiana

The Jackson Laboratory
Bar Harbor, Maine

Center for Cancer Research
Massachusetts Institute of Technology
Cambridge, Massachusetts

Eppley Institute
University of Nebraska Medical Center
Omaha, Nebraska

Cold Spring Harbor Laboratory
Cold Spring Harbor, New York

American Health Foundation
New York, New York

Wistar Institute
Philadelphia, Pennsylvania

Fels Research Institute
Temple University School of Medicine
Philadelphia, Pennsylvania

Cancer Center
University of Virginia Health Sciences
Center
Charlottesville, Virginia

McArdle Laboratory for Cancer
Research
University of Wisconsin
Madison, Wisconsin



Memorandum

Date: September 25, 1996

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

Subject: Follow-up to Questions raised in 9/25 Phone Call

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

Q. When will the Office of Cancer Survivorship be up and running?

A. As you know the Office has already been established and Dr. Meadows named to head it. A major purpose of the conference that will be held November 4,5 will be to gather input from the cancer research and survivor communities that will be used to formulate the research agenda for the OCS. The exact budget for OCS will be determined in the context of this agenda. I will note for your information that the agenda for the OCS will indeed be research relevant to survivorship. The OCS will be located in the NCI's Division of Cancer Treatment, Diagnosis, and Centers, the Director of which is Dr. Robert Wittes. The NCI has several existing mechanisms whereby cancer survivors can get information regarding their cancer and its impact on their lives. The Office of Cancer Communications (OCC) operates a cancer hotline (1-800-4-CANCER) and produces a large number of publications for consumers. The International Cancer Information Center (ICIC) manages an extensive WEB page and PDQ (Physicians' Data Query) which provides accurate, up-to-date information to patients/survivors through their doctors. Both OCC and ICIC are offices within the Office of the Director, NCI.

Q. What is the total budget of NCI?

A. I had said \$2.3B in FY96—\$2.25B would be a slightly better figure. As you are aware the FY97 for NCI has not been determined.

Q. What are the activities of the President's Cancer Panel (PCP) and how does these mesh with the activities foreseen for the National Cancer Policy Board (NCPB) within the National Academy of Sciences?

A. I am providing the following background information on the PCP for your information.

1. Names, addresses, and dates of appointment of the current PCP along with the address of Dr. Maureen Wilson of the Office of the Director, NCI who serves as Executive Secretary of the PCP.
2. Charter of the PCP.
3. Meetings of the PCP from July 1991 to those scheduled through November 1996 including topics of each of these meetings.
4. Statement from the PCP meeting of July 30, 1996 regarding the assessment of managed care's role in the war on cancer.
5. Schedule, venues, and topics for the remaining PCP meetings on managed care.
6. Report of a PCP Special Commission on Breast Cancer published in October 1993.
7. Report of the Chairman, PCP covering the period January 1, 1992 to January 31, 1994. Note on p. 2 of this document that the coordination of a "joint offensive against cancer" is a recommendation of the Chairman to the President. The NCPB is intended to address the issue of coordination by providing a venue for those who need to mount this "joint offensive."

Q. How much has been announced regarding the NCPB?

The draft press release that I sent to you yesterday has been provided to the PCP members and to members of the National Cancer Advisory Board (NCAB). The press release has not been released more broadly because we envisioned that the Secretary and/or President might wish to be involved in

the formal announcement of the formation of the NCPB. As I mentioned on the phone, the NCPB has been discussed in open meetings of the NCAB and two articles in very specialized publications have resulted. I enclose copies of the articles that appeared in The Blue Sheet on July 10, 1996 and in The Cancer Letter August 16, 1996. The latter article also has some commentary relevant to the previous question.

Please contact me if you have questions regarding any of the material provided.

With regard to your second phone call today, be assured that Dr. Klausner has made it very clear that discussions with your office are of a confidential nature. We will once again make this point with all involved parties. Please feel free to call either Dr. Klausner or me if you wish to discuss this matter further.



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

The President's Cancer Panel

Harold P. Freeman, M.D.
Director of Surgery
Harlem Hospital Center

Chairman
Appointment April 15, 1991 to
February 20, 1997

Frances M. Visco, Esq.
President
National Breast Cancer Coalition

Member
Appointment May 14, 1993-
May 14, 1996

Paul Calabresi, M.D.
Professor & Chairman, Emeritus
Department of Medicine
Brown University
Rhode Island Hospital

Member
Appointment May 1, 1995 -
February 20, 1998

Maureen O. Wilson, Ph.D.
National Institutes of Health
National Cancer Institute

Executive Secretary

President's Cancer Panel

Harold P. Freeman, M.D.

Director of Surgery
Harlem Hospital Center
Room 11-104
506 Lennox Avenue
New York, NY 10037

Chairman, President's Cancer Panel
Appointment April 15, 1991 to February 20, 1997
Secretary - Stephanie Harper

Phone: 212/939-3533

FAX: 212/939-3536

Frances M. Visco, Esq.

President
National Breast Cancer Coalition
200 South Broad Street
8th Floor
Philadelphia, PA 19102

Member President's Cancer Panel
Appointment May 14, 1993-May 14, 1996
Secretary: Bertha Adams

Phone: 215/731-1170 (Main # and Bertha)

215-731-1482 (Fran)

215-731-1582 (Jean Sachs/Dev Director)

Fax: 215/731-1174

Washington D.C. Office:

Phone: 202/296-7477

Fax: 202/265-6854

Paul Calabresi, M.D.

Professor & Chairman, Emeritus
Department of Medicine
Brown University - Aldrich 138
Rhode Island Hospital
593 Eddy Street
Providence, Rhode Island 02902

Member President's Cancer Panel
Appointment May 1, 1995 - February 20, 1998
Secretary: Patti Jensen

Phone: 401/444-8977

Fax: 401-444-8483

Maureen O. Wilson, Ph.D.

Assistant Director
National Cancer Institute
9000 Rockville Pike
Building 31 Room 4B43
Bethesda, Maryland 20892

Executive Secretary
President's Cancer Panel
Secretary: Nora Winfrey

Phone: 301-496-1148

Fax: 301-402-1508



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

PRESIDENT'S CANCER PANEL

Purpose

The National Cancer Act of 1971 (Public Law 92-218) and the Health Research Extension Act of 1985 (Public Law 99-158) enlarged the authorities of the National Cancer Institute and the National Institutes of Health, in order to advance the national effort against cancer by conducting and supporting research with respect to the cause, diagnosis, prevention and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and also the families of cancer patients under Title IV, Part A, Public Health Service Act (42 U.S. Code 281 et seq). The statutory responsibility of the President's Cancer Panel is to appraise the National Cancer Program.

Authority

42 U.S. Code 285a-4; Section 415 of the Public Health Service Act, as amended. This Panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Function

The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President.

Structure

The President's Cancer Panel shall consist of three persons appointed by the President, who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two of the members of the Panel shall be distinguished scientists or physicians. Members shall be appointed for three-year terms. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred. The President shall designate one of the members to serve as Chair for a term of one year. The Chair may serve until a successor has been appointed.

Management and support services shall be provided by the Office of the Assistant Director, National Cancer Institute.

Meetings

Meetings shall be held not less than four times a year, at the call of the Chair with the advance approval of a Government official who shall approve the agenda.

A Government official shall be present at all meetings. Meetings shall be open to the public except as determined otherwise by the Secretary; notice of all meetings shall be given to the public.

A transcript shall be kept of the proceedings of each meeting of the Panel, and the Chair shall make such transcript available to the public.

Compensation

Members who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the duties of the Panel compensation at rates not to exceed the daily equivalent of the annual rate in effect for Executive Level IV of the General Schedule, including travel time; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by Section 5703, Title 5, U.S.C., for persons in the Government service employed intermittently.

Annual Cost Estimate

Estimated annual cost for operating the Panel, including compensation and travel expenses for members, but excluding staff support, is \$47,501. Estimate of annual person-years of staff support required is .8, at an estimated annual cost of \$52,367.

Reports

The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

In addition, an annual report shall be prepared not later than December 31 for submission to the Secretary through the Assistant Secretary for Health and the Director, National Institutes of Health, which shall contain, as a minimum, the Panel's functions, a list of members and their business addresses, the dates and places of meetings, and a summary of the Panel's activities and recommendations during the year. A copy of the report shall be provided to the Department Committee Management Officer.

Duration

Continuing (unless renewed by appropriate action prior to its expiration, the charter for the President's Cancer Panel will terminate May 31, 1996).

APPROVED:

JUN 27 1994

Date

Don E. Shala
Secretary

PRESIDENT'S CANCER PANEL MEETINGS

1991 - 1994

July 9, 1991	NIH - Bethesda, MD Cancer and Poverty
September 20, 1991	Morehouse College of Medicine - Atlanta, GA Training and Science
December 9, 1991	M.D. Anderson - Houston, TX Breast Cancer Research: Progress and New Perspectives
February 21, 1992	University of California, SF - San Francisco, CA Cancer Research and Technology Transfer in the 1990's: Old Tools, New Tools
June 8, 1992	American Health Foundation - New York, NY Cancer in Minority Populations: Opportunities and Obstacles
October 5, 1992	NIH - Bethesda, MD The Role of Voluntary Organizations in the National Cancer Program
November 13, 1992	NIH - Bethesda, MD Prostate Cancer
April 1, 1993	University of California, SF - San Francisco, CA Breast Cancer Specialized Program of Research Excellence (SPORE) at the University of California, San Francisco and the Relationship with Area Breast Cancer Patient Organizations
July 30, 1993	Preceding American Cancer Society Meeting - LaJolla, CA Cancer and the Family
September 22, 1993	NIH - Bethesda, MD Evaluating the National Cancer Program: An Ongoing Process
November 15, 1993	La Guardia Hotel, New York Cancer Statistics and Related Issues
January 30, 1994	NIH - Bethesda, MD The Role of Government Agencies in the National Cancer Program
April 7-8, 1994	Holiday Inn, Bethesda, MD Avoidable Causes of Cancer
October 5, 1994	Holiday Inn, McLean, VA Lung Cancer: Clinical, Societal and Governmental Challenges
November 30, 1994	San Francisco Hilton and Towers, San Francisco, CA Cancer and Cultures of America

PRESIDENT'S CANCER PANEL MEETINGS

1995 - 1996

March 28, 1995	Bethesda, MD The Human Genome Project
June 6, 1995	Bethesda, MD Health Communications: The Information Superhighway
July 20, 1995	Chicago, IL Progress in Leukemia
September 15, 1995	University of Maryland, Baltimore Campus AIDS Neoplasms
July 30, 1996	Fred Hutchinson Cancer Center, Seattle, WA Where Are We Today -- Existing Problems For Health Care Research In Today's Environment
September 24, 1996	San Antonio, TX Issues Of Access In Today's Health Care Environment/Managed Care And The Provision Of Services
October 25, 1996	Rhode Island Hospital, RI Issues In Translational Research/The Crisis And Solutions For Phase I Trials And Associated Issues
November 22, 1996	Duke University, Durham, NC Coping Strategies For Maintaining Outreach, Information Dissemination, Teaching, Recruitment And Care -- The Changing Face Of The Stand-Alone And State-Supported Institution

PRESIDENT'S CANCER PANEL

AGENDA - 1996

OVERALL TITLE: **Managed Care's Role In The War On Cancer**

THEME: ***Bringing Cancer Advances To The Public – How Has The Changing Health Care Environment Affected The Stages Of Research And Development And Delivery*** (A series of four meetings)

July 30, 1996 Seattle, Washington
[OPEN TO THE PUBLIC]

Where Are We Today – Existing Problems For Health Care Research In Today's Environment

Host: Robert Day, M.D., Director, Fred Hutchinson Cancer Center

Lay out the issue: Maintaining the capacity of clinical investigators to conduct research, expand outreach activities, research dissemination, and improve geographic availability of quality health care nationwide.

Location: Fred Hutchinson Cancer Center, Seattle

Sept. 24, 1996 San Antonio, Texas
[OPEN TO THE PUBLIC]

Issues Of Access In Today's Health Care Environment/Managed Care And The Provision Of Services

Host: Charles Coltman, M.D., Chairman, SWOG

Lay out the issue: Focus on access to include health care academic, patient, provider and Federal groups. Focus on the Southwest.

Location: San Antonio Convention Center

Oct. 25, 1996 Providence, Rhode Island
[OPEN TO THE PUBLIC]

Issues In Translational Research/The Crisis And Solutions For Phase I Trials And Associated Issues

Host: Donald Marsh, M.D., Dean of the Brown University Medical School, Brown University/Rhode Island Hospital

Lay out the issue: Research, health care and industrial organizations - coping and strategizing in the Northeast.

Location: Rhode Island Hospital

Nov. 22, 1996 Raleigh, North Carolina
[OPEN TO THE PUBLIC]

Coping Strategies For Maintaining Outreach, Information Dissemination, Teaching, Recruitment And Care – The Changing Face Of The Stand-Alone And State-Supported Institution.

Host: Barbara Rimer, M.D., Director, Cancer Prevention, Detection and Control Research, Duke University. [Coordinator - Rita Beskie]

Lay out the issue: Traditional clinical research institutions are facing tremendous changes in their ability to accomplish a research and public health service mission. What are these changes and how are institutions adapting. Who will fill the gap? Issues affecting the Mid Atlantic and South Eastern portion of the Nation.

Location: Duke University

PRESIDENT'S CANCER PANEL

National Cancer Program - National Cancer Institute

Chairman
Harold P. Freeman, M.D.
Harlem Hospital Center

Frances M. Visco, J.D.
National Breast Cancer Coalition

Paul Calabresi, M.D.
Brown University
Rhode Island Hospital

Executive Secretary
Maureen O. Wilson, Ph.D.
Assistant Director
National Cancer Institute
Building 31, Room 4A48
Bethesda, Maryland 20892

PHONE: 301-496-1148
FAX: 301-402-1508

August 5, 1996

STATEMENT FROM THE PRESIDENT'S CANCER PANEL MEETING TO ASSESS MANAGED CARE'S ROLE IN THE WAR ON CANCER

Where are we today?

Existing problems for cutting edge clinical research in today's environment.

July 30, 1996

"Increased penetration of managed care into the health care system in the United States presents both a problem and an opportunity for cancer care." This was the conclusion articulated by Dr. Harold Freeman, Chairman of the President's Cancer Panel, following a day of presentations by representatives of California, Oregon, and Washington Academic Health Centers, Community Clinical Oncology Programs, and managed care organizations. The July 30 meeting, which continued a constructive dialog between researchers and managed care institutions opened by the National Cancer Institute, was the first in a series of four meetings designed to explore how to maintain the capacity of clinical investigators to conduct cancer research, expand outreach activities and research dissemination, and improve geographic availability of quality cancer care nationwide in today's changing health care delivery environment. The meeting was held at the Fred Hutchinson Cancer Center in Seattle, Washington. The Panel is a three-member, Presidentially appointed advisory committee that meets regularly to assess the effectiveness of the National Cancer Program.

Declared in 1971, the "war on cancer," waged in part through patient access to clinical trials, has resulted in a substantially improved outlook for cancer patients. The President's Cancer Panel believes that Federal funding constraints and the impact of managed care on drug development, translational research, and clinical research threatens this outlook. The explosion in managed care is profoundly changing not only the way that medical services are delivered, but the way in which clinical research is conducted. This belief was supported by testimony heard at the July 30 meeting by Panel members and by Dr. Richard Klausner, Director, National Cancer Institute. Dr. Freeman acknowledged that "managed care has succeeded in controlling costs, but, in doing so, has brought about the rise of other problems. A medical care system which is predominantly driven by the marketplace rather than by concerns for human benefit raises significant social, moral, and ethical questions related to advancing research and providing quality patient care."

Recurrent themes emerging from the day's discussions revealed both the "problem" and "opportunity" aspects of managed care. The managed care system, it was confirmed, is fully present and continues to be on the rise in the West and Northwest. Clinical trials are being affected. The research questions

that are being asked are based on managed care's response-when no reimbursement is provided for experimental therapies, the type and number of patients that get into a trial are changed; the type of clinical trial that is conducted is changed; and the speed of the trial is changed. Dr. Freeman expressed the Panel's fear that the cost of research will be shifted to patients who can afford it. He said that this would limit our ability to know how research results would impact all patients and that "this must not be allowed to happen."

Certain valuable consequences have accompanied the managed care movement. Clinical researchers, agreeing that managed care is very likely here to stay, have accepted that they will be asked to provide more evidence of the added value and relevance of clinical trials to the health care delivery system. Approval from third party payers will depend, in large part, on well-thought-out, scientifically efficient, and cost-effective studies that propose to answer specific questions. This fact has forced a streamlining of study protocols and an elimination of some costly tests for protocol patients. Partnerships have been formed and collaborative efforts undertaken by cancer centers, insurers, physicians, and drug and biotech companies to reduce duplicative studies and resource depletion.

Some needs became evident from the day's discussions. The cancer research community, in its effort to educate the public, patients, insurers, providers, and lawmakers about the real value of supporting clinical research have heretofore relied, to a large extent, on anecdotal data; hard data are needed. It is not enough, for example to say that patients are not entering into protocols; reasons for non-participation must be monitored and supported by data. Outcome and cost data are critical for contracts. Once information is available, improved techniques for disseminating that information are needed to allow immediate sharing of information across specialties, between physician and patient, and with the public. The results of research must be brought quickly to the bedside; it is difficult to convince the public of the significance of results when information is lacking.

Future meetings of the President's Cancer Panel to assess the impact of managed care on the war on cancer will focus on several major issues: standardization of language across all concerned parties, including a definition of managed care and a rearticulation of the definition of clinical research and what constitutes the various phases of clinical trials; the differential cost of delivering managed care versus traditional care; whether or not patients' access to clinical trials should be mandated and become "standard" care; the impact on the quality of care of increasing outpatient care versus inpatient care; who will assume responsibility for payment for patients on clinical trials; and whether there are there existing paradigms to guide the future direction of cancer research as it faces a changing health care delivery environment. The next meeting of the President's Cancer Panel is scheduled to be held in San Antonio, Texas, on September 24, 1996.

Speaking for the National Cancer Institute, Dr. Richard Klausner, Director, said that, for its part, the NCI must evaluate its own efficiencies before it can ask or expect cancer centers to be efficient. The process of examination has been set in motion, he said.

In a final concluding remark, President's Cancer Panel Chairman, Dr. Harold Freeman, observed that the American public is fickle. While it demands low-cost health care, it will tolerate neither low-quality care nor lack of access to the most advanced care. The question arises whether, in time, the system will be accepted as a growing number of sick patients experience the effects of managed care. In the final analysis, these factors may determine the future form or existence of the managed care system.

PODESTA

associates, inc.

Memo

Date: September 12, 1996

To: Elizabeth Drye

From: Tony Podesta

Subject: Cancer Research Event for the President

Here's a shorter summary of our scheduling request:

WHAT IT WOULD LOOK LIKE: Pictures of the President visiting patients and/or researchers in federally funded trials of new cancer treatments, and/or signing the National Coalition of Cancer Survivors' "Ribbon of Hope," **followed by** remarks to an audience of researchers, cancer center employees, patients, and cancer survivors who have benefited from the results of research.

WHERE IT WOULD BE: Major cancer centers throughout the country are eager to host the President. We'd love to have him in Philadelphia. Other attractive locations include Georgetown and Yale and these cities: Los Angeles, Miami, Detroit, New York, Houston, Tucson, AZ, and Columbus, OH.

WHAT HE WOULD SAY: Cancer research is the kind of program all Americans want the government to support, but **its future may be jeopardized by Republican budget cuts if the Dole tax plan is enacted.**

In the 25 years since President Nixon declared war on cancer, we have made some dramatic gains. Death rates from children's cancers have declined by almost two-thirds. But we haven't "cured" cancer. Research offers that promise.

New research has begun to identify the genetic keys to the disease. Now the National Cancer Institute (part of NIH) is launching a project that will enable doctors to identify the specific cancer genes within tumors and to target their treatment accordingly. Breakthroughs like these depend on continued support of research.

WHY HE SHOULD DO IT: Cancer kills one out of every five Americans. Every voter knows someone who has cancer -- usually in their own family. The President has a strong record of support for cancer research and other cancer initiatives. This issue, on the 25th anniversary of the National Cancer Act, provides another chance to dramatize the risk of electing Bob Dole and his team of budget cutters.

THE WHITE HOUSE
WASHINGTON

September 24, 1996

MEMORANDUM FOR DON BAER

FROM: Elizabeth Drye
Debbie Fine

SUBJECT: Potential Cancer Event

This memo provides further background for a potential POTUS event celebrating the 25th Anniversary of the National Cancer Act (NCA). It assumes the President will announce the National Cancer Institute's (NCI's) new Office of Cancer Survivorship (OCS) and perhaps report on progress implementing the FDA cancer initiative he announced in March. The memo summarizes the history of the NCA; describes the OCS; lists three potential event sites; and provides an update on FDA's cancer initiative. It also discusses a third possible component for the event -- the announcement of a new National Cancer Policy Board at the National Academy of Sciences.

National Cancer Institute and National Cancer Act

President Roosevelt signed the National Cancer Institute Act in 1937, establishing the NCI. The law mandated the new institute "to provide for, foster, and aid in coordinating research relating to cancer."

President Nixon signed the NCA on December 23, 1971. His statement on the bill, attached, notes that he had called for the legislation in his January '71 State of the Union address. In July of '71 Congress also approved his request to dramatically increase NCI's budget by \$100 million (to \$337.5 million). The NCA, among other things:

- made the NCI Director a presidential appointee and expanded the Director's mandate;
- established two advisory boards appointed by the President;
- initiated the **National Cancer Program**, calling on NCI's Director to "plan and develop and expanded, intensified, and coordinated cancer research program encompassing . . . NCI research, related programs of other research institutes, and other Federal and non-Federal programs;
- authorized the first cancer centers; and
- required NCI to submit its budget directly to the President.

Nixon noted in his statement that these provisions "place the full weight of the Presidency behind the national cancer program . . . the President will be able to take personal command of the Federal effort to conquer cancer."

Office of Cancer Survivorship (OCS)

NCI is establishing the OCS to conduct research on the full range of concerns affecting this country's 10 million cancer survivors. This new emphasis on cancer survival is an indicator of the progress we have made in the last 25 years. The center will conduct research on and help survivors cope with, for example:

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

NCI has chosen the new OCS director, Anna T. Meadows, M.D., and has announced her selection. She is currently Director of the Oncology program at the Children's Hospital in Philadelphia (bio attached). NCI has not yet defined a research agenda for the office or opened its doors. NCI is convening a meeting of experts in November to help set the research agenda. We're checking with NCI to see if the President could announce a date for the opening.

Possible Sites

Attached are one-page descriptions of each of three possible sites.

- 1) The Children's Hospital of Philadelphia -- probably the most promising. The new OCS Director currently runs the Oncology program there. The Hospital placed second among all pediatric hospitals in U.S. News and World Report's 1995 physician's rating.
- 2) The University of PA Cancer Center -- a 23-year NCI-designated "comprehensive cancer center," 1 of 27 nationwide.
- 3) The Fox Chase Cancer Center -- a 22 year old facility, and also 1 of 27 comprehensive cancer centers.

Update on FDA Oncology Initiative

In March, 1996, the President announced that FDA would take four steps to speed development and availability of cancer drugs. We can report some, although not dramatic, progress in each of these areas.

- 1) FDA is speeding approval of cancer drugs by using tumor shrinkage as a surrogate endpoint. **FDA has approved 2 new drugs under this program since March -- Taxotere, for breast cancer, and Camaptosar, for colo-rectal cancer.** (The drugs were on an accelerated-approval schedule prior to the March announcement).
- 2) FDA pledged to expand access to experimental cancer drugs approved in other countries by encouraging manufacturers to seek U.S. approval. **FDA has contacted 25 countries to**

identify promising drugs. FDA is reviewing drugs identified by 14 countries. FDA has not yet actually increased access to drugs through this program.

3) FDA committed to place patient representatives on all advisory committees reviewing cancer drugs. FDA has fully met this commitment.

4) FDA pledged to expand investigational new drug (IND) exemptions to reduce paperwork for doctors. FDA has increased the number of IND exemptions awarded by 50%.

Possible Announcement of National Cancer Policy Board

At the request of the NCI, the President's Cancer Panel, and the National Cancer Advisory Board (also appointed by the President), the National Academy of Sciences (NAS) is establishing a National Cancer Policy Board. The Board would bring together public and private research and advocacy groups to make recommendations on the nation's cancer policy. The Board will look not just at NCI's programs but at broad cancer policy issues such as insurance and privacy issues, manpower needs, payment for clinical trials, smoking policy, etc. It will help implement the National Cancer Act's intent that this country have a National Cancer Program, not just a research-based cancer agenda. NAS is planing to appoint the chair by Nov. 1, name the members by Dec. 15, and hold the first meeting in January. Like other NAS boards, it is expected to be permanent.

Please let us know if we should explore announcing the National Cancer Policy Board further.

Attachments

Fax Transmittal

Office of the Director National Cancer Institute

Date: September 24, 1996

To: Elizabeth Drye

Fax No. 202-456-7028

From: Dr. Joe Hanford

Bldg. 31; Room 11A 03
National Cancer Institute, Bethesda, Maryland 20892

Fax No. 301-402-0338 Telephone No. 496-5615

or

Fax No. 301-456-6005

Cover Sheet Plus 1 Pages Transmitted

Additional Comments:

Please replace the attached memo with the copy you received earlier. The only change on the memo is the "subject".

Thank you.

NATIONAL
CANCER
INSTITUTE



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.



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)

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PODESTA

associates, inc.

CONFIDENTIALITY NOTICE: This communication is intended for the addressee. Distribution, reading, copying or use of this communication by anyone other than the addressee is prohibited and may be unlawful. If you received this in error please call 202-393-1010 and inform our receptionist.

FACSIMILE TRANSMISSION

TO: ELIZABETH DRYE

FAX #: 456-7028 CODE: 202

DATE & TIME: 9/12, 230 P

FROM: REID DETCHON / TONY PODESTA

NUMBER OF PAGES INCLUDING COVER SHEET: ✓

MESSAGE

PODESTA

associates, inc.

Memo

Date: September 12, 1996

To: Elizabeth Drye

From: Tony Podesta

Subject: Cancer Research Event for the President

Here's a shorter summary of our scheduling request:

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WHERE IT WOULD BE: Major cancer centers throughout the country are eager to host the President. We'd love to have him in Philadelphia. Other attractive locations include Georgetown and Yale and these cities: Los Angeles, Miami, Detroit, New York, Houston, Tucson, AZ, and Columbus, OH.

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New research has begun to identify the genetic keys to the disease. Now the National Cancer Institute (part of NIH) is launching a project that will enable doctors to identify the specific cancer genes within tumors and to target their treatment accordingly. Breakthroughs like these depend on continued support of research.

WHY HE SHOULD DO IT: Cancer kills one out of every five Americans. Every voter knows someone who has cancer -- usually in their own family. The President has a strong record of support for cancer research and other cancer initiatives. This issue, on the 25th anniversary of the National Cancer Act, provides another chance to dramatize the risk of electing Bob Dole and his team of budget cutters.

Fax Transmittal

**Office of Cancer Communications
Office of the Associate Director**Building 31, Room 10A31
Bethesda, Maryland 20892301-496-6631
Fax 301-402-4945**NATIONAL
CANCER
INSTITUTE**

Date 9/11/96
To Elizabeth Dye
Fax Number 202-456-7023 7431
From Dr. Klausner
Cover 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.]

Item #1

Office of Cancer
CommunicationsBuilding 31, Room 10A24
Bethesda, Maryland 20892

For Response to Inquiries

NATIONAL
CANCER
INSTITUTE

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

Mtg
Scheduled
for
November

(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:

25th Anniversary of National Cancer Act

2014-0046-S

rc1445

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.

(002] Born in (b)(6) Meadows is a 1969 graduate of the Medical College of 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.

#

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 (dial 301-402-5874 from the handset on your fax machine).

THE WHITE HOUSE
WASHINGTON

September 18, 1996

MEMORANDUM FOR: CAROL RASCO
BRUCE REED
DON BAER
DOUG SOSNIK
ALEXIS HERMAN
KAREN HANCOX
BILL CURRY

FROM: Elizabeth Drye
Debbie Fine

SUBJECT: Proposal for POTUS to Visit Cancer Center

- 100 million helped by research
- 7 million live from survivors
- 1/5 deaths are from cancer
- Progress in 25 years -
62% ↓ in death rates from
childhood cancers

- Vision - bridge to 21st Century
- Not Partisan

Paul Neville

This year marks the 25th Anniversary of the National Cancer Act, which gave the National Cancer Institute a mandate to pursue new scientific leads in research and apply the results to improve methods of cancer detection, treatment, prevention and control.

Several groups in the private sector have formed a coalition to raise public awareness about the importance of cancer research in honor of this Anniversary. This coalition and the National Cancer Institute have both approached us to request a Presidential event commemorating the Act's 25th anniversary in the next couple of months. Tony Podesta has been representing the private sector coalition, which consists of the American Cancer Society, National Breast Cancer Coalition, American Nurses Association, survivors, researchers and others.

Below for your consideration is a potential Presidential event on the road or in DC in the near future. If you think it's worth pursuing, we will draft a formal scheduling proposal. We would like to get back to Tony Podesta by next week if possible with a sense of whether or not this is a possibility.

SUGGESTED PROPOSAL

1. The President could visit one of the major cancer centers, which are located all over the country. There he could make remarks to patients, researchers, cancer center employees, and cancer survivors on his accomplishments and agenda for the future. Prior to remarks, the President could also tour the facility and/or sign the National Coalition of Cancer Survivors' "Ribbon of Hope." (The

"Ribbon of Hope" is similar to the AIDS quilt in its symbolism; it travels all over the country for people to sign as an expression of hope and concern. At the outset of its tour approximately one year ago, the First Lady signed it. It is due to be put on display in Albuquerque at the annual meeting of the National Coalition of Cancer Survivors October 4-6.)

2. Podesta also suggested the President deliver remarks at the Nina Hyde Breast Cancer dinner on the evening of September 24th in Washington D.C.

SUGGESTED MESSAGE

- In the 25 years since passage of the Cancer Control Act, we have made dramatic gains. Death rates from children's cancers have declined by almost two-thirds. Today, 10 million Americans owe their lives directly to cancer research.
- But cancer still kills one out of every five Americans. This year nearly 1.4 million people in the U.S. will be diagnosed with cancer, and more than 550,000 people will die of cancer--more than 1,500 people a day. Research offers tremendous promise to improve survival rates.
- President Clinton has a strong record of support for cancer research and other cancer initiatives. Review record of accomplishment, specifically touching on FDA's cancer initiative, breast cancer research, the tobacco initiative (smoking is the cause of over 30% of cancer deaths), etc.
- Under President Clinton's leadership, the Administration is continuing to build on that record with several initiatives that will help us as we move into the 21st century. See attached for specific potential announcements of NCI activities.

COURSE OF ACTION

1. Would you support consideration of an event commemorating the 25th Anniversary of the Cancer Control Act?

✓ YES NO

Bill Curry

cc: Jennifer Klein
Barbara Woolley

POTENTIAL CANCER INITIATIVES FOR POTUS TO HIGHLIGHT/ANNOUNCE

NCI has initiatives underway to:

1. **Identify the keys to each cancer.** NCI's **Cancer Genome Anatomy Project** will speed cancer detection and improve treatment by helping doctors quickly identify specific cancer genes within tumors. Under the project, NCI is building a complete index of genes expressed as tumors and is investing in developing technologies that can identify these genes in minutes.

#3
Gene
Characterization

Status: NCI has announced to scientific community.

2. **Speed the approval and use of new treatments.** NCI's **Informatics Initiative** will link NCI, the FDA, and public and private research centers throughout the nation to provide instant access to the latest data and support FDA's new drug approval process.

Status: NCI has not formally announced; known to scientific community.

3. **Develop novel, targeted drug therapies.** NCI is supporting the development of cancer cell-specific viruses and other novel therapies that carefully target cancer cells and better spare healthy cells.

Status: NCI has not formally announced; known to scientific community.

4. **Expand veterans' access to clinical trials of cutting-edge therapies.** NCI has crafted an agreement with the VA to increase veterans' participation in and speed completion of clinical trials. NCI announced a similar arrangement for DoD beneficiaries earlier this year. NCI will work to bring private insurers into the initiative.

Status: VA agreement is ready and has not been announced.

5. **Build collaboration.** NCI has catalyzed and will help underwrite the creation of the National Cancer Policy Board. Modeled on the National Academy of Sciences, the board will bring together many sectors of society -- including business, government, doctors, and advocacy groups -- to debate cancer policy issues affecting the nation (e.g. tobacco control and regulation of environmental toxins).

Status: NCI has announced to scientific community.

Mary McCabe worksto
- Bob witness

Survivorship

started months ago

Consumer Advisory Panel
~~Committee~~

Has started

- In the process of inviting advocates -

- Directors Consumers Liaison group to meet
w/ Klausner Liaison group -

- Months ago -

- Eleanor has advisory group to her
for her office -

- Consumer Advisory Panel -

Office of Cancer Survivorship

Anna Meadows - Children's Hospital in PA
Part time at NCI now -

known to
Cancer
Community

Research agenda - Advocates/Divisions
[will meet in November

Klausner has announced at a number
of meetings - advocacy groups

VA -

Head of Oncology, Children's Hospital -

Contact

- Anna Meadows U PA -
- descriptions
of venues

- Joe Hartford - NCI -
301-496-5534

- Harvo
 - Victor - 69a 6343
 - Joe Harford
- man

~~XXXXXXXXXX~~

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Schneeman

- Schneeman -

Don what are we commemorating

what action ~~we want~~ POTUS would announce

where

opening date. —

THE WHITE HOUSE
WASHINGTON

SEP 18 1996

September 18, 1996

MEMORANDUM FOR: CAROL RASCO ✓
BRUCE REED
DON BAER
DOUG SOSNIK
ALEXIS HERMAN
KAREN HANCOX
BILL CURRY

FROM: Elizabeth Drye
Debbie Fine

SUBJECT: Proposal for POTUS to Visit Cancer Center

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Several groups in the private sector have formed a coalition to raise public awareness about the importance of cancer research in honor of this Anniversary. This coalition and the National Cancer Institute have both approached us to request a Presidential event commemorating the Act's 25th anniversary in the next couple of months. Tony Podesta has been representing the private sector coalition, which consists of the American Cancer Society, National Breast Cancer Coalition, American Nurses Association, survivors, researchers and others.

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COURSE OF ACTION

1. **Would you support consideration of an event commemorating the 25th Anniversary of the Cancer Control Act?**

☒ **YES** ☐ **NO**

cc: Jennifer Klein
Barbara Woolley

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Status: NCI has announced to scientific community.

Mary Beth Donahue

- Klausener proposal on VA-NCI agreement. —
- 620 5923

PODESTA

associates, inc.

Memo

Date: September 10, 1996

To: Elizabeth Drye

From: Tony Podesta

Subject: Cancer Research Event for the President

Post-It [®] Fax Note 7671		Date 9/10/96	# of pages 5
To Elizabeth Drye	From Tony Podesta,		
Co./Dept.	Michelle Ballentine		
Phone # 456-7028	Phone # 879-9306		
Fax #	Fax #		

Attached is a slightly revised version of the memo I sent over last month for the President's calendar. I've spoken to Bill Curry and a number of others about it since then. This would be an excellent "message of the day" event for the President. I'd be happy to do it in Philadelphia, but the other cancer centers are champing at the bit for the opportunity themselves. Please call me or Reid Detchon if you have any questions or comments.

Klausner 9/10/96

~~Many Goodhouse program~~

- ① New Technologies (announced last week to Scientific community)
 - Finally know the nature of each cancer
 - Cancer genome anatomy project —
 - Soon we will know every gene that determine cancer.

Informatics initiative went to Board.
Treatments — — targeted. — For the first time, putting together all designated cancer centers — linking people together linking 9,000 physicians involved in cancer research

patients /
— beginning —

Access — DOD — refer military families
VA — treatment choices. —

Society Working together — Teachers, Bus. &

— Council —
- NRC —
- NAS —
- NCI > Joint w/ private organization
w/ a common

Bringing together stakeholders to address

Analogous to national academies of sciences —
bring together people

- manpower needs
- technical
-

Fax Transmittal

Office of the Director National Cancer Institute

Date: 9/17/96

To: Elizabeth Dye

Fax No. 202-456-7028

From: Dr. Richard Klausner

Bldg. 31; Room 11A48

National Cancer Institute, Bethesda, Maryland 20892

Fax No. 301-402-0338

Telephone No. 496-5615

or

Fax No. ~~301-496-6005~~

Cover Sheet Plus 5 Pages Transmitted

Additional Comments:

NATIONAL
CANCER
INSTITUTE

DRAFT

INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF VETERANS AFFAIRS AND THE NATIONAL CANCER INSTITUTE FOR A PARTNERSHIP IN CLINICAL TRIALS FOR CANCER

INTRODUCTION

The National Cancer Institute (NCI) sponsors and actively coordinates an extensive clinical trials program for the evaluation of therapy in a wide range of cancers. The NCI's program includes sponsorship of studies of treatments in single institutions, as well as large, multicenter randomized trials in cooperative networks. The trials encompass studies of cancers occurring in virtually all anatomical sites and in all stages of disease. The NCI clinical trials program has been the means by which the oncology community has developed most of the formal evidence for the clinical efficacy of the various treatment approaches in human cancer. More recently the NCI has developed an extensive program in cancer prevention, and a variety of interventions are under study in prospective trials carried on in multicenter and single center settings. NCI is also anticipating a major expansion in its programs in diagnostic imaging and molecular diagnostics relating to cancer.

The Department of Veterans Affairs (VA) has responsibility for the health care of veterans of the US Armed Forces. In furtherance of this goal it operates an extensive health-care delivery system that includes 171 medical centers (about 80,000 beds) and more than 360 clinics; the outpatient services of the VA register about 23 million visits a year. There is at least one VA medical center in each of the 48 contiguous states, Puerto Rico, and the District of Columbia. Approximately 2.7 million individual veterans receive care in this system annually.

The VA medical system has substantial expertise in the diagnosis and management of cancer and has currently designated or proposed 56 institutions as comprehensive cancer centers. In addition to health-care delivery, the VA has had a longstanding commitment to clinical research. For several decades the VA's Cooperative Studies Program (CSP) has sponsored an extensive clinical research program spanning many areas of medicine, including cancer. In addition to cancer clinical trials performed under the auspices of the CSP, 52 VA medical centers are affiliated with the NCI's cooperative group program. Many VA institutions that are part of major academic medical centers also participate actively in NCI-sponsored early clinical trials of new agents. Thus the VA has long recognized its responsibility to participate in national efforts to lessen the burden of cancer, which is a particularly important threat to the VA patient population.

PURPOSE

The purpose of the interagency agreement is to expand the already productive relationship between the VA and the NCI into a more formal and extensive partnership. The

fundamental feature of the NCI/VA partnership is to 1) increase the access of mandatory veterans (as defined by Public Law 99-272 and Public Law 101-508) to NCI-sponsored trials of new approaches to the diagnosis, treatment, and prevention of cancer, and 2) provide VA clinical investigators with expanded opportunities to participate in clinical cancer research.

Five of the major benefits of this agreement are:

(1) Mandatory veterans throughout the country gain access to the full range of promising new approaches to diagnosis, treatment, and prevention available on NCI-sponsored studies. In particular, a close working relationship with the VA's primary-care delivery system will facilitate access to patients and physicians interested in participating in diagnostic and prevention efforts.

*grant participation
of Veterans in NCI-
sponsored studies*

(2) The NCI's clinical trials program will realize a potentially significant increase in accrual rates; this will result in more timely completion of its studies.

*- faster
completion of trials*

(3) VA clinical investigators will have expanded opportunities to participate in clinical cancer research.

(4) The cancer center and cooperative group clinical trials programs will be strengthened with the expanded pool of VA cancer researchers.

(5) Involvement of the NCI and the VA in each other's planning of clinical research will improve the quality and efficiency of planning in both agencies.

SCOPE

This agreement covers the full range of NCI-sponsored studies in diagnosis, treatment, and prevention. There are four non-mutually exclusive categories that define "NCI sponsorship". They include trials reviewed and approved by NCI staff; NCI cooperative group studies; studies that are conducted in clinical and comprehensive cancer centers under an NCI-approved protocol review and surveillance mechanism; and protocols performed under the direct support of an NCI peer-reviewed grant.

TYPES OF AFFILIATIONS

To realize the full benefits of an NCI/VA partnership, this agreement will be implemented through several types of affiliations, depending on the capabilities and interests of the individual VA hospitals and their professional staffs. These include:

1. Enhanced linkages between the VA system and the NCI's clinical cooperative groups. Individual VA institutions will be considered for the group membership status most appropriate for its own circumstances. The options for membership will include main membership; participation in NCI's Community Clinical Oncology Program (CCOP); or

affiliate membership. All VA facilities providing oncology services will be allowed to apply for participation in the NCI cooperative group program and will be reviewed according to the usual peer-review processes applicable to the several mechanisms of support.

2. For VA hospitals that are part of academic medical centers, more extensive participation in the NCI's early clinical trials program. The close affiliation that exists now between VA institutions at the University of Texas Health Sciences Center (San Antonio, TX), and at the University of Wisconsin (Madison, WI) will serve as a model that can be extended to additional centers, where appropriate, to allow mandatory veterans access to new agents in early stages of clinical testing.

3. Under special circumstances, such as trials of particular importance to the VA or trials of rare tumor types, mandatory veterans may be offered access to NCI-sponsored clinical trials in nearby civilian facilities participating in such studies. This option is to be defined by the VA in individual cases and implemented through the VA Comprehensive Cancer Centers and regionalized referral system.

4. Closer linkages between the cancer planning activities in the VA CSP and the NCI clinical trials program. Such cooperation currently exists to a limited degree, as evidenced by joint sponsorship of the PIVOT trial in early prostate cancer. Expanded and active participation by both VA experts and NCI-supported investigators and staff in a common consensus development process for future trials in a variety of malignancies will substantially strengthen the planning efforts for the VA and NCI alike.

5. Establish linkages between VA and NCI health services researchers to develop and initiate an agenda based on mutual research goals. Cost effectiveness evaluation is of increasing importance to investigators in the VA and NCI systems and both groups will benefit from a coordinated effort in addressing economic research questions.

TERMS OF THE AGREEMENT

A. For mandatory veterans participating in trials at VA sites:

1. All medical care, including tests, treatment, follow-up, the management of complications and the costs of commercially available drugs will be the responsibility of the VA, as it is for the delivery of conventional care.

2. The NCI will provide funding for the research costs of participation in NCI-sponsored studies. These may include costs considered allowable by PHS policy as well as the provision of any investigational agents used in the protocols. These research costs will not be the responsibility of the mandatory veteran participating in the trial.

B. For mandatory veterans meeting the criteria established by the VA for clinical trial participation at non-VA sites:

1. All medical care required as a result of participation in NCI-sponsored clinical trials - for example, purchasing and administering of non-investigational chemotherapy agents, management of the complications of care, and diagnostic tests - will be reimbursed by the VA. This may include necessary follow-up care and testing that takes place after the period of active treatment on the protocol is completed if such followup cannot be done at a VA facility.
2. The NCI will provide funding for the research costs of participation in NCI-sponsored studies. These may include costs considered allowable by PHS policy as well as the provision of any investigational agents used in the protocols. These research costs will not be the responsibility of the mandatory veteran participating in the trial.

C. Additional Terms

1. NCI will provide to the VA hospitals participating in the partnership access to a user-friendly information system through the Physician Data Query (PDQ) system. This data base provides quick access to comprehensive information on NCI-sponsored trials open to patient accrual throughout the country. All NCI-sponsored treatment trials are included in PDQ and prevention and diagnosis trials will be added to the database as soon as feasible. Users can easily identify clinical trials and participating investigators at the nearest or most appropriate medical facility, whether inside or outside the VA system. Information from the PDQ database may be accessed on-line via computer. Customized clinical trials information can be obtained through the toll-free PDQ search service (1-800-345-3300) or through e-mail (pdqsearch@icic.nci.nih.gov).
2. The PDQ system will be enhanced to include a search field that enables users to identify VA hospitals and the specific trials in which they are participating.
3. The NCI and VA will each identify an individual responsible for coordinating all activities related to this joint effort. These individuals will have oversight of the administrative support required for the initiative as well as the educational and promotional efforts.
4. The VA and NCI will jointly plan and participate in educational initiatives to inform the DVA eligible community of the expanded opportunity to participate in NCI-sponsored studies.
5. The VA and NCI will jointly develop promotion initiatives to inform VA physicians throughout the system of the expanded opportunity to participate in NCI-sponsored studies.

6. This joint demonstration will be conducted for three years from the effective date of the agreement.

7. The effective date of the agreement will be January 1, 1997.

8. This agreement may be terminated at the request of either party. The party desiring termination of the agreement shall provide, in writing, a 120 day advance notice to the other party indicating the intent to terminate agreement.

9. Soon after the establishment of this agreement, the VA and NCI will determine evaluation criteria for this clinical trials partnership and time points for the conduct of such evaluations. The information to be collected will include, but not be limited to, clinical trial accrual, resource utilization and relative costs.

PODESTA

associates, inc.

MEMORANDUM

Date: August 1, 1996
To: Debbie Fine
Cc: Elizabeth Drye, Jennifer Klein, Barbara Woolley
From: Tony Podesta
Subject: Cancer Research Event for the President

Cancer touches almost every American family.

The good news: Ten million Americans owe their lives directly to cancer research, according to the National Cancer Institute. Put another way, one out of every 10 Americans has a family member who is alive because of advances in the prevention, diagnosis, and treatment of cancer.

The bad news: More than 40 percent of us will develop cancer, and more than 20 percent of us will die of it. Soon cancer will surpass heart disease as the leading cause of death in the U.S.

The President has a strong record of support for cancer research and other cancer initiatives.

During his Administration, funding for the National Cancer Institute has totalled more than \$8 billion. The Institute's new director, Rick Klausner, is an energetic and highly respected leader in this field. Earlier this year the President announced (and won wide support for) a Reinventing Government initiative to enhance patient access to new cancer treatments under review by the FDA. (A description is attached.)

There is an opportunity this fall to announce new initiatives that will remind voters of what has been accomplished, and identify the President as a leader in the war against cancer. Major cancer centers are located at his two alma maters and in key campaign states like Illinois, Ohio, Pennsylvania, and Wisconsin.

- This is the 25th anniversary of the National Cancer Act, which gave the National Cancer Institute a mandate to comprehensively and energetically exploit new scientific leads in research and apply the results to improve methods of cancer detection, treatment, prevention and control.

- The NCI is establishing an **Office of Cancer Survivorship**. This new emphasis on cancer *survival* is an indicator of the progress that has been made through research over the last 25 years. The purpose of the new Office is to explore the research issues and consequences of cancer survivorship, involving scientific disciplines ranging from those involved with genetics and clinical trials to behavioral research and the quality of life. Survivorship issues for children and adults will be addressed -- including long-term and late side effects -- the physical/medical and psychosocial aspects of cancer survival. The new Office's programs will take advantage of existing programs and develop new research initiatives.
- Coordination of cancer research activities across all sectors, public and private, is vital to the success of the National Cancer Program. In working with the President's Cancer Panel, NCI Director Richard Klausner has developed a plan to create a **National Cancer Council**, a group that will represent a full range of public and private sector constituents with interest in the outcome of a national cancer effort, including researchers, voluntary organizations, the pharmaceutical industry, insurance and health care providers, professional organizations, and the public. The purpose is to identify ways to improve detection and treatment of cancer and share information more widely by working together and coordinating activities without any single institution's bias. For this reason, the National Academy of Sciences has been asked to implement the Council as an academy roundtable. This mechanism will catalyze and enable communication between the sectors on such critical issues as cancer screening, pain management, information dissemination, and achieving state-of-the-art detection and treatment.

We recommend that the President announce these initiatives and associate himself with the pioneering medical research in this field at an event at one of the nation's major cancer centers.

The cancer community is very well organized and has joined together to mark the 25th anniversary of the National Cancer Act with a series of public events. A presidential event could be structured and sited according to your guidance. Some suggestions follow:

WHAT: A short speech to a large group of researchers, cancer center employees, patients, families, and invited cancer survivors who have benefited from the results of research.

This could be preceded by a briefing and tour of the research facility, a visit with patients and/or survivors, or other media opportunity.

WHERE: Major cancer centers are located in virtually every state. A list is attached. Some examples of suitable sites in politically important states include:

- Fox Chase Cancer Center, Philadelphia, PA
- University of Chicago Cancer Research Center, Chicago, IL
- Barbara Ann Karmanos Cancer Institute, Detroit, MI
- Kenneth Norris Jr. Comprehensive Cancer Center (or) Jonsson Comprehensive Cancer Center, Los Angeles, CA.

Attachment 1:**Remarks by Dr. David Kessler on White House cancer initiative, 3/29/96**

The four initiatives that the President announced today have a single significant meaning. American cancer patients from now on will have faster and easier access to more promising therapies. Here in a nutshell is the importance of each of the President's and the FDA's four proposals.

First, for patients with refractory, hard-to-treat cancer, instead of requiring evidence of clinical benefits, such as survival, FDA will rely on objective evidence of partial response, such as tumor shrinkage, as an initial basis for approval. This will allow us to rely on smaller, shorter studies for the initial approval of cancer drugs.

This accelerated procedure, which will be followed up by further studies on clinical safety and effectiveness in larger groups of patients, should and will simplify and speed up the evaluation and approval of drugs for advanced stages of solid tumors. Use of similar approaches to drug evaluation and review in our experience with AIDS therapies has been a powerful stimulus to the development of new and important agents, especially for people who need them most.

The second proposal, we will expedite the availability of promising medications that have been approved in certain other countries. If there is a promising drug approved in a foreign market, we will invite the manufacturer to submit to us the same information that made possible the approval abroad and whenever possible use it as a basis for making such therapy available under our expanded access programs to critically ill patients in this country.

Third, we will include representatives of cancer patients in FDA's cancer advisory committees and thereby make sure that their views are heard when it comes to recommending approval or nonapproval of cancer drugs.

And, fourth, we will eliminate unnecessary paperwork that used to delay or discourage cancer research by noncommercial, clinical investigators.

Two important points about these initiatives are of importance. First, they are designed to accomplish their aims without lowering FDA's high standards of drug safety and effectiveness, or reducing the amount of information available to patients and physicians. And second, they are not to be seen as one-time measures, but rather as part of a continuing FDA and administration effort to improve the quality and availability of drugs for all people with serious and life-threatening diseases.

Attachment 2:**NCI-Designated Comprehensive Cancer Centers**

University of Alabama Comprehensive Cancer
Center
Birmingham, Alabama

University of Arizona Cancer Center
Tucson, Arizona

Jonsson Comprehensive Cancer Center
University of California at Los Angeles
Los Angeles, California

Norris Comprehensive Cancer Center
University of Southern California
Los Angeles, California

Yale University Comprehensive Cancer Center
New Haven, Connecticut

Lombardi Cancer Research Center
Georgetown University Medical Center
Washington, D.C.

Sylvester Comprehensive Cancer Center
University of Miami Medical School
Miami, Florida

Johns Hopkins Oncology Center
Baltimore, Maryland

Dana-Farber Cancer Institute
Boston, Massachusetts

Barbara Ann Karmanos Cancer Institute
Detroit, Michigan 48201

University of Michigan Comprehensive Cancer
Center
Ann Arbor, Michigan

Norris Cotton Cancer Center
Dartmouth-Hitchcock Medical Center
Lebanon, New Hampshire

Roswell Park Cancer Institute
Buffalo, New York

Memorial Sloan-Kettering Cancer Center
New York, New York

Kaplan Comprehensive Cancer Center
New York University Medical Center
New York, New York

UNC Lineberger Comprehensive Cancer
Center
University of North Carolina School of
Medicine
Chapel Hill, North Carolina

Duke Comprehensive Cancer Center
Durham, North Carolina

Comprehensive Cancer Center of Wake Forest
University at the Bowman Gray
School of Medicine
Winston-Salem, North Carolina

Ohio State University Comprehensive Cancer
Center
Columbus, Ohio

Fox Chase Cancer Center
Philadelphia, Pennsylvania

University of Pennsylvania Cancer Center
Philadelphia, Pennsylvania

University of Pittsburgh Cancer Institute
Pittsburgh, Pennsylvania
The University of Texas M.D. Anderson
Cancer Center
Houston, Texas

San Antonio Cancer Institute
San Antonio, Texas

Vermont Regional Cancer Center
University of Vermont College of Medicine
Burlington, Vermont

Fred Hutchinson Cancer Research Center
Seattle, Washington

University of Wisconsin Comprehensive
Cancer Center
Madison, Wisconsin

Julia
Moffett

Paul Van Neill. — Assoc. Dir. Communication /
Head of Public Affairs, NCI.

Ellen Sigal — includes all major groups —
on Nat. Cancer Advisory Board — provide
advice to Director of Cancer Institute
and approve every —

Paul is
Starting working grp

— Consider of creating SOI C(3) —

— Chair — 25th Anniversary of NCA Act working
grp.

— get meeting notices out,
provide meeting place —

— honorary board members —

~~Donna~~
Fran Tractenburg — RWETA (husband is
president)

Podera — big staff — pr firm —

— wish post providing services

pro bono through Podera firm.

EXECUTIVE OFFICE OF THE PRESIDENT

09-Jul-1996 07:47pm

TO: Elizabeth E. Drye

FROM: Jeanine D. Smartt
Domestic Policy Council

SUBJECT: updates

Updates

1) I am finally able to communicate! Well as you can see I am on the network and now just awaiting a printer. Apparently Ashley is taking care of that paperwork.

2)Cancer - As I mentioned earlier I spoke with Paul VanNevel yesterday. He faxed me a draft of the "Science Support Strategic Communications Plan" which outlines a variety of ways that the Office of Cancer Communications can proactively work with the media, national organizations, scientists etc.. These activities are not, at least as far as I can tell, geared specifically for the 25th anniversary. However, he did mention that he was trying to coordinate activities with outside organizations such as Friends of Cancer Research as well as find out what was going on within NCI. He also mentioned some focus groups but I am not sure around what.

Basically he had no specific instructions from Dr. Klausner to put together an accomplishments piece. Dr. K will be back on July 18 and Ellen Segal will be back on July 14. How do you want to handle this? VanNevel was certainly willing to have a conversation if you want to talk with him before the others return.

Oh and yes, he did send me the budget propsal document!

3)Rio Grande Valley Empowerment Zone Grant application - I have put in a request through the HHS EZ/EC Central Support Team to track down the status of this request. Apparently they have a system in place to do this type of thing. From what I have been told this was an unsolicited grant which makes it a little more difficult to track. I hope to have some idea of where it is by COB tomorrow.



Fax Transmittal

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

Date 7-8-96
To Jeanine Smartt
Fax Number 202-456-7028
From Paul Vanhevel
Cover Sheet plus 13 Pages Transmitted

Message

Science Support Strategic Communications Plan

1996-1998

DRAFT DRAFT DRAFT DRAFT

Office of Cancer Communications
National Cancer Institute

DRAFT 6/28/96

Rationale for Plan

As the number of important cancer-related scientific discoveries increases, keeping the American public up-to-date and educated about these findings is a critical task. The findings can impact the public's medical and lifestyle decisions as well as their understanding of the importance of basic research.

Americans are interested in learning more about health and medical discoveries and they support federal funding for basic research, even when it produces no immediate benefits¹⁻². According to a report conducted by the Chicago Academy of Sciences, about 60 percent of Americans can cite some current health or medical information, often based on recent media reports¹. However, despite feeling well-informed about health issues, only a small segment of the public understands the basic scientific concepts that underlie modern biomedical science and even fewer understand the nature of scientific inquiry¹. Nevertheless, Americans tend to support federal funding for basic research¹. In 1995, 65 percent of Americans opposed cuts in medical research dollars and 73 percent would pay higher taxes to support more medical research³.

Americans primarily receive their health information from television news shows, while some rely on print media. In addition, well-over half would like more information on medical research in the print and broadcast media³. Despite using the media as a primary source of health information, Americans report low levels of confidence in the health and medical information they provide. In contrast, of the 49 percent of Americans familiar with the National Cancer Institute (NCI), 90 percent believe the information provided by NCI⁴.

Public support for medical research is high; however, there remains a need to reach people with credible, objective information about scientific breakthroughs and important health behaviors. As the voice of NCI, the Office of Cancer Communications (OCC) is responsible for disseminating health information and late-breaking research findings to patients and their families and the general public. In addition, OCC provides objective, state-of-the-art information on cancer research to the media and the general public. By proactively working with the media and other related organizations, OCC can impact the public's knowledge and support of health information and cancer research.

Purpose of Plan

To build upon the growing interest in biomedical research and to increase the public's understanding of health information and medical discoveries, the National Cancer Institute's (NCI) Office of Cancer Communications (OCC) has developed a plan to proactively work with the media, national organizations, scientists, and NCI's Cancer Information Service. The purpose of the plan is to highlight OCC's ongoing and future activities to increase public awareness of the importance of biomedical research and recent scientific discoveries.

Roles of NCI and OCC

NCI is the lead Federal agency for research on the causes, prevention, diagnosis, and treatment of cancer. The agency is charged with supporting and conducting high quality biomedical research on cancer and translating results into decreases in the cancer burden in the United States.

OCC is charged with communicating research findings and relaying messages on prevention, early detection, and state-of-the-art treatment to facilitate medical and lifestyle decision-making. OCC develops and disseminates cancer education programs and information to address the specific needs of the general population as well as specific minority populations.

Science Support Strategic Communications Plan

The plan's programmatic objectives (see next page) are an effort to contribute to NCI's efforts to support high quality biomedical research and to increase the percentage of people who benefit from cancer research. The plan's communication objectives reflect OCC's area of responsibility, including increasing the public's knowledge and understanding of the importance of research. To measure the progress and performance of OCC in reaching its communications objectives, evaluation procedures are included. These assessments will keep OCC informed of program progress, alert OCC to needed changes, and help determine the effectiveness of strategies and tactics.

The following objectives, strategies, and tactics will be used to coordinate OCC's science support activities. It is understood that environmental factors may impact this plan in the future (e.g., public policy, health statistics). Therefore, the strategies and tactics presented here may evolve over time in response to such changes.

¹ Miller, J.D. & Pifer, L.K. (1995). *The public understanding of biomedical science in the united states, 1993: A report to the National Institutes of Health.*

² (Spring 1993). SIPI/Harris Poll: Public is hungry for science news. *The Newsletter of the National Association of Sciencewriters*, 41(1), pp 1-5.

³ Louis Harris & Associates (November 1993). Medical research and health care concerns: A survey of the American public.

⁴ ICR Survey Research Group (May 1994) Results of omnibus survey on cancer organizations.

Overall Goal

To translate biomedical concepts in cancer research into accurate, simplified information that:

- provides individuals with access to basic facts that they can use in cancer prevention and medical decision-making; and,
- increases public support of the scientific process that will reduce the cancer burden in the United States, thereby improving people's lives.

Programmatic Objectives

Support high quality biomedical research.

Increase the percentage of people who benefit from cancer research.

Communications Objectives

Increase the public's understanding that laboratory, clinical, and population-based research is essential to achieving progress against cancer and improving the health of Americans.

Increase the public's knowledge of cancer research results.

Target Audiences

Both the gateway and primary audiences listed below are equally important for the success of this plan. OCC will work with the organizations listed under the gateway audiences to reach the primary audiences.

Primary Audiences

- Patients and their families
- General public

Gateway Audiences

- News media
- Leaders in cancer research community
- Organizations that support cancer research
- Science teachers
- Professional and academic organizations

Key Messages/Concepts

1. We have made great strides in understanding cancer and have benefitted many patients.
2. There is still much to learn about cancer, but we are continually making progress in ways that will benefit both treatment and prevention.

3. Understanding research and how it works empowers patients and their families and the public.
4. As part of a revitalized National Cancer Program, NCI partners in the private sector are crucial to winning the war on cancer.
5. Spin-off from other research benefits cancer research, and cancer research benefits other health programs.
6. The future of cancer research is impacted by the next generation of researchers; we need to encourage students to pursue careers in biomedical research.

Strategies

- A. Develop educational products for the target audiences, including patients and their families and segments of the general public.
- B. Support and enhance clinical studies through public outreach.
- C. Work with media organizations and outlets to increase understanding of cancer research.
- D. Work with NCI's Cancer Information Service to disseminate NCI research information.
- E. Collaborate with cancer research, professional, and academic organizations to increase their awareness of the importance of cancer research.
- F. Evaluate science support efforts.

Tactics

Strategy A: Develop educational products for the target audiences, including patients and their families and segments of the general public.

1. Conduct consumer research to gain insight into how key segments of the public think about cancer research, its contributions to the health of Americans, and its perceived relevance in their lives.
2. Based on results from consumer research, develop materials/resources that explain the importance of research and the role of NCI sponsorship. Possible products include fact sheets on success over first 25 years of National Cancer Program, current successes/opportunities, research that improves lives/research heroes, and spin off research benefits.

3. Develop a user-friendly publication on cancer statistics.
4. Develop an online news magazine on the NCI home page.
5. Integrate science support messages/statements into NCI publications.

Strategy B: Support and enhance clinical studies through public outreach.

1. Develop resources for the media, e.g., press statement, drop-in news article, print advertisements, and broadcast interviews.
2. Develop resources for the community, e.g., posters, flyers, etc.
3. Develop a background kit describing the study for media inquiries and interested organizations.

Strategy C: Work with media organizations and outlets to increase understanding of cancer research.

1. Use established mechanisms to disseminate ground breaking research results to the general public (e.g., press conferences, press rooms, news releases, interviews, etc.).
2. Conduct one-on-one media outreach to develop relationships, pitch science support story, establish NCI presence beyond day-to-day research results announcements.
3. Identify and train spokespersons to answer questions about cancer research. Possible spokespersons include the NCI Director, NCAB members, Board of Scientific Counselors, etc.
4. Explore opportunities for placing articles and/or interviews about the importance of cancer research in women's magazines and general interest magazines as well as on talk radio shows, TV talk shows, and news magazine shows. This includes trade press as well.
5. Develop materials to support media outreach efforts, including talking points and b-roll footage about the importance of cancer research to respond to media inquiries; Op-Eds and other by-lined articles for placement and for response to editorials and columns; and drop-in articles for trade press.

6. Identify non-traditional media outlets, e.g., reporters who cover international health, managed care, minority health issues, etc.
7. Promote NCI's access points, including PDQ, CancerNet, CancerFax, and the NCI home page as well as NCI's toll-free Cancer Information Service.
8. Hold semi-annual background briefings for selected media in conjunction with a breaking news story.
9. Work with other NIH institutes to develop common media strategies regarding support of basic research.

Strategy D: Work with NCI's Cancer Information Service to disseminate NCI research information.

1. Coordinate OCC and International Cancer Information Center information products for CIS use.
2. Provide CIS with talking points and background materials for new research findings/scientific discoveries.
3. Alert CIS about upcoming media events.
4. Disseminate NCI research information to cancer patients and their families, the general public, the media, and regional organizations.

Strategy E: Collaborate with cancer research, professional, and academic organizations to increase their awareness of the importance of cancer research.

1. Conduct consumer research to develop and disseminate science/research strategies, messages, and activities targeted to organizations.
2. Develop a promotion plan to disseminate science education products to special audiences, e.g., *Understanding Gene Testing booklet and slide kit*.
3. Develop informational packets about accomplishments and priorities in cancer research for NCI staff to use in their communications with professionals and the public.

4. Improve accessibility to information about NCI programs for physicians, scientists, and health professionals via materials and services on the WWW and via materials disseminated from NCI exhibits at professional meetings.
5. Explore partnership opportunities to disseminate science education and/or science support materials.
6. Explore opportunities for increasing personal outreach to cancer research, professional, and academic organizations. For example, provide NCI speakers at meetings/conferences.

Strategy F: Evaluate science support efforts.

1. Conduct pre- and post-test omnibus surveys to measure changes in knowledge of scientific concepts and research results as well as understanding of importance of research.
2. Conduct pre- and post-project surveys of primary care physicians and health professionals to measure changes in awareness of NCI-sponsored research and knowledge of ways to access information about NCI programs.
3. Use existing CIS evaluation mechanisms to track patient/public inquiries related to ground breaking research findings (i.e., Call Record Form).
4. Conduct content analysis of media placements.

- DRAFT -

**National Cancer Institute
Office of Cancer Communication
Science Support Initiative
Formative Research Plan – Consumer Focus Groups**

1. Background

In recent years, there has been little systematic effort to inform the public about the dramatic accomplishments and promise of recent cancer research. Accomplishments in basic, population-based, and clinical research, and how these accomplishments are changing the future of cancer control and cancer care, have been reported sporadically at best. Adequately informing the public is of special importance at this time because of the serious and pervasive nature of cancer, and because now more than ever, Americans can: 1) take actions to minimize their risk through lifestyle choices and participation in cancer screening activities; 2) have newly occurring cancers effectively treated; and 3) directly contribute to the rapidly accelerating progress of the National Cancer Program by participating in research. As a result, the Office of Cancer Communication (OCC) at the National Cancer Institute (NCI) proposes to undertake a systematic educational campaign to enhance the public's understanding of the dramatic advances in cancer control and cancer care. Such an effort will help prepare individuals, families, and communities to make the best possible cancer-related decisions.

2. Communication Objective

Increase the public's understanding that laboratory, clinical and population-based research has dramatically improved the health of Americans and is essential to achieving further progress against cancer and further improving the Nation's health.

3. Research Objectives

The primary objective of the proposed research is to gain insight into how key segments of the public think about cancer research, its contributions to the health of Americans, and its perceived relevance to their lives. Specifically, the research will explore perceptions and understanding about cancer research and its accomplishments, beliefs concerning how and in what ways cancer research is (or is not) a wise use of public resources, and beliefs about the personal (versus societal) value of such research.

4. Methodology

A total of six focus groups will be conducted with three audience segments (two groups per segment) in two geographic locations (Baltimore, MD, and Richmond, VA) during late July and early August, 1996. Each group will consist of 8 to 10 participants, and will be moderated by an experienced focus group moderator. Recruiting will be conducted in a manner to ensure that each group contains a mix of women and men, younger and older adults, and people of various racial/ethnic groups, education (high school graduates and above), and income as appropriate.

A. Target Audience Segments

1. Community thought leaders. This group will be defined using a series of questions developed by Roper Reports that identify people who participate actively in community and civic activities. Approximately 11 percent of the general public are considered to be community thought leaders as defined by Roper.

Rationale: This group represents a small but important segment of the American population – people who actively participate in defining the agenda of our local and national community. By virtue of their activities (e.g., writing to the editors of local and national newspapers and magazines, participating in community organizations), they are an important source of information and influence for other segments of the community. The understanding and support of this “multiplier” audience is important because their influence can enhance or “multiply” the impact of OCC communication efforts. Community thought leaders represent a sub-segment of the “attentive public” as described by Miller & Pifer.¹

2. People “touched” by cancer. This group will be defined as people who have had cancer, who have had a primary family member (spouse, parent, child, sibling) with cancer, or who have provided (on a non-professional basis) a significant amount of assistance (e.g., providing meals, transportation) to a person with cancer, within the last 5 years.

Rationale: Given the prevalence of cancer, this audience segment is likely to be substantial in size (perhaps as high as 20 to 25 percent). By virtue of their direct personal experiences, they are likely to be both interested in and at least somewhat knowledgeable about cancer. Moreover, also by virtue of their direct personal experiences, they are likely to serve as a channel of information and opinions to others who have not had direct personal experience. As a result, OCC should attempt to understand these individuals, with the intention of possibly harnessing their influence as a source of cancer information to the community at large.

¹ Miller, J.D. & Pifer, L.K. (1995). *The Public Understanding of Biomedical Science in the United States*, 1993. Chicago: Chicago Academy of Sciences.

3. The interested public. People who are interested (but not especially knowledgeable about) biomedical research are a third audience segment. Miller & Pifer indicate that this segment may be as large as 54 percent of the U.S. population. They can be identified through a brief series of survey questions designed by Miller.

Rationale: While this group may be too large to be considered an audience segment per se (in that they are not likely to share enough qualities to render them a single true audience), the segment may nevertheless provide a useful means for identifying, in the broadest sense, the type of people who are receptive to OCC's message about advancements in cancer research. Perhaps more importantly, this segment excludes the portion of the public who are not receptive to information about advancements in cancer research. By excluding the non-attentive public, formative research will be able to reveal a clearer picture of the communication opportunities and challenges for OCC in reaching the interested public with its message about cancer research advancements.

B. Participant Recruitment and Topic Guide

Porter/Novelli, with input from members of the Science Support Working Group at OCC, will develop a screening instrument and moderators guide. Screening will be conducted by telephone to determine eligibility for each of the groups. The audience segments as currently defined are not mutually exclusive in that a person can be both a community thought leader and have been "touched" by cancer. By excluding (i.e., not recruiting) community thought leaders who have also been touched by cancer, the three target audiences represented in the focus groups will be mutually exclusive. The differences between target audience segments will be clearer as a result of convening groups representing mutually exclusive audiences.

5. Topics for Discussion

A. Perceptions about biomedical research in general:

- accomplishments/progress made; greatest breakthroughs; challenges
- personal relevance of biomedical research
- perceived outlook for future biomedical research; what would be most significant/valued
- comprehension of different types of research – lab, clinical, and population-based
- use of public resources for biomedical research
- how "essential" is biomedical research as a national priority; how does it compare to other investments we could be making?

B. General perceptions about cancer research:

- accomplishments/progress made; greatest breakthroughs; challenges
- perceived outlook for future cancer research; what would be most significant/valued
- benefits of cancer research

C. Importance/value of cancer research:

- how "essential" is cancer research? in what ways? why?
- which types of cancer research are most "essential?"
- where should cancer research fit into our national priorities for bio-medical research?

D. Perceived role of public funding for cancer research:

- knowledge of who conducts cancer research
- knowledge of where funding comes from
- perceived role of public funding
- return on investment of public funding; how much good comes of it?

E. Barriers to cancer research:

- outcome of reduced government support for research
- outcome of reduced government support for career development

F. Concept/message testing:

- Cancer research: It's working. We have made great strides in understanding cancer and have benefited many people. This work needs to continue.
- Great progress is continually being made to understand effective prevention, detection and treatment.
- Cancer research helps all Americans, young and old, rich and poor.
- Cancer research is helping people get diagnosed earlier — that saves lives.
- Cancer research at a crossroads: Scientists and funding are needed now more than ever.
- Cancer research helps Americans now and in future generations — our children's children.
- The more we invest in cancer research, the faster the progress will be.
- Knowledge empowers: By understanding the results of research, individuals empower themselves to safeguard their and their family's health.
- The government and the private sector can work together to win the war on cancer.
- Money invested in cancer research returns important economic benefits in increased productivity and more effective prevention, diagnosis and treatment.

6. Planned Use of Research

The results of this research will be used to revise and extend the Science Support Operational Plan. Specifically, the research will allow OCC staff to revise its message concepts, develop actual messages, and position those messages to maximum effect. Moreover, this research may help shape future quantitative data collection efforts designed to measure and track public understanding and opinion about cancer research.

7. Timeline

Science Support Working Group to approve proposal in concept:	July 3, 1996
Develop draft screening instrument:	July 9, 1996
Develop draft moderators guide:	July 15, 1996
Finalize screening instrument:	July 16, 1996
Begin screening to identify participants:	July 18, 1996
Finalize moderators guide:	July 26, 1996
Conduct groups:	7/29 - 8/2, 1996
Draft report:	August 23, 1996
Feedback from Science Support Working Group members:	August 30, 1996
Final report:	September 6, 1996

THE WHITE HOUSE
WASHINGTON

OFFICE OF THE FIRST LADY

TO Elizabeth Dye

FROM Jennifer Klein

FAX # _____

PHONE # _____

OF PAGES (including cover) _____

COMMENTS I thought you might be
interested in this.

SPECIALEXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

7/22/96

LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 6118

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Total Page(s): 9

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN

(101) Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI 395-4871 Legislative Assistant's Line: 395-7362

C=US, A=TELEMAIL, P=GOV+EOP, O=OMB, OU1=LRD, S=PELLICCI, G=ROBERT, INJ
pellicci_r@o1.eop.gov

SUBJECT: HHS Proposed Testimony on advances in genetic technology.

DEADLINE: Tuesday, July 23, 1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Hearing is before the Senate Committee on Labor and Human Resources on Thursday, July 25th. Dr. Francis Collins, Director of the National Center for Human Genome Research is the witness.

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**SENATE HEARING ON GENETIC TESTING
STATEMENT OF DR. FRANCIS COLLINS
DIRECTOR OF THE NATIONAL CENTER FOR HUMAN GENOME
RESEARCH
July 26, 1996**

Madame Chairman and members of the Committee, we are pleased to appear before you today to discuss advances in genetic technology and the resultant challenges for public policy. The Human Genome Project is an historic 15-year international research endeavor with the goal of producing detailed maps of the 23 pairs of human chromosomes and sequencing the 3 billion nucleotide bases that make up the human genome. Launched in 1990, the project is supported in the United States by the National Center for Human Genome Research (NCHGR) at the National Institutes of Health (NIH) and the Department of Energy (DOE). The primary mission of the project is to develop research tools--genetic and physical maps, DNA sequence information, and new technology--to allow researchers to find and analyze genes quickly and efficiently. The project thus far has been successful in meeting or exceeding the goals outlined in its original plan.

In October 1995 the Human Genome Project completed its fifth year with a record of excellent progress toward its goals. The first goal of the Human Genome Project, creating a detailed genetic map for the human genome, has been accomplished. Recently, a team of U.S. investigators published a physical map of the human genome composed of over 15,000 well-ordered markers; this represents a major milestone on the way to the next goal--a comprehensive physical map of the human genome. Though original projections were that this map would not be finished until the end of 1998, completion is now expected in 1997. These accomplishments have set the stage for the project's ultimate goal, sequencing all the DNA in the human genome by 2003.

In 1996, the NCHGR has increased its investment in two areas of DNA sequencing research. Pilot projects were initiated to address and resolve issues that will be confronted in large-scale sequencing of human DNA. These pilot projects are expected to generate between 50 and 100 million base pairs of human DNA sequence by 1998 and, in doing so, develop the methods that will be used in the determination of the complete human DNA sequence.

The NCHGR has also increased its investment in the development of new technology for DNA sequencing, concentrating on miniaturization and automation of current techniques. This approach has focused on improving speed and lowering cost. Progress in these projects has been remarkable as several laboratories have obtained at least 1 million base pairs of DNA sequence at a cost of about 50 cents per base pair. This represents a dramatic reduction in the cost of DNA sequencing from \$5-\$10 per base pair when the Human Genome Project began.

We do not have to wait for the first complete human genome sequence however, to begin to reap the benefits. New genetic information has already enormously increased the number and kind of disease genes being isolated. Not only are the so-called "single-gene" disorders giving up their secrets, but we are beginning to see the same discoveries for complex disorders, such as diabetes, schizophrenia, and breast cancer--disorders that are quite common in this country and in almost every corner of the globe.

In NCHGR's Division of Intramural Research (DIR) and in many institutions around the country, scientists are already using large-scale genome-based approaches to study human genetic diseases. DIR investigators utilize cutting-edge genome science to develop streamlined techniques to rapidly isolate and analyze disease-linked genes, generate improved methods to diagnose inherited and acquired genetic disease, and investigate treatment strategies. Animal models with disease that mimic genetic human disorders are being developed to aid in understanding causes and possible treatments of several diseases. For example, earlier this month researchers at NCHGR and their collaborators reported the development of a laboratory mouse with a disease which has virtually all the characteristics of Ataxia-Telangiectasia (A-T) observed in people, including neurologic problems, cancers of the immune system, slow growth, radiation sensitivity, and abnormal development of sperm and eggs. A-T is of particular importance since carriers are estimated to represent 1% of the population, and are apparently at increased risk of a variety of cancers, including breast cancer. Although scientists have gleaned clues about the function of the human A-T gene from similar genes in single-celled yeast, the new mouse model gives them the first opportunity to study the disease in a controlled way in multi-celled animals other than humans.

THE ETHICAL, LEGAL AND SOCIAL IMPLICATIONS PROGRAM

As an integral part of the Human Genome Project, the NCHGR and the DOE have each set aside a portion of their funding to anticipate, analyze, and address the ethical, legal, and social implications (ELSI) of the new advances in human genetics that have resulted from the HGP. The current goals of the ELSI program are to improve the understanding of these issues through research and education, to stimulate informed public discussion, and to develop policy options intended to ensure that genetic information is used for the benefit of individuals and society. The NCHGR ELSI program is focusing on several high-priority areas raised by the most immediate potential applications of new genetic technologies: privacy and fair use of genetic information; responsible clinical integration of new genetic technologies; ethical issues surrounding the conduct of genetics research; and, professional and public education about these issues. The ELSI program is now positioning itself to address the issues which will arise once the complete sequence is known.

Privacy and fair use of genetic information:

As our knowledge grows about the genetic basis of disease, so too does the potential for discrimination and stigmatization based on the information contained in our genes. Of particular

concern is the fear of losing jobs or health insurance because of a genetic predisposition to a particular disease. A woman with a positive family history who tests positive for BRCA1 has an estimated 85 percent likelihood of developing breast cancer, and a 50% risk of ovarian cancer. Fighting those risks with intensive surveillance or surgery, without health insurance, would for many individuals result in economic ruin and probable tragedy.

Last year, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) developed and published recommendations for state and federal policy makers to protect against genetic discrimination:

Definitions

"Genetic information" is information about genes, gene products or inherited characteristics, that may derive from the individual or a family member.

"Insurance provider" means an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded.

1) Health Insurance Access, Renewability, and Portability

Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment or contribution requirements.

2) Health Insurance Affordability

Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information, or an individual's request for genetic services.

3) Genetic Privacy

Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

In order to assure that the nation benefits from the fruits of genetic research, safeguards must be in place to protect individual privacy and prevent insurance and employment discrimination. Despite the initiatives of various states including New Hampshire, Ohio,

Minnesota, Maryland and most recently New Jersey to pass legislation aimed at protecting individuals from being denied health insurance based on their genetic status, we have at best a patchwork of privacy and anti-discrimination proposals. In addition, state laws do not provide protection for the many Americans who obtain their health insurance coverage through employer-based plans, because the Federal Employee Retirement Income Security Act (ERISA) exempts self-funded plans from state oversight. Therefore, to provide minimum protection nationwide, these issues must be addressed at the federal level.

I am extremely gratified at the Congressional response to the development of these recommendations. Several bills have been introduced to address the potential misuse of genetic information in health insurance. It is quite remarkable that a year ago there were no bills that addressed these critical issues and today there are nearly a dozen legislative proposals. The Senate Labor and Human Resources Committee is to be commended for its efforts on S. 1028, The Health Insurance Reform Act of 1995, and the inclusion of genetic information among the factors an insurer may not use to deny or limit coverage. While this is a significant step forward, it would not prohibit insurers from using genetic information to set exorbitant rates and thereby make insurance coverage essentially inaccessible for many Americans.

Currently, the NAPBC and the ELSI Working Group are collaborating on the next area of potential discriminatory use of genetic information: the employment arena. A workshop on the use of genetic information in the workplace will be held this fall to delineate potential policy options.

Responsible clinical integration of new genetic technologies:

As a result of the Human Genome Project, new disease genes are discovered almost weekly. Once a disease gene is identified it is virtually only a matter of months before a diagnostic test can be made available. Developing effective treatment and preventive measures is a much more prolonged endeavor. These new diagnostic technologies are moving quickly from research into clinical practice, which raises concerns about the impact of these findings on people's lives and health.

This year, tests became available in the research arena for identifying mutations in the BRCA1 gene that predisposes individuals to breast cancer, the HNPCC genes that predispose individuals to colon cancer, and the apolipoprotein E gene that plays a role in the inherited form of Alzheimer's disease. Predictive genetic testing in the face of poor or uncertain preventative or therapeutic interventions raises many concerns regarding benefits and risks. The safety and effectiveness of these new predictive tests must be addressed to ensure a level of quality and reliability.

Three key initiatives are underway to address crucial questions surrounding genetic testing, especially for cancer susceptibility. NCHGR and several other NIH Institutes are co-sponsoring a Cancer Genetics Studies Consortium, focusing on the psychological and social

impact of cancer testing on individuals and their family members. Recommendations for approaches to genetic testing and counseling for cancer risk are being developed. The studies are well underway, and the investigators have developed draft recommendations for the optimal medical management of patients and families who carry mutations in the major gene for heritable breast cancer, BRCA1, and the HNPCC colon cancer genes.

A second initiative is the National Cancer Genetics Network, sponsored by the National Cancer Institute (NCI). It is currently suggested that the 28 NCI cancer centers would act as a hub for the network. Individuals interested in undergoing testing will be enrolled by physicians who are participating in the Network. Those physicians would receive educational materials to facilitate their ability to deliver these complex genetic services, which is essential because most physicians have not received this type of training. Patients would follow a uniform informed consent process and would be provided with up-to-date and validated educational information about the benefits and risks of testing. This would enable them to make an informed decision about whether or not to proceed. All patients, regardless of mutation status, would be enrolled in a confidential registry, so that the consequences of deciding whether or not to be tested and the effectiveness of various follow-up interventions can be evaluated. The network is critical because the premature introduction of cancer susceptibility testing into general clinical practice in the absence of large-scale follow-up studies may prevent our ability to answer crucial management questions.

The final NCHGR initiative on testing, the Task Force on Genetic Testing (TFGT), was established by the ELSI Working Group to examine the development and delivery of safe and effective genetic tests and the quality of the laboratories providing the tests. The Task Force includes representatives from the biotechnology industry, professional medical and genetics societies, the insurance industry, consumers, and federal agencies. In light of the rapid pace of disease-gene discovery and genetic test development, the findings of the TFGT will be crucial to the development of sound policies and practices for the introduction of new genetic tests. The group has now issued draft principles and expects to complete its work in early 1997.

Ethical issues surrounding the conduct of genetic research:

Genetic research may result in the discovery of information that is powerful and potentially predictive. In addition, such information may have familial implications. While in some cases such information may be beneficial to research subjects and their families, there is also potential for misinterpretation or misuse. Special concerns have arisen about the process of informed consent, particularly when the risks and benefits of research participation may not be fully known. Concerns have also arisen about how best to prevent the preliminary or premature release of research results and to protect individual privacy rights for genetic research participants. Examination of existing research guidelines and recommendations over the past five years has revealed that current guidance and protections need to be enhanced in order to deal with the special considerations related to genetics research.

Stored tissue samples are valuable resources for genetics research. Due to increasing concerns about the adequacy of informed consent and privacy protections when stored tissue samples are used in genetics research, the Centers for Disease Control and Prevention (CDC) and the ELSI program supported a meeting to explore these issues. After intensive deliberations, recommendations were developed and published in December, 1995 in the Journal of the American Medical Association. As a direct result of these deliberations, a number of other groups have now taken up this issue including the American Society of Human Genetics and the American College of Medical Genetics, the College of American Pathologists and numerous other organizations which represent the pathology community.

Professional and public education:

As more genetic tests become available to the public, the use and interpretation of those tests and the information they generate will no longer be managed by genetic specialists alone. There will be too few professionals with the advanced training in genetics to meet the expected demand for genetic testing and services. As patients ask more questions about genetic tests and disease risk, responsibility for the use and interpretation of tests and genetic information will increasingly fall to primary care physicians, nurses, physician assistants, and public health professionals who are not specialized or trained in genetics.

Therefore, it is imperative that all of our nation's health care professionals have the knowledge, attitudes, skills and resources they need to effectively integrate genetics into the diagnosis, prevention, and treatment of disease, and to address the related ethical, legal, and social issues. In 1995, NCHGR held a meeting of health professional and education experts to define education priorities for the ELSI grant program. These experts concluded that while public education is important, professional education is of the highest priority, because most individuals will seek genetic information from medical professionals. To this end, NCHGR is now working with professional organizations and consumer groups on a proposal to establish a National Coalition for Health Professional Education in Genetics. Yesterday, we concluded the first planning meeting of the Coalition and I believe these successful discussions will provide the necessary direction for our health professionals in this important area.

The Future of genetic research

As we begin to look beyond the completion of the DNA sequence, it becomes evident that genetic information will affect not only how we perform biomedical research but how we treat and prevent disease. In this regard, the decision of the Committee to confer Institute status on the NCHGR is most welcome. In fundamental ways, the creation of the National Human Genome Research Institute (NHGRI) will recognize NCHGR as the national leader in this medical and research revolution. The new NHGRI will be critically positioned to exploit several important scientific opportunities that might otherwise be neglected:

- 2 Functional genomics.
New technologies and methodologies will facilitate the study of gene function, not gene by gene, but thousands at a time. This will allow us to begin to unravel the complex networks of interactions between genes in health and disease.
- 2 Technology development.
Sequencing technology, like computer technology, is open ended. Improved engineering techniques will continue to drive down costs and increase productivity as we expand our sequencing efforts.
- 2 Comparative genome analysis.
The genomes of several mammalian species will be sequenced and compared to identify key regulatory and control sequences. The regulation of when and where a gene is expressed is critical to understanding the role of genes in disease.
- 2 ELSI research and policy development.
The NHGRI will continue to support research and policy development on key ethical, legal, and social implications of human genome research.

The establishment of a National Institute to lead and support the Human Genome Project and its promising new approach to biomedical science is imperative if the United States is to maintain its global leadership in biomedicine. As this new technology wave spreads throughout the world, international competitors will quickly adapt this trend to their own national research programs.

Conclusion

Congress, and particularly this Committee, has long been the leader in supporting genetic research and the Human Genome Project. Therefore, it is fitting that this Committee is now taking the lead in addressing the important policy issues raised by this research. Protecting privacy and preventing the misuse of genetic information is essential not only for us to reap the benefits of this research but indeed, in order to carry on the research at all. Increasingly we hear of people unwilling to participate in genetic research out of fear that information about their genes might be used against them by insurers or employers. Genetic discrimination has been hailed as the "civil rights" issue of this decade. We have the unique opportunity to address genetic privacy and discrimination issues now as the scientific information unfolds, before we find ourselves in a full-fledged crisis. I look forward to continuing to work closely with the Congress to develop sound policies to ensure that the Human Genome Project and new genetic information is used to benefit, not harm, the American people.

This concludes my remarks. I would be pleased to answer any questions you may have.

Fax Transmittal

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Middle East Cancer Consortium Fights a Common Enemy

The Ministers of Health of Cyprus, Egypt, Israel, Jordan, and the Palestinian Authority formed a historic partnership May 20, 1996 with the official signing in Geneva of the Middle East Cancer Consortium (MECC) agreement.

This is one of the first regional agreements to be signed in the Middle East. It builds on the significant political breakthrough in the Middle East peace process, particularly since the signing of the Israeli-PLO Declaration of Principles.

Donna Shalala, Secretary of the U.S. Department of Health and Human Services, and the official U.S. representative, witnessed the signing at the U.S. Mission in Geneva, Switzerland. Richard Klausner, M.D., director of the National Cancer Institute (NCI), which played a major role in orchestrating the agreement, was also present.

"I am very pleased that our National Cancer Institute will play an important part in the Middle East Cancer Consortium," stated Secretary Shalala, at the inauguration. "This Consortium will help build bridges of understanding and teamwork so that, together, we can defeat one of our greatest enemies: cancer."

(more)

The MECC is an official, inter-governmental organization aimed at increasing knowledge about cancer and decreasing its burdens for the people of the Middle East. Its main objective is "to promote and support cooperation in the Middle East in cancer control," the agreement states.

In a region where few countries maintain cancer registries, especially population based ones, and cancer statistics are scarce, MECC's main areas of focus will include cancer surveillance, information, and education. The Consortium will also concentrate on training, basic research, enhancing public health and patient care, quality control, and international communications. On the clinical side, cooperation may involve basic and applied research, and include programs of clinical guidelines and protocols.

By linking cancer research and treatment facilities, and allowing for the exchange and sharing of unique expertise and knowledge, the Consortium will help save resources, already scarce in many of the participating countries. The sharing of information and resources could also reduce the cost of providing cancer care, a consequence welcomed by those governments that have to pay for many of their citizens' tertiary health care, but cannot afford to establish and maintain the necessary facilities.

One of the potential benefits to the international scientific community will be the prompt availability of summaries of the results from cooperative research projects. These will be published in English and made readily accessible to the public.

NCI's role in the establishment of MECC is another of the Institute's ongoing efforts to support and encourage cooperation among cancer researchers and practicing oncologists in the Middle East region. In 1994, NCI played a pivotal role in the creation of the Middle East Cancer Society (MECS). While MECC is an inter-governmental body, the slightly older MECS is a

(more)

regional, scientific society, a nongovernmental organization that encourages the collaborative efforts of the region's cancer researchers and oncologists. Since its inception, MECS has held meetings and assigned task forces on lymphoma, cancer registration and epidemiology, breast cancer, pediatric oncology, and quality assurance.

It was the Society's initial progress and its members' enthusiasm that moved Klausner, and the Israeli Minister of Health, Ephraim Sneh, M.D., to call for a meeting in November 1995 with representatives from Cyprus, Egypt, Jordan, the Palestinian Authority, and Turkey. Those discussions, followed by others, resulted in the signing and creation of MECC. As stated in the MECC agreement, there will be much cooperation and coordination between the two organizations "to accomplish the common goal of scientific regional collaboration." Most of the Society's members are from parties to the Consortium.

MECC funding will be based on contributions made by the member parties. The National Institutes of Health of the United States will also contribute initial financial support. These funds will be aimed at helping premier institutions, such as universities and cancer centers, in the Middle East develop 1) cancer registries; 2) cancer information dissemination programs; and 3) training programs in cancer research, education, and patient care.

MECC will be governed by a Ministerial Steering Committee (comprising the ministers of health of the Consortium members), responsible for overall policies; and a Board of Governors (comprising representatives appointed by each of the parties, and the United States, responsible for financial and managerial policies. The NCI director will serve on the Board as the U.S. representative. Administration of daily activities will be carried out by an executive director appointed by the Board.

(more)

Membership in the Middle East Cancer Consortium is not limited to the founding members, and can be expanded to include other countries in the region. As a full-fledged member, a country must contribute to the Consortium fund, and name a representative on the Ministerial Steering Committee and Board of Governors.

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The Cancer Information Service (CIS), a program of the National Cancer Institute, provides a nationwide telephone service for cancer patients and their families, the public, and health care professionals. CIS information specialists have extensive training in providing up-to-date and understandable information about cancer and cancer research. They can answer questions in English and Spanish and can send printed material. In addition, CIS offices serve specific geographic areas and have information about cancer-related services and resources in their region. The toll-free number of the CIS is 1-800-4-CANCER (1-800-422-6237). People with TTY equipment may call 1-800-332-8615.

This document is also available through the NCI's CancerFax and CancerNet services, and in the News Section of the PDQ database. To get the document from CancerFax, dial 301-402-5874 from the handset of your fax machine and follow the recorded instructions to receive the contents list. Individuals who have access to the Internet may access the document on CancerNet, through an electronic mail (E-mail) service or via the National Institutes of Health (NIH) gopher. To get the CancerNet contents list from the E-mail service, send an E-mail message that says "help" in the body of the message to cancernet@icicc.nci.nih.gov. To get the document from CancerNet via the NIH gopher, point your gopher client to gopher.nih.gov and look for CancerNet under "Health and Clinical Information." To get the document from NCI's PDQ database, access PDQ News on the National Library of Medicine's MEDLARS system or consult a medical librarian for assistance. Additional information on this and other research topics may be found on the home page of the NCI's International Cancer Information Center's World Wide Web server located at <http://www.icic.nci.nih.gov>.

A LOOK AT...

DNA Dilemmas

Genie Out of the Bottle

Genetic Testing and the Discrimination It's Creating

By Wendy McGoodwin

WHEN JOHN Mayfield and Joseph Vlacovsky enlisted in the U.S. Marine Corps, they were prepared to give four years of their lives to serve their country. What they didn't bargain for was having intimate aspects of their personal lives controlled by the Marine Corps for the next 75 years. This is, however, what the Pentagon has succeeded in doing by seizing highly personal genetic information from every member of the armed services for inclusion in a "DNA registry." The stated purpose of this DNA registry is to help identify the bodies of soldiers killed in battle, but the coercive aspects of the DNA collection have raised troubling concerns about genetic privacy.

The case of the two Marines, who last month were court-martialed for refusing to submit to gene testing, highlights a growing fear of what has become known as genetic discrimination. A recent study by researchers at Harvard and Stanford universities documented more than 200 cases where healthy people were refused health insurance, fired from their jobs or barred from adopting children simply on the basis of their genes. Unfortunately, the same technology that can be used to help doctors identify and treat illness is also being misused to discriminate against people perceived to be at risk for future ill health. Nowhere is the potential misuse of genetic technology more apparent to ethicists—or frightening to average Americans—than in the potential for people to be unfairly classified and punished according to their genetic makeup.

The science of genetics is a flourishing new industry, nourished in large part by the federally funded Human Genome Project. The goal of this ambitious research endeavor is to identify every gene found in the human body, approximately 100,000 in all. Much of the research fo-

Wendy McGoodwin is executive director of the Council for Responsible Genetics, a national bioethics organization based in Cambridge, Mass.

cuses on genetic diagnostics: tests designed to identify genes thought to be associated with various medical conditions. More than 50 new genetic tests have been identified in the past five years alone.

This massive scientific endeavor has also opened up a Pandora's box of ethical problems we are not yet prepared to address. It is true that 10 years ago, genetic tests were only available for relatively rare genetic conditions. Today, doctors can screen for hundreds of genetic conditions, such as cystic fibrosis, sickle cell anemia, Huntington's disease and muscular dystrophy. Scientists recently discovered two genes associated with certain kinds of breast and colon cancer, common diseases that strike millions of Americans every year. For a handful of treatable genetic conditions, such as hemochromatosis or PKU, genetic testing can save lives through early diagnosis and intervention.

But for most genetic disorders—where treatment is either unavailable or limited—it is not at all clear how rapidly genetic research will lead to new treatments or cures. In the meantime, diagnoses unaccompanied by cures are of questionable value to patients. And in the absence of clear medical benefits, genetic testing can create real harms. Scientists working with the Council for Responsible Genetics have documented numerous cases where healthy people have been denied insurance or employment based on genetic health predictions:

■ A pregnant woman whose fetus tested positive for cystic fibrosis was told that her health maintenance organization (HMO) would be willing to cover the cost of an abortion but would not cover the infant under the family's medical policy if she elected to carry the pregnancy to term.

■ A healthy woman who casually mentioned to her family doctor that her father had been diagnosed with Huntington's disease, and that she herself was at risk for inheriting this genetic disorder, which can cause the brain to deteriorate, was later denied disability insurance. The insurance company rejected her because they found a note about her father's diagnosis

written in the margin of her medical records.

■ A healthy boy who carried a gene predisposing him to a heart disorder was denied health coverage by his parents' insurance company, even though the boy took medication that eliminated his risk of heart disease.

Further evidence of genetic discrimination was published recently by Harvard and Stanford medical researchers who discovered cases in which employers had used predictive genetic information to make employment decisions. A 24-year-old social worker alleges she was fired from her job after she revealed her genetic risk for Huntington's disease, even though she had received outstanding performance reviews in the months prior to the firing. An Army enlisted man who developed symptoms of a genetic disorder was discharged and denied full disability benefits when the military classified his genetic makeup as a "pre-existing medical condition." An adoption agency refused to let a married couple adopt a child because of the wife's risk for genetic disease.

Insurance companies claim they will go bankrupt if forced to insure people at risk for genetic diseases. That claim is hard to take seriously, however, since such genetic diseases have always existed. It's only our ability to detect them that is new.

"Genetic disorders are not epidemic, which means that the number of people with inherited conditions has been stable for as long as health insurance has existed in this country," says Stanford's Paul Billings, who co-authored the recent genetic discrimination study. "There is no justification for exclusion simply on the basis of technical developments which make detection of genetic conditions earlier, simpler or more precise."

Genetic discrimination no longer targets only those families afflicted with rare genetic disorders. With the discovery of genes linked to certain types of cancer, insurance companies are already arguing that they also should be allowed to deny insurance to people who carry these so-called "cancer genes." Not only is this discrimination unjust, it is scientifically inaccurate. Genes can tell us only part of the story about why some people get sick and others do not. Many genetic tests predict, with limited accuracy, that a disease may become manifest at an undetermined time in the future. But the severity of many diseases, such as sickle cell anemia and spina bifida, varies widely among individuals, and the presence of a "defective"

can't, unless you're a research subject?" Shultz



gene cannot foretell how disabling a disease will be for a specific person. People who are perfectly healthy today are being denied insurance and jobs based on unreliable predictions that they may become sick in the future.

Fear of this kind of discrimination can undermine whatever benefits might be derived from new developments in genetic testing technology, in part because people are already avoiding genetic testing for fear of the test results being used against them. The threat of discrimination compromises their ability to take full advantage of their medical options; they could miss out on early diagnosis, treatment and in some cases, prevention.

Beyond the risk of discrimination, society's fascination with genetic determinism has other social and political consequences. An overemphasis on the role of genes in human health neglects environmental and social factors. For example, strong evidence points to links between environmental contamination and cancer. Current research priorities, however, are skewed toward identifying genetic predispositions to cancer. If cancer is cast primarily as a genetic disease, then legislators may discard efforts to clean up environmental carcinogens in favor of a search for "cancer genes."

In effect, we encourage a "blame the victim" mindset, where we condemn people with "faulty" genes. Social conditions such as poverty or environmental pollution, which correlate directly with poor health and higher mortality rates, become less important. And economic and social resources end up being diverted into finding biomedical "solutions" while societal measures get short-changed.

All this is beginning to unfold far before the law is ready. While some forms of job discrimination may be prohibited under the Americans with Disabilities Act, no federal law prohibits genetic discrimination in insurance. Only 12 states have enacted legislative protections against genetic discrimination. And even then, employers who provide health insurance benefits through "self-funded" plans are not bound by these state laws. As evidence of mounting concern over genetic discrimination, four bills have been introduced in Congress and at least 20 state legislatures to prohibit genetic discrimination.

The military judge ruled last month that John Mayfield and Joe Vlacovsky can keep their DNA, but unless legislative safeguards are put in place, millions of other Americans remain vulnerable to genetic discrimination.

remaining recruiting pool—which also includes

Women Need Not Apply

classified and punished according to its makeup.

The science of genetics is a flourishing new industry, nourished in large part by the federally funded Human Genome Project. The goal of this ambitious research endeavor is to identify every gene found in the human body, approximately 100,000 in all. Much of the research fo-

Wendy McGrover is executive director of the Council for Responsible Genetics, a national bioethics organization based in Cambridge, Mass.

Women Need Not Apply

The DNA Test That Doctors Don't Want to Share

By Meredith Wadman

THE INFORMATION age is upon us, but you wouldn't know it from watching the keepers of the gates of medicine. Once again, they are showing their penchant for knowledge control, especially when it comes to women.

The issue is genetic testing for breast and ovarian cancer, and the impulse of the medical community to corner this market may be epitomized by the case of Joy Simha. She is a 28-year-old New Jersey woman who lost a breast to cancer two years ago and who would love to know the results of a new genetic test researchers ran after her mastectomy. If it shows that she has inherited a defective gene, she would almost certainly face an unusually high risk of recurrent cancer in her healthy breast. She says she wouldn't hesitate to have it removed, as a preventive measure. Conversely, she says she'd be mightily relieved—but not lulled into complacency—if the test came back clean.

But, she says, the researchers who tested her in New York aren't coughing up the results, even though they said they would when she took the test, and she has since signed a form requesting their release. Simha says she wouldn't have agreed to be tested if she hadn't wanted the results. "I think [they] need to realize that women have brains," she says. "We're not going to just jump on the operating table. Who are they to tell me that knowing the results could do me more harm than good?"

Many women may soon be pondering this question, if the scientists have their way. Since the first breast and ovarian cancer-linked gene, BRCA1, was identified in 1994, numerous and august biomedical bodies have rushed to proclaim the dangers of commercial testing for more than 100 identified mutations in the gene. According to early studies, carriers of many of these inherited misspellings in the genetic alphabet have an estimated 85 percent lifetime risk of getting breast cancer, and a 50 percent risk of getting ovarian cancer—if they have

close relatives, like mothers and sisters, who have had the same diseases.

Today, testing for most of these mutations is difficult and expensive. But one mutation—the one for which Simha, who is Jewish, would most like the results—is relatively easy to test for. What's more, it has been shown to occur in almost 1 percent of Ashkenazi Jews—those of central and eastern European origin, who make up about 90 percent of American Jews. In the world of genetic diseases, this is an astonishing frequency—eight times that in the general population. Francis Collins, the highly-regarded director of the National Center for Human Genome Research, told a congressional subcommittee last month that the mutation "is about the most common serious genetic disorder yet described in any ethnic group."

Collins is nonetheless among the leading lights who are miffed by the activities of Joseph Schulman, a maverick colleague at the Genetics & IVF Institute in Fairfax. Schulman is offering the test to Jewish women who have been referred by a physician for \$295. (One of his first clients was his 38-year-old wife, who tested positive and has since had both breasts removed.) Another establishment heavyweight, Neil Holtzman of the Johns Hopkins Medical Institutions, who is heading a government task force on the issue, says that women "are being misled" by Schulman and would "reject" the testing if they knew how badly they were being hoodwinked. It's worth noting that the National Breast Cancer Coalition and the National Action Plan on Breast Cancer agree that testing should be confined to research settings.

But one crack appeared in this seemingly unified front last month. The mostly female Advisory Committee on Research on Women's Health at the National Institutes of Health rewrote a resolution calling for the restriction of genetic testing to research settings. Marjorie Shultz, a law professor at Berkeley, warned its author, David Brown, of the University of Minnesota School of Medicine, of "lay outrage" if scientists appear to be jealously guarding this new technology.

"Can you imagine yourself saying to a woman who comes to a center to do testing, 'No you

can't, unless you're a research subject?'" Shultz asked.

"Yes," Brown promptly replied.

The committee ignored him and dropped the research setting provision. Instead, it called for careful counseling in any setting where these genetic tests are offered.

Scientists argue that testing in non-research settings is fraught with peril. Negative test results, they say, could lull women into a false sense of security, when in truth 90 to 95 percent of breast and ovarian cancers aren't inherited but occur spontaneously.

Conversely, the medical community says, a positive test may be no favor to a woman, since prevention and treatment of these cancers is still far from satisfactory. Mammography isn't foolproof. Neither is surgery; cancer cells can be left behind even if both breasts are removed. Ovarian cancer is often even harder to detect and remove. So what favor is it to a woman to saddle her with the knowledge of such risk?

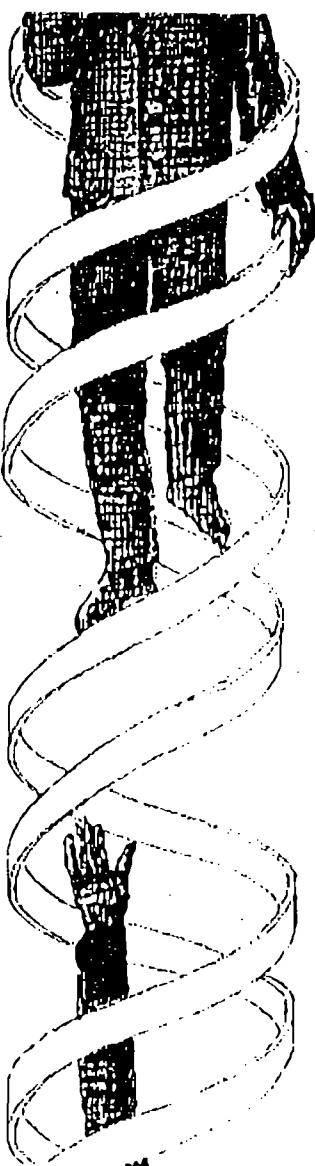
Researchers also worry that a stampede of women to clinics like Schulman's (apparently the only U.S. clinic now offering on-demand testing for the Jewish mutation in the BRCA1 gene) will drain scientists of subjects for their own experiments, which are still needed to answer a plethora of questions. For instance, what is the cancer risk for a woman who carries a BRCA1 mutation but who has no close relatives with breast or ovarian cancer?

To answer these and other questions, studies—like one currently being run by the National Institutes of Health, involving more than 5,000 Ashkenazi Jewish volunteers from the Washington area—depend on volunteers' willingness to forgo their test results. This is hard to accept when the Schulmans of the world will tell you your result in two weeks.

Finally, the medical community cautions, a woman with a positive test will be an instant magnet for discrimination by employers and insurers. For all these reasons, and others, Collins declares, "The technical ability to perform tests for mutations should not be confused with a mandate to offer them." The information they render, he told Congress, can be "toxic."

Such concerns have some merit but are in the main self-serving and patronizing. Do the doctors honestly believe, for instance, that a woman informed and motivated enough to seek out a test will be unaware, or incapable of absorbing, the fact that at least 90 percent of breast cancers are not inherited, and that she must therefore continue to be vigilant with breast exams and mammography?

Do they really believe that women who test



positive are going to immediately race to the nearest operating room to summarily demand the removal of both breasts and ovaries—procedures which, in any event, would require the concurrence of a surgeon? "They are underestimating our intelligence to the millionth degree," Simha says.

As for the loss of research subjects, this argument seems at best a camouflage. Consider that the NIH study took just two months to surpass its recruitment target of 5,000 volunteers. And with another 84,300 women expected to get breast cancer and another 27,000 to get ovarian cancer this year, any imminent shortage in the

remaining recruiting pool—which also includes healthy volunteers—seems exceedingly unlikely. Nor does the prospect seem to bother researchers at two of Canada's most respected research universities, McGill and the University of Toronto. In last week's New England Journal of Medicine, they report that they are offering on-demand testing for the Jewish mutation. "They say negative tests have already allowed them to tell women scheduled for preventive breast removal that they don't need the surgery."

On the other hand, the concern with potential discrimination by insurers and employers is entirely legitimate. But the scientists are burying their heads in the sand when they invoke this as a reason to deny testing. This exploding technology is not going to go away because insurers and employers are likely to discriminate. The answer is to bar discrimination legislatively, as Congress has recently begun to do in the Kassebaum-Kennedy health reform bill, and its House counterpart, both of which forbid insurers from using "genetic information" to discriminate against people moving between jobs.

At the nub of the scientists' argument is the paternalistic notion that—when it comes to female reproductive cancers, anyway—what a woman knows may hurt her, and shouldn't be her province until the doctors have all the answers. It's also hard to resist concluding that one of the scientists' paramount, if subtly stated, concerns—that women will lose their heads and chop off their breasts—might be more muted if weren't the appendages in question.

In fact, preventive breast removal may be a serious and reasonable option for some women with these mutations, according to some surgeons. But "women are being told, 'Dear, you're too emotional to handle the idea,'" says one female breast cancer doctor. Strangely, men considering surgery for prostate cancer don't seem to receive this kind of counsel, even though the benefits of surgery haven't been proven and the operation usually leaves men impotent, incontinent or both.

An acquaintance of mine has thoughts on all of this. She is a gynecologist in her thirties and an Ashkenazi Jew. She plans to get tested commercially for the Jewish mutation and, if she is positive, have her teenage daughters tested, too. "Knowledge can cause you trouble and pain," she says. "But the lack of knowledge means you're living blindly."

The genie (or should I say the gene?) is out of the bottle. It is incumbent upon aspiring medical gods to surrender their stranglehold on her gracefully, and to respect the rights of women who have the best available knowledge of their own bodies.

Meredith Wadman reports on biomedical policy for the journal Nature.

CONGRESSMAN JOE KENNEDY

Press Release



FOR IMMEDIATE RELEASE
April 25, 1996

PLEASE CONTACT:

DAN HOLLY
(202) 225-5111

BRIAN O'CONNOR
(617) 242-0200

REP. KENNEDY AND OTHER MEMBERS OF CONGRESS URGE SAFEGUARDS AGAINST GENETIC DISCRIMINATION

A bipartisan congressional panel, a leading geneticist and a Richmond, Va. couple who have suffered insurance discrimination today said safeguards against genetic discrimination were needed immediately and urged Congress to pass such safeguards.

"The question is whether we as a society are going to begin to provide protections for the American people so that we don't find a situation where insurance companies or employers or others use the information that is available to them to deny us insurance and a secure job rather than to fight illnesses," said Rep. Joseph P. Kennedy II (D-MA). "We have a very diverse group of Congressmen and Senators who recognize the importance of setting aside liberal or conservative policies, Democratic or Republican policies and coming together and saying this is an issue that affects all Americans."

The comments came at a press conference hosted by Kennedy and attended by other Members of Congress who have co-sponsored Rep. Kennedy's legislation prohibiting insurance discrimination based on genetic information. Also attending were Rep. Cliff Stearns (R-FL) and Sen. Connie Mack (R-FL).

Sen. Dianne Feinstein (D-CA) was detained by Senate business but provided a statement.

Also attending were Francis S. Collins, director of the Human Genome Project at the National Institutes of Health in Bethesda, MD.; as well as Larry and Michelle Allen, whose family has a history of either having sickle cell anemia or having the trait.

Rep. Kennedy's genetic discrimination prohibition is in the health care reform bill that has passed the House and Senate and is currently in conference. They urged conferees to retain the provision during House-Senate negotiations.

From a single sample of a patient's blood, doctors will be able to spot genetic mutations that signal approach not only of rare hereditary diseases, but also the common killers, including breast cancer, heart disease and diabetes. The Stearns/Kennedy amendment to the health care bill mandates that insurers may not deny health coverage on the basis of genetic information that indicates a predisposition to certain diseases.

"Our family has faced years of struggles with insurance companies denying us access to good coverage," Mr. Allen said. "We've faced countless nights trying to figure out how to pay our insurance and our medical bills. The insurance companies put profits ahead of people. They don't want to provide us access to good insurance simply because our family has a genetic history."

The provision is only a first step, but it is important and needed, participants stressed.

"I congratulate the Members of Congress who have exerted leadership in putting -- for the first time -- the words 'genetic information' in federal legislation dealing with health insurance as something that should not be used to deny people coverage," Collins said. "That is an enormous step forward."

Added Sen Mack: "This is one of those occasions where the Congress of the United States has anticipated a problem and moved before it became a major problem."

Boston Herald

P. 1

April 21 1996

Genetic tests can kill your medical coverage

By MICHAEL LASALANDRA

Jamie Stephenson's health insurer canceled her family's policy when the company found out that her son had a genetic disorder that causes mental retardation.

"My son, David, had gone to a neurologist, but when the insurance company got the bill, instead of paying it, they asked for his medical file," said the Atkinson, N.H., woman.

"The results of his genetic test were in his file. Based on that, they said they were canceling our policy," Stephenson,

Turn to Page 24

From Page 1

a writer, said she was shocked.

"At first, I thought 'They can't do this. That's discrimination.' But we found out that they can do it. They can do a lot."

The New Hampshire family is just one of many around the nation to find that getting tested

for genetic disorders is a double-edged sword.

A survey recently done by researchers at Harvard and Stanford universities found that discrimination against those who undergo genetic testing is common on the part of insurers and others who gain access to the information.

Stephenson's case was among

imperial insurance

more than 200 cited in the report that looked at cases involving people at risk or who had families affected by Huntington's disease, hemochromatosis (an iron storage disorder) and two disorders that can cause mental retardation.

Although most of those studied were not ill, they said they lost jobs, insurance, chances at adoption and educational opportunities.

Some of the examples cited in the study were:

■ A man in the Air Force learned he had a 50 percent chance of developing Huntington's disease and was refused reenlistment. Huntington's disease is a hereditary disorder characterized by uncontrollable body movements, eventually leading to a gradual loss of mental function.

■ A social worker was fired when her employer learned that a family member had Huntington's.

■ A woman whose fetus had a gene for cystic fibrosis was told by her HMO that it would pay for an abortion but not for a delivery.

Although insurance companies routinely deny coverage on the basis of pre-existing medical conditions, the Stephenson boy's genetic disorder, Fragile X syndrome (a common form of inherited mental retardation) in no

way puts the child at risk for illness or increased medical bills, experts said.

"It is horrifying that an entire family could lose their insurance on the basis of one person's diagnosis," said Marvin Natowitz, who is director of Medical Genetics at the Eunice Kennedy Shriver Center in Waltham and a co-author of the report.

"It was irrational," he added. "These are robust, healthy kids."

Worries about the abuse of genetic data are on the rise as scientists find genes that cause or predispose a person to a disease. When a disease gene is identified, biotechnology firms rush to develop a test for it.

The emerging issue came to a head last week as a court-martial trial began in Hawaii for two Marines who refused to give DNA samples for a registry designed to help the Pentagon identify servicemen's remains.

The Marines planned to call as an expert witness Dr. Paul Billings, a co-author of the Harvard-Stanford report. The Marines have cited concerns about how their genetic information could be used in the future.

"People should think about 10 times before being tested as long as we have a health-care system that can discriminate on the basis of pre-existing conditions," said George Annas, a medical ethicist at Boston University.

'Genetic testing is coming fast, and once any testing agency has a sample of your DNA they can test for anything.'

— George Annas,
Boston University
medical ethicist

DNA screening tests for common conditions such as heart disease, Alzheimer's, breast cancer, diabetes and rheumatoid arthritis are being developed and probably will become commercially available within a decade. A Virginia doctor is already testing for a breast cancer gene.

"Genetic testing is coming fast, and once any testing agency has a sample of your DNA they can test for anything," Annas said.

The new genetic information must be kept confidential and laws must be enacted to prevent insurance companies and others from discriminating on the basis of that data, Annas said.

Stephenson said that when her family lost their insurance coverage on the basis of David's genetic test she decided to fight back.

She began lobbying the New Hampshire Legislature for an anti-discrimination law. Three years later, legislators, advocates and insurers crafted a bill that bans genetic discrimination.

Now, Stephenson's family has insurance again.

So far, 11 states have passed such laws. In Massachusetts, a special task force has been set up to study the matter.

Annas, a member of the panel, said a report is due this summer, but he warned that even if a law is passed, it would apply only to about half of all residents.

The rest, those covered by insurance plans that are federally regulated or employers who self-insure, would not be helped.

"We're going to need a federal law," he said.

A bill proposed by Sen. Nancy Kassebaum (R-Kan.) would prohibit discrimination based on pre-existing conditions — genetic or otherwise.

In the meantime, however, Annas said people may want to hold off on getting genetic tests.

"You certainly don't want to do it before you have talked with a genetic counselor," he said.

Stephenson said having David get a genetic test did have some value.

"It gave us peace of mind," she said. "We finally know what it was. It helped us psychologically."

But she said it may not have been worth it, considering the trouble it caused.

"People are going to have to think it through," she said.

"They should make sure the benefit they can get by having the test outweighs any trouble they may have by having the test results in their hands."

Experts say knowing results not best for all

By MICHAEL LASALANDRA

Even if there were no discrimination against those who test positive for bad genes, the jury is still out on the value of the new genetic screening techniques.

Some experts say that since "knowledge is power," people who are worried about certain diseases should be screened if tests are available to them.

"Having information lets people plan their lives, especially when it comes to reproductive planning," said geneticist Marvin Natowicz of the Harvard Medical School.

But others argue that interpreting the test results still can't be done with any certainty, and that even if doctors knew for sure what the results meant, there is little that can be done at this point to alter the course of most genetic illnesses.

"If we do it too quickly, it may hurt more people than it helps," said Dr. Daniel Hayes, a breast cancer expert at the Dana-Farber Cancer Institute.

Natowicz, however, noted that while most genetic tests only show a predisposition for a certain illness, some, like the test for Huntington's, show a certainty that the disease will develop, although the test can't say when.

On top of that, tests can give some peace of mind to those who turn out not to have the defect gene for which they screen, test boosters say.

"Even if there isn't a specific remedy, the information can be helpful," Natowicz said.

But George Annas, a professor of medical ethics at Boston Uni-

versity, says having such information can actually be harmful in some cases.

"You can discriminate against yourself," he said. "You see yourself as sick and you limit your possibilities."

Right now, the test for the breast cancer gene BRAC1 is creating the most controversy.

Although Dr. Joseph Schulman of the Genetics and IVF Institute in Fairfax, Va., is offering the test for \$295 to any woman who wants it, he has outraged many geneticists, most of whom are recommending the test only for those with at least two cases of breast cancer in the family.

If the test proves positive, there are some steps that can be taken, such as getting more frequent mammograms or even preventative mastectomies.

"But that may be an overreaction," Annas said.

Hayes said the discovery of the gene, and others linked to breast cancer may help doctors find out why some people get the disease and others don't. And

they may lead to new treatments, although he said they are likely to be at least five years away.

But right now he said it is premature for women to rush to be tested.

He noted doctors aren't sure just what a positive test result means.

The discoverers of the gene cautioned in their paper that

they could not say for sure that all women with the mutated gene were at risk for cancer.

And Hayes noted that there is still no way to prevent breast cancer. Even radical mastectomies as a preventive measure aren't foolproof, he noted.

"There are huge psychological, social and economic reasons not to do these tests willy-nilly," he said.

BOSTON SUNDAY HERALD, APRIL 21, 1996 23

PAGE 08d

TO WASH. D.C.

FROM CONG. JOE KENNEDY

21:11 96, P2 APR

05/06/96 12:58

6202 225 9322

REP KENNEDY

007/007

TO: Janice Enright
John Sutton
FROM: Jennifer Klein *J.K.*
DATE: 5/24/96
RE: Possible Cancer Events

I promised I would get back to you after Elizabeth Drye and I met with Dr. Richard Klausner, Director of the National Cancer Institute (NCI). NCI is developing plans to commemorate its 25th anniversary, and Dr. Klausner believes the anniversary would be a great opportunity for the President to show his commitment to the fight against cancer and to outline a vision for the future. NCI is currently planning to celebrate the anniversary in October. Elizabeth and I asked Dr. Klausner to keep us informed as they make more definite plans.

cc: Elizabeth Drye



Fax Transmittal

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

Date 5/30/96
To Elizabeth Dye
Fax Number 302-456-7028
From Paul Van Nevel
Cover Sheet plus 2 Pages Transmitted

Message

Here's the list
you requested -
Paul

May 30, 1996

Working Group to Recognize the 25th Anniversary of the National Cancer Act

Dr. Ellen Sigal, Chair
National Cancer Advisory Board
Sigal Environmental, Inc.
3299 K Street, NW
Washington, DC 20007
202-944-6710
202-333-3468 FAX

Patrick Butler
The Washington Post
1150 15th Street, NW
Washington, DC 20007
202-334-6635
202-334-1031 FAX

Dr. Paul Calabresi
The President's Cancer Panel
Rhode Island Hospital
593 Eddy Street
Providence, RI 02903
401-444-8977
401-444-8483 FAX

Su Lin Chong
NCI Cancer Centers Public Affairs Network
Lombardi Cancer Research Center
Georgetown University Medical Center
3800 Reservoir Road, N.W.
Washington, D.C. 20007
202-687-5713
202-687-5718 FAX

Mrs. Debbie Dingell

202-775-5057
202-775-5077 FAX

Dr. John Durant
American Society of Clinical Oncology
225 Reinekers, Suite 650
Alexandria, VA 22314
703-299-0150
703-299-1044 FAX

Margaret Foti
American Association for Cancer Research
Public Ledger Building, Suite 816
150 S. Independence Mall West
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215-440-9300
215-440-9354 FAX

Barbara Gimbel
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212-861-6453 FAX

Michael Heron
American Cancer Society
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404-329-7909
404-325-2217 FAX

Amy Langer
National Alliance of Breast Cancer
Organizations
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212-689-1213 FAX

Marlene Malek
National Cancer Advisory Board
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McLean, VA 22101
703-522-6848
703-522-9436 FAX

Pearl Moore
Oncology Nursing Society
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412-921-6565 FAX

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National Breast Cancer Coalition
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215-731-1174 FAX

Dr. Philip Schein
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404-329-7530 FAX

Ellen Stovall
National Coalition for Cancer Survivorship
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Silver Spring, MD 20910
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301-565-9670 FAX

Fran Trachtenberg
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Washington, DC 20013
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Fran Visco
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215-731-1174 FAX
Washington D.C. office:
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202-265-6854 FAX

Kerrie Wilson
American Cancer Society
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Washington, D.C. 20003
202-546-4011
202-546-1682 FAX

Dr. Robert Young
Fox Chase Cancer Center
7701 Burholme Avenue
Philadelphia, PA 19111
215-728-2781
215-728-2571 FAX

TO: Janice Enright
John Sutton
FROM: Jennifer Klein *JK.*
DATE: May 13, 1996
RE: Memo from Ellen Sigal, Ph.D.

You asked me for my thoughts on a memo that Harold received from Ellen Sigal, Ph.D. I agree with her view that we should focus on the community of cancer survivors and their families in the next several months for two reasons. First, tens of millions of Americans are affected by the disease. In addition, the President has a great record on fighting cancer.

Some of her specific suggestions are probably a bit optimistic. Elizabeth Drye (Domestic Policy staff) and I are meeting with Dr. Klausner, the Director of the National Cancer Institute, this week and will discuss possible events and initiatives with him.

Please let me know if you need more information.

April 25, 1996

TO: Jen Klein

FROM: Janice Enright
John Sutton

Could you please review the attached memo to Harold and let us know your thoughts and reactions. We need help in responding to her memo. Thanks.

Memorandum

TO: Harold Ickes, Deputy Chief of Staff
FROM: Ellen V. Sigal, Ph.D.
RE: Mobilizing the Cancer Community
DATE: April 22, 1996

During our conversation at the National Realty Committee event on April 16th, you requested that I put in writing some ideas about how the White House can support Americans affected by cancer in this year of the 25th anniversary of the National Cancer Act. As you know, cancer touches almost every American family and is one area in which Americans expect their national government to actively fight on their behalf.

First, a few statistics that will help you understand the scope of the constituency.

- There are 10 million organized cancer survivors living today.
- One in three people will get cancer in their lifetime.
- One in five people will die of cancer. Cancer will cause one of every four deaths this year.
- Each day, 1,500 people die of cancer. More than half of a million people will die in 1996.
- By the year 2000, cancer will be the number one cause of death.
- Cancer's impact on the American economy is approximately \$100 billion today.

The President has a terrific record at the National Cancer Institute, which was emphasized most recently by his appointment of a new, highly respected director, Dr. Richard Klausner. In addition, just last week, the President announced steps to streamline and expedite the FDA approval process for cancer drugs.

We who work in the cancer research believe the White House can effectively score political advantage and mobilize the community of cancer survivors and their friends and families by communicating the President's record more widely and by being more visible on cancer-related concerns. There will be many opportunities in the coming year for the President to demonstrate his commitment to finding a cure for this dreaded disease that touches almost every American family. Following are just a few initial ideas.

For instance, between now and November, the White House/President could:

- join Dr. Klausner at the National Cancer Institute to announce a battle plan against cancer for the next 25 years;

- visit a cancer research center to highlight a type of cancer against which research at that center has improved our life chances and to call for continued/increased funding;
- announce a national cancer coalition of experts from the fields of insurance, business, prevention, research, and media who would be dedicated to looking at the disease in a holistic light, determining how all organizations working to help survivors and potential victims can coordinate their activities for greater effectiveness;
- participate in a PSA reminding people of what they can do themselves to improve their chances against cancer;
- organize a White House ceremony with cancer survivors to signal the round trip of the National Coalition for Cancer Survivorship's Ribbon of Hope that started last year with Mrs. Clinton's signature and has been signed by Americans all over the world who have been touched by cancer;
- help create incentives for universities to help medical students to pursue careers in oncology and basic cancer research.

The cancer community is very well organized. The White House could benefit significantly from embracing the community and its concerns. It would be worth having a meeting to discuss ideas such as those above in greater detail. I will call you in the coming week to determine how to proceed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

April 17, 1996

Ms. Carol H. Rasco
Assistant to the President
c/o Ms. Gaynor McCown
The White House
Domestic Policy Council
West Wing
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Ms. Rasco:

Dr. Klausner asked that I forward a copy of the National Cancer Institute's Bypass Budget. I am pleased to enclose a copy of the draft document. This year we have titled the budget proposal: *The Nation's Investment in Cancer Research: A Budget Proposal for Fiscal Years 1997/98*. We expect the final document to be ready by mid-May.

Dr. Klausner, Dr. Rabson or I would be pleased to discuss it with you.

Sincerely,

Edward J. Sondik, Ph.D.
Associate Director for Strategic Planning

Enclosure

cc:
Dr. Klausner
Dr. Rabson

Dr. Klausner
(301) 496-5615

WHT looks to Setz -

- For total NIH budget

- Cancer Institute Request is

- "pie in sky" -

- Bypass authority - "special"

Have been used in AIDS / Cancer funding wars

Met w/ Donna Shulala

- 25th Anniversary of the Campaign -

- In the road -

Jennifer Klein

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

03-May-1996 08:53pm

TO: John O. Sutton

FROM: Carol H. Rasco
 Domestic Policy Council

CC: Christopher C. Jennings
CC: Elizabeth E. Drye

SUBJECT: 25th Anniversary of National Cancer Act

Harold:

I was delighted to learn this week from OSTP staff who had visited with Chris Jennings of DPC that you have received a memo in late April from Ellen Sigal regarding the potential involvement of the President in some event surrounding this 25th anniversary. I had met with director of National Cancer Institute and the President's Cancer Panel a few months ago where we talked about the potential of such involvement and have maintained contact with them. If DPC can assist in anyway you wish to see this move let me know. I believe it is a terrific idea to do something significant on this!

Thanks.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

06-May-1996 06:42pm

TO: Carol H. Rasco

FROM: Elizabeth E. Drye
Domestic Policy Council

CC: Jennifer L. Klein

SUBJECT: RE: Would the two of you confer and one of you return this c
SUBJECT: _____

all

I'll return his call. As discussed below, I don't think there is any urgent need to meet with him.

I learned Friday that NCI's report on 97/98 budget is not one we can really participate in. By law it's a "pass through" budget -- NCI sends it to the Congress w/out Secretary or POTUS sign off. Hence, it's a dream budget that typically requests \$1 billion more than POTUS budget. Further, it does not reflect consideration of competing health research spending needs, and can be viewed as antagonistic by advocates for other types of research (e.g. AIDS). This "pass through" approach allows Congress and cancer advocacy groups to use the report as a tool to push Admin. and Congressional Committees for greater U.S. investment in cancer research (OMB tells me other groups have pushed successfully for similar pass through budgets).

On a more positive note, the report does try to set priorities and target spending within the cancer research budget. For that reason it might make sense to meet with Dr. Sondik about it at some point.

More generally, Jen and I think it might be helpful to look broadly at this Administration's cancer accomplishments and find other opportunities for WH involvement, if you think it makes sense.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

06-May-1996 06:50pm

TO: Elizabeth E. Drye

FROM: Carol H. Rasco
Domestic Policy Council

CC: Jennifer L. Klein

SUBJECT: RE: Would the two of you confer and one of you return this c
SUBJECT: _____

all

Whatever you all feel should be done is fine by me. I just don't want this group ignored as this Administration had not met with them , that word got back to both POTUS and me and we decided I should have that earlier meeting....we then need to do something at some point that allows them to know they are indeed being heard by potus.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

30-May-1996 11:43am

TO: Jennifer L. Klein
TO: Elizabeth E. Drye
TO: Barbara D. Woolley

FROM: Deborah L. Fine
 Domestic Policy Council

SUBJECT: cancer meeting

Ellen Sigal has given me two dates for the meeting where we would learn more about the 'campaign' for promoting cancer research and celebrate the 25th anniversary of the cancer act, and how we might plug in. (As you know, the NCI is working on ideas -- as is a private sector group that consists of American Cancer Society, Nurses, National Breast Cancer Coalition and many others.)

She would bring Tony Podesta along. Mary Beth Donohue, HHS, will also come with someone from National Cancer Institute (she will invite Klausner.)

The dates we're working with now are June 10th and 13th. Will you all be here then?

(Barbara: This is what you and I had spoken about a couple of weeks ago. I will call you and bring you up to date on what has been happening.)

Thanks.