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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. list	Nominations for NIH Directors Approval, National Cancer Advisory Board (2 pages)	nd	b(6)
001b. forms	HHS 532, Request for Approval of Nominees for Public Advisory Committees (10 pages)	11/29/1997	b(6)
002. memo	Martie Kendrick to Jerry Mande re Intercultural Cancer Council (partial) (1 page)	01/27/1998	b(6)
003. resume	Judith Gasson (partial) (1 page)	nd	b(6)

COLLECTION:
Clinton Presidential Records
Office of Science and Technology Policy
Jerold Mande
OA/Box Number: 13033

FOLDER TITLE:
Cancer Panels: Cancer Panels

2008-1524-F
kc1217

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
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Freedom of Information Act - [5 U.S.C. 552(b)]

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Klausner
3-12-98

① NCPB - Independent Body - Nat'l Ca Prog.
Leave their affiliations at the door.
Neutral but highly visible & relevant
VP - Could highlight wonderful nature of NCPB
Not about control
Klausner's creation.

② NCAB - NCI's Council - Legal requirement
- Nat'l Ca Act '71

③ PCPs - ? ~~MEET~~ for a long time
'71
haven't access to Potus.

National Cancer Policy Board

About the Board

The Board will confront obstacles and address issues that arise in the prevention, control, diagnosis, treatment, and amelioration of cancer. It will meet at least three times annually to examine (1) implications of ongoing research and new technologies, (2) issues arising in prevention and delivery of care, and (3) problems faced in the Nation's battle against cancer. The Board intends to pursue activities balanced among prevention, cancer care, and research. It will be a common meeting ground for the many federal agencies that sponsor or directly conduct relevant work, as well as state and local health authorities.

The Board's reports will make findings and recommendations to advance the Nation's effort against cancer. The Board will also convene workshops, gather information, commission papers, and forge collaborations with other groups working on national policy issues concerning cancer. In addition to its own work, the Board intends to help spawn activities conducted by other groups, both within the National Academy complex and outside it.

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IOM Homepage
National Cancer Policy Board Homepage

National Cancer Policy Board

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Analyst: **Maria Hewitt**
Program Officer: **Catharyn Liverman**
Senior Project Assistant: **Stacey Patmore**

TOWARD A RENEWED NATIONAL CANCER PROGRAM PLAN

Burden Of Disease

Cancer is an important public health concern in the United States and around the world. The National Cancer Institute (NCI) estimates that about 8 million Americans alive today have a history of cancer; and, in 1988, the American Cancer Society predicts that 1,228,000 men and women will be newly diagnosed with cancer and that 564,800 persons will die from the disease.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. One in three people in this country will be diagnosed with cancer, and one in five will die from it.

Lung cancer is the leading cause of cancer death in both men (93,100 deaths) and women (67,000 deaths). While lung cancer incidence and mortality have been decreasing in men since the mid-1980's, lung cancer incidence and mortality in women continue to increase. The leading cause of cancer in men is prostate cancer (184,500 cases) and in women is breast cancer (178,700 cases). The four most common cancers (prostate, breast, lung, and colon/rectum) account for more than half of all cancer deaths and all new cancer diagnoses.

The resulting health care costs, lost productivity and personal tragedy are staggering. The financial costs of cancer are great both for the individual and for society as a whole. The NCI estimates overall annual costs for cancer at $107 billion: $37 billion for direct medical costs, $11 billion for morbidity costs, and $59 billion for mortality costs. Treatment of breast, lung and prostate cancers account for over half of the direct medical costs associated with this disease.

Rationale For Developing A National Cancer Plan

The National Cancer Act of 1971 mandated that: "In carrying out the National Cancer Program, the Director of the NCI shall, with the advice of the National Cancer Advisory Board, plan and develop an expanded, intensified, and coordinated cancer research program emcompassing the programs of the NCI, related programs of the other research institutes, and other Federal and non-Federal programs." The nation can be proud of the progress that has been made, though it has been slower than expected.

In the early 1990s, the National Cancer Advisory Board (NCAB) reported on its evaluation of the NCP and brought forth recommendations for the future. A consensus was reached that if this nation fails to address the following six major issues, we will not prevail in our War on Cancer:

1. Current *health care reform* proposals are devastating to the War on Cancer by denying resources for research and quality cancer care.

2. The National Cancer Program suffers from an *absence of national coordination* of cancer fighting efforts in the public, private, and voluntary sectors.

3. Many people in this country, especially the poor, elderly and uninsured, receive *inadequate cancer care*.

4. Current *laws, public policy and government regulation* undermine cancer prevention, treatment, and control efforts.

5. Failure to support *translational research* hinders rapid development of cancer fighting advances.

6. Current investment is insufficient to capitalize on *unprecedented opportunities in basic science research.*

Today, to combat the cancer problem, an extremely impressive array of organizations has been created, and a great amount of excellent work is being done. Unfortunately, the existing organizations and priorities evolved in response to specific scientific, geographical, organizational, and budgetary needs, without any global vision, comprehensive plan, or coordinated management structure. The result is that, while each individual organization is filling an important need, there is no common vision or coordination. Thus, large gaps, redundancies, wide variations, gross inefficiencies, wasted opportunities, variable-quality care, excessive budgets, and unnecessary suffering exist.

Cancer control objectives have been established by the National Cancer Institute and the Office of the Secretary of Health and Human Services (Healthy People 2000-2010), but they are short-term, uncoordinated, unfunded, and not connected to any concrete plan for implementation, and don't involve the not-for-profit sector, business community or health care groups.

A long-term, visionary and collaborative national cancer plan must be developed which is inclusive of input from such National-level Committees as the President's Cancer Panel, the NCI's National Cancer Advisory Board and the newly-formed National Cancer Policy Board.

The number of organizations in cancer research and control, and the scope and excellence of their work is breathtaking. Federal organizations support basic and clinical research (e.g., NCI), and provide epidemiological and cancer control support to state and local programs (e.g., the Centers for Disease Control and Prevention). Additional state and local programs are funded by grants of various types. On the private side, voluntary health organizations, specialty societies, pharmaceutical corporations, universities, cancer centers, and foundations contribute to the national cancer control effort. But, with this multiplicity and decentralization come fragmentation, poor communication, lack of coordination, and loss of effectiveness.

The actual care of cancer patients is being delivered through thousands of hospitals, clinics, cancer centers and other delivery sites. But poor coordination, local variations in therapy, uneven budgets, and lack of national guidance lead to huge variations in practices and outcomes.

At the bottom of the pile are the cancer patients and the still-healthy but cancer-concerned public. They have identified cancer as the most important health problem, the single disease that they fear most, and crave information and direction. But, the available information comes from a wide variety of sources that differ greatly in their credibility and accuracy.

In short, the resources already spent on cancer are huge, and innumerable organizations are actively and valiantly involved in its care and control. But, the lack of a clear national vision, goal and leadership has left the effort fragmented and uncoordinated. The net result is that the effectiveness of cancer control in this country falls far short of its potential; hundreds of thousands of lives are unnecessarily lost and billions of dollars are needlessly wasted.

Solving this problem will require the development of a *New National Cancer Plan* based on a truly collaborative effort to review the current status of all sectors, evaluating successes and failures of past efforts. Having completed this important task, specialty groups of *the country's best minds in the cancer field will need to come to agreement on (a) a VISION of where the country should be headed in the next 25 to 30 years; (b) aggressive but achievable objectives; (c) practical strategies, specific programs and science-based practices; (d) roles of all the participating organizations and agencies; (e) a stable budget that is linked to the objectives and strategies; (f) an information system for coordinating activities and monitoring outcomes; and, (g) a management structure at the national level that has the authority to ensure success.*

Potential Goal of a Collaborative National/Nationwide Cancer Plan

To create an overall long-term plan and implementation strategies to eliminate cancer as a major public health problem in this country by synergizing the private, public and non-profit sectors in a collaborative effort against the disease; one that provides clear focus on a definitive common vision and the best places for government, corporations and the voluntary sector to leverage their respective strengths and resources.

Note: The American Cancer Society has gone on record calling for a 50 percent reduction in age-adjusted reduction in cancer mortality rates by the Year 2015 (June 1996).

National Cancer Policy Board

Upcoming Board Meetings

April 17-18, 1998
Washington, DC

July 30-31, 1998
Woods Hole, MA

October 2-3, 1998
Washington, DC

NAS Homepage
IOM Homepage
National Cancer Policy Board Homepage

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Valerie Mealy, Committee Management Assistant
Clara Murphy, Committee Management Assistant

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To: Jerry Mande
White House

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Fax: (202) 456-6027

Subject: New Nominees on NCAB

Reference:

[X] Phone Call [ ] Visit [ ] E-mail [ ] Meeting

11 pages including coversheet.

REMARKS:

Nomination Roster
Other Relevant Info

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From: Linda Quick-Cameron, CMO

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Subject: NCAB Roster

Reference:

[X] Phone Call [ ] Visit [ ] E-mail [ ] Meeting

_____ pages including coversheet.

REMARKS:

Per your call to Dr. Klausner's Offic

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DEC 16 1996

December 6, 1996

Carol Rasco
Assistant to the President for Domestic Policy
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Washington, D.C. 20500

Dear Ms. Rasco:

On behalf of the President's Cancer Panel, I am pleased to enclose the Press Statements from the 1996 meetings of the President's Cancer Panel addressing the topic *Managed Care's Role in the War on Cancer.* We are anticipating delivery of the final report to President Clinton in early 1997. As previously discussed, we look forward to meeting with your office to discuss the report and the ongoing efforts of the Panel with regard to managed care.

Sincerely,

Harold P. Freeman

Harold P. Freeman, M.D.
Chairman

Attachments:
Press Statements for meetings held
July 30, 1996, September 24, 1996
October 25, 1996, November 22, 1996

cc: Dr. Paul Calabresi
Ms. Frances Visco
Dr. Richard Klausner
Dr. Maureen Wilson

PRESIDENT'S CANCER PANEL

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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.

PRESIDENT'S CANCER PANEL

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September 30, 1996

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

Issues of Access in Today's Health Care System

September 24, 1996

Resource-intensive approval processes, denial of standard patient care costs associated with clinical research, mismanagement of pediatric and adolescent health care delivery, misdiagnoses and improper referrals by primary care providers, and fragmentation of service delivery were only some of the issues raised at a September meeting of the President's Cancer Panel held in San Antonio, Texas, regarding the impact of managed care penetration in the Southwest United States.

This was the second of four meetings on managed care issues scheduled by the Panel; the first was held in Seattle, Washington in July. The Panel, a three-member, presidentially appointed advisory committee that makes recommendations to the President on issues affecting the National Cancer Program, gathered testimony from the perspective of research institutions, providers, and patient advocacy groups regarding the effect of managed care systems on cancer care and particularly access to clinical trials testing promising new cancer therapies.

Expert presenters agreed that progress in the war against cancer is inextricably linked to the ability to conduct clinical research trials. Standards of cancer care today are the direct result of clinical research and such research remains, "incredibly important if we are to improve health care and...bring about state-of-the-art health care," stated Dr. Otis Brawley, Assistant Director of the National Cancer Institute and Director of the Office of Special Populations.

The view that the best or most appropriate cancer care for patients is often available only through clinical research studies, along with the view that continued progress against cancer is dependent upon the outcomes of such studies, was prevailing. Unfortunately, at present, only about 3 percent of adults participate in cancer clinical trials—a very small percentage. Thus, access to clinical research remains a compelling issue for both providers and patients alike.

Two of the leading cancer centers in the State of Texas—The San Antonio Cancer Institute (SACI) and M.D. Anderson Cancer Center (MDACC)—presented to the Panel that managed care penetration has not

yet caused a noticeable decline in the number of patient's able to access clinical trials, however, maintaining access is becoming increasingly difficult. Both institutions agreed that, as a result of movement toward a managed care health system, substantially more resources are required to enroll patients into research protocols, leaving less resources to devote to performing research, patient care, and education. In an SACI survey of 27 in-house and Southwestern Oncology Group (SWOG) physicians, 83 percent reported increases in the cost and time to obtain reimbursement and referrals due to managed care, with an average increase in overhead costs of 30-40 percent. MDACC has had to invest in new infrastructure processes in order to maintain its patients' access to clinical trials and quality medical care. Case management program personnel now work with faculty and staff to make sure that clinical therapies will be paid for and that necessary paperwork is completed.

The increased "cost of doing business" faced by these institutions will eventually have an impact. Implicit in remarks to the Panel were concerns that as overhead costs rise from new administrative realities and revenues decline due to increased competition for patients, reimbursement denials, and capitation of costs, the ability to perform cancer clinical research (and thus advance the state of our knowledge) will be affected.

Associations such as the American Cancer Society, American College of Physicians, American Medical Association, and Oncology Nursing Society were more vocal in their concerns regarding managed care. While acknowledging the importance of the cost efficiencies that managed care promotes, presenters cautioned against measuring cost effectiveness at the expense of access and quality of patient care. Of particular concern was the policy many managed care organizations adopt of denying standard patient care costs if they happen to be associated with a clinical trial. As one presenter noted, "it is acceptable to treat the patient as long as you don't learn from it." Another concern is whether more fragmented and closed provider networks may be impeding access to research studies and appropriate cancer care.

The responsibility of "for-profit" managed care was raised. Dr. Richard Corlin of the AMA, questioned who should profit from delivering health care services, pointing out that "[i]nsurers used to provide value by spreading risk," however under capitated reimbursement that risk is now passed to physicians and hospitals. An inherent problem was seen in a health care system that accumulates profits on behalf of shareholders without providing value back to the health care community. Dr. Harold Freeman, Panel Chair, acknowledged the conflict between medical ethics and fundamental business principles, and expressed concern that medical ethics not be overshadowed by business motivation as health care becomes a profit-driven enterprise.

Advocacy groups representing the "voices" of cancer patients presented the most dramatic testimony of the day. The predominant view among patients is that managed care has resulted in a decline in the quality of their care—important services such as counseling, pain control, and rehabilitation are not reimbursed; referrals to specialists are impacted by primary physician "gatekeepers"; and access may be denied to clinical trials that offer superior or equally beneficial (if unproved) therapeutic options.

Many patients perceive their access to care is directly related to their ability to challenge the decisions of their health care plan. One presenter called it the "survival of the fittest" of those who will fight the hardest to obtain care. More patients are turning to litigation to obtain access to desired treatment protocols, which is seen as a "no-win" situation for all. In an informal survey presented by The Anderson Network of its membership, comments included, "We have such a fight to live. Please quit

making us fight for our care." Another patient asked the Panel, "Please don't cut funding. Let us have access to clinical trials. That is our future. That will win the war [on cancer]."

A related issue raised to the Panel is the rippling effect of managed care on indigent citizens' access to health services. "[A]s physicians, hospitals, and other cancer care providers face decreased revenue under new managed care reimbursement systems, they are becoming increasingly reluctant or contractually unable to provide charity care" stated Emily Untermeyer, Executive Director of the Texas Cancer Council. Since charity care has traditionally been a primary source of health care for the poor, uninsured, and underinsured, this raises the question of how these individuals will obtain not only cancer care, but basic health care, in the future.

The Panel also heard testimony on difficulties being experienced in pediatric oncology and the conduct of pediatric clinical trials. Over 70 percent of children and adolescents with cancer are treated on clinical trials, making clinical trials the standard of care. Managed care decisions in this setting are having a significant impact. For example, guidelines developed for adult cancers are being inappropriately applied to children with cancer; services are being fragmented with different sites performing different procedures, making it more difficult to monitor care and coordinate results; and integral costs of treatment are not being covered. Recent reports indicate that when adolescents are treated on adult clinical trials they have poorer outcomes. However, many managed care organizations continue to refer adolescents to adult oncologists. The result is that these patients cannot access pediatric clinical trials where health outcomes are known to be better.

Recommendations for improving access to clinical trials varied. Several speakers felt that some form of regulation of for-profit managed care may be appropriate at the Federal level, similar to the regulation of for-profit hospitals in the 1970s. Legislation mandating comprehensive cancer care coverage for children was recommended. It was also suggested that the National Committee for Quality Assurance play a role in incorporating research into managed care activities by applying new standards as part of the accreditation process. Others felt that the market may enforce its own corrections—providers and patients are challenging at an increasing rate the right of managed care companies to interfere with treatment options, and should the Health Care Financing Administration (HCFA) recommend coverage of clinical care costs, competition will likely increase among managed care entities to participate in clinical trials.

The Panel asked presenters "who should pay" for the costs of clinical research. "If we are to include all individuals who are eligible and who want to go onto clinical trials, how those clinical trials are paid for is going to be very important" emphasized Dr. Brawley. Most concluded that no single source of funds is likely, rather funding will be a collaboration between institutions, cooperative groups, Federal agencies, managed care organizations, and industry.

Increasingly industries, such as pharmaceutical and biotechnology companies, are sponsoring clinical trials in order to expedite drug approval processes. Per Dr. Corlin of the AMA, Smith, Kline, Beechum plans to infuse $5 billion into clinical trials. Dr. Harold Freeman, Chair of the Panel, acknowledged the important role of industry in funding research, but wondered how this would impact the types of research conducted. "If we are moving toward greater participation of industry in funding research, will it limit the questions we can ask and answer?"

Some presenters saw an opportunity to conduct more clinical research in the context of managed care, if agreement is reached on appropriate standards (i.e. peer review) and priorities. Similar concern, however, was expressed related to managed care funded research—will more control be exerted over the delivery of research similar to the control being exerted over the delivery of patient care?

Presenters advocated for more Federal funding to support Phase I and Phase II clinical trials that are normally not covered by third party payers, with the observation that support for basic research goes unquestioned by the National Institutes of Health.

Several Federal initiatives underway to improve funding and access to clinical trials were discussed. NCI is currently in negotiations with the Department of Veterans' Affairs, the Health Care Financing Administration, and a number of private insurers regarding issues of coverage for individuals for treatment trials as well as cancer control and prevention trials. Representatives from the Department of Defense presented progress in implementing the joint demonstration agreement entered into with NCI that allows military health care beneficiaries under CHAMPUS to access care under NCI sponsored Phase II and III clinical trials. The Department is working with HCFA to incorporate coverage for military personnel over age 65, who are currently not covered by the program.

Dr. Freeman closed the meeting by summarizing the many issues raised and acknowledging that many questions remain to be answered. Ultimately, as a market-driven system, he concluded that patients may have to play a larger role in determining the final form of their health care.

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December 10, 1996

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

Translational Research - The Interface With Insurance Reimbursement
A North East Perspective

All phases of clinical trials need to be incorporated into our health care delivery system as standards of care for cancer patients, and everyone should share in the risk and the cost—Government, health insurers, research sponsors, and patients. These principles were echoed over and over by presenters testifying at the President's Cancer Panel meeting hosted by Brown University at Rhode Island Hospital in Providence, Rhode Island on October 25, 1996.

The President's Cancer Panel is a statutorily created, three-member, Presidentially appointed advisory committee that meets regularly to assess the effectiveness of the National Cancer Program. It's current membership includes Harold Freeman, M.D., Chair, Frances Visco, J.D., and Paul Calabresi, M.D., M.A.C.P.

As the third in a series of four regional meetings in which the President's Cancer Panel is looking at the impact of managed care on cancer research and patient care, this forum brought together physicians, researchers, legislators and consumers who share the opinion that progress in the war on cancer is inextricably linked to the ability to conduct clinical research trials.

Presenters testified that phase I and II trials represent an essential gateway to progress in the war against cancer, particularly in the context of today's molecular biology revolution, where many more new opportunities for progress exist. At present, many insurers will not reimburse even routine patient care costs associated with clinical trials, particularly phases I and II, even though such costs would have been incurred regardless of trial participation. This failure to provide support for early clinical trials will be the principal barrier to translating effective research from the laboratory to the patient group at large.

Rhode Island has mandated coverage by insurers for certain standards of care, i.e., cancer therapies being provided pursuant to Phase III or IV clinical trials approved by the NCI, Department of Defense, Food and Drug Administration, Veteran's Administration, or "a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants." Significantly, testimony

obtained from managed care organizations in that state indicates that compliance with this law has had no financial impact; however, there is continued resistance to covering phase I/II studies.

Per Paul Calbresi, this resistance to reimbursing for phase I trials "is not because of cost...but because [health care organizations] think it is research and don't want to set a precedent of paying for research." As a Nation, we can not accept a health care mentality that allows us to treat patients only if we gain no knowledge from the experience.

Managed care organizations must be made to better understand that the reimbursement needed for clinical trials is limited to covering routine patient care costs, not the extra costs incurred from the research component. Likewise, the clinical research community must re-examine its definition of clinical trials at all phases -- phase I trials for cancer patients have a therapeutic intent, in addition to assessing toxicity and dose. For patients with cancer, clinical trials are often the best, if not the only, therapeutic options. In this way, phase I studies with anti-neoplastic agents are distinct from clinical trials of every other class of pharmaceutical or biological for treating non-life threatening conditions, conditions which can be conducted in normal human subjects.

Cancer centers, industry, and the NCI appear uniformly ready to step up to the plate and share in the costs of clinical research. Cost sharing would take into account differing responsibilities of the parties. As an example, insurers would pay for routine patient care costs, the research sponsor (i.e., NCI, cancer centers, etc.) for research costs, and the pharmaceutical company would pay for the costs associated with the agent being tested.

While most researchers felt positive about the role of industry in clinical research, they emphasized that industrial trials should not replace traditional studies. Industry is more bottom-line, outcome-oriented, with less need to consider the training aspects of clinical research for the medical profession.

In a more optimistic vein, Dr. Vincent DeVita, former Director of the NCI and current Director of the Yale Comprehensive Cancer Center, emphasized that the potential benefits of performing clinical research in a managed care environment should not be overlooked. In his view, the greatest threat to research is the exploding cost of medical care, not <u>how</u> it is paid for. This is due, in part, to the tremendous impact of health care costs on the national economy and the propensity to curtail research when the economy is doing poorly. From this perspective, he pointed out, "managed care represents a healthy way of controlling costs, if it is done right."

Other speakers were less optimistic, viewing managed care as an opportunity, but cautioning that a proactive approach is needed to ensure that clinical research continues -- an approach that will probably require some level of mandated support for clinical research through legislation.

Recommendations for overcoming the disincentives for managed care organizations to support clinical trials included:

- Regulation of for-profit managed care organizations to assure that they assume their fair share of responsibility for the health of this nation

- Legislation of comprehensive cancer care coverage for children as representing a unique health care population

- Development of an accreditation standard for managed care organizations which includes clinical research participation

- Additional grant funds provided to the General Clinical Research Centers to allow greater participation in both inpatient and outpatient cancer care.

Concluding the day, Ms. Marlene McCarthy, Chair of the Rhode Island Breast Cancer Coalition, placed the issues discussed into perspective. "Patient care and access have to be at the forefront" of these discussions, she told the Panel. She advocated for strong Government support for a national program of access to clinical trials. For their part, consumers need to become better educated and drive standards of action and access to treatment.

Per Harold Freeman, "...in the history of this nation, the American citizen has always battled to achieve the best that this nation can offer. Testimony at this meeting has told us that cancer centers, industry, and the NCI appear uniformly ready to share in the costs of clinical research. The President's Cancer Panel has heard your voices and it is our duty to promote this joint responsibility before the President and the insurance industry."

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December 10, 1996

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

Coping Strategies for Maintaining Outreach, Information Dissemination, Teaching, Recruitment, and Care in Today's Health Care Environment

November 22, 1996

As in other regions in which the President's Cancer Panel has heard testimony, increased managed care penetration in the Southeast United States has evoked feelings of both optimism and distress. In its final meeting addressing the impact of managed care on cancer research and patient care, many concerns were reiterated to the Panel, and some new concerns raised. Solutions, however, remained elusive. Presenters focused specifically on how managed care is affecting the ability of the cancer research community to maintain outreach, information dissemination, and education.

Testimony indicated that for-profit managed care organizations are generally not investing in prevention and outreach activities, despite continued profit-shifting in their direction. "These programs are easy to ignore," noted Dr. Otis Brawley, Assistant Director of the Office of Special Populations at the National Cancer Institute, "since they don't often result in immediate benefits or cost savings." There is also little incentive to create outreach and prevention programs in which benefits to the insurer may not be apparent until long after the program ends.

"Mature" managed care markets, i.e., those with a high market share, seem more committed to health assessment, outreach and education than "less developed" markets, according to some observations. Mature markets focus more on improving the overall health of their covered population since they carry the long-term financial risk for this population. In less developed markets, the primary focus is still on gaining market share and establishing stable networks. Under this paradigm, as managed care "matures" it will, theoretically, improve. However, even optimists agreed that maturity will not necessarily ensure that profits go back into research—"managed care organizations may be willing to apply new knowledge, but it is not clear what their investment in research and education will be," noted one speaker.

Presenters also distinguished between for-profit and not-for-profit managed care, emphasizing that many not-for-profit organizations are intimately involved in supporting integrated health care delivery and have strong affiliations with private medical centers.

A "spirit of cooperation"—establishing community coalitions and alliances—was recommended to help fund integrated health care delivery, particularly for the underserved. Many academic medical centers are seeking partnerships with community hospitals, community-based organizations, and foundations to improve access to health services and maintain research efforts. The missing partner in most alliances, however, is managed care. Strategies need to be developed to improve collaboration with managed care organizations and encourage them to share in this funding responsibility, since they also have a stake in improving the health status of the population.

In addition, implementing measures for screening and prevention activities would provide needed data to report back to the public, who can then hold managed care organizations accountable for their policies. National organizations can assist by recommending health care guidelines, since coverage of prevention and outreach activities by insurers is typically limited to proven approaches.
The reluctance of managed care organizations to invest in training and education was viewed by some as the most serious threat to cancer research, with long-term consequences for patient care. "If we don't refuel our ability to stay on the cutting edge of advances, then 10 years from now we will have fallen behind," predicted Dr. Harold Freeman, Panel Chair. The question of who will support clinical investigators remained unanswered.

Changes in the dissemination of cancer information in the context of managed care were also addressed. Representatives of the Cancer Information Service (CIS) and American Cancer Society stated that while access to information is increasing through sources such as the Internet, access to "impartial scientific information in easy-to-understand terms" is more difficult to obtain.

Cautious consumers are seeking out their own information through online databases (MEDLINE, CANCERLIT), the Physician's Data Query, and cancer discussion groups. Instead of decreasing the number of calls to public cancer information services, the opposite has occurred—more people are requesting help in understanding the complex information they are reading. More calls are also being received from consumers concerned about the quality of their cancer care, describing delays in treatment and referrals back to primary caregivers for followup. This points to additional resource needs not previously contemplated.

The managed care trend toward early discharge and outpatient care is also creating unique information needs. For example, the early discharge of mastectomy patients has increased the calls to the CIS regarding home care issues. The Panel noted that such service is really subsidizing patient care that should be paid by insurers. Another area being indirectly "subsidized" is family counseling on cancer issues.

The Panel heard moving testimony that the emphasis on "managed cost" may be occurring at the expense of quality care and further erosion of access to care for vulnerable groups such as minorities, the elderly, the poor, and the uninsured. According to one report, poor and elderly Medicaid recipients in the Southeast have experienced poorer health outcomes using health maintenance organizations than with traditional point-of-service programs. Academic health centers testified that they must continue to underwrite care for the indigent, and that these populations are virtually excluded from clinical protocols. In general, cultural factors are not being competently addressed in research, cancer care, or preventive practices.

To halt the decline of patient accruals in clinical research, most experts agreed that cost sharing should occur, with managed care organizations being responsible for standard patient care costs. Consumer pressure to move managed care in this direction should be adequate, but legislation may be necessary. Mandating oversight mechanisms and information systems to ensure quality and continuity of patient care was also recommended. Federal and State governments that contract with managed care organizations should negotiate support for clinical trials.

The Panel was reminded by one of the many victims of cancer that Americans must not forget they are fighting a war with this disease—a war in which more than 1,500 lives are lost each day. We need to seek ways to ensure that the enemy is not ourselves—that evolving systems of health care delivery provide patients with the best weapons to fight their disease, provide access to the necessary tools to build upon cancer research advances, and "put the CAN into curing cancer."

The Panel will integrate the results of its four meetings assessing managed care's impact on the war against cancer, and present conclusions and recommendations to the President. An important issue will be to define the values that should be part of our health care system and articulate how these can be infused into a market-driven system. From the consumer perspective, it is still better to prevent cancer than to treat it, and measuring only cost-effectiveness will ultimately lead to distortions in the values we desire to promote. In his conclusions, Dr. Freeman recognized this, stating, "the issue of values, ethics, and morals is hard to quantify, but nothing is more important. Quality must coexist with efficiency."

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
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Room 4A48 - MSC 2473
Bethesda, Maryland 20892-2473

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

December 11, 1996

Mr. Christopher Jennings
Special Assistant to the President for Health Policy
Executive Office of the President
2nd Floor, West Wing
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Jennings:

On behalf of the President's Cancer Panel, thank you for the opportunity to meet with you on January 24, 1997 at 1 p.m. to discuss managed care's role in the war on cancer. I am also pleased to enclose the Press Statements from the 1996 meetings of the President's Cancer Panel addressing that topic.

The Panel is mandated by its charter to prepare an annual report of its activities for the President. We are anticipating delivery of the 1996 report to President Clinton in February 1997.

Again, we are looking forward to meeting with you in January.

Sincerely,

Harold P. Freeman

Harold P. Freeman, M.D.
Chairman

Attachment: Press Statements for
July 30, 1996, September 24, 1996
October 25, 1996, November 22, 1996

cc: Ms. Carol Rasco
Dr. Paul Calabresi
Ms. Frances Visco
Dr. Richard Klausner
Dr. Maureen Wilson

PODESTA
associates, inc.

November 25, 1996

TO: ELIZABETH DRYE

FROM: TONY PODESTA

RE: EVENT REQUEST (ATTACHED)

Elizabeth, you were a key reason why we were able to pull off the President's recent cancer event in the Rose Garden and why it did so well with the press and the public. The cancer research event described in the attached memo would be a great way to build on that success. As you know, both the President and the First Lady have been outspoken on the importance of cancer research, and this offers an excellent opportunity to keep their support in the public eye while doing some good for a good cause.

If you agree, a quick commitment to a date is absolutely essential. The calendars of the top people in the entertainment industry fill up literally months in advance. Your help in getting an early decision would be most appreciated.

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Web Site: http://www.podesta.com

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.

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- 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

PODESTA
associates, inc.

Memo

Subject: Cancer Research and the Entertainment Industry -- An Opportunity for Public Education about Cancer

From: Tony Podesta

Date: November 25, 1996

Summary: The President received widespread praise for recent cancer initiatives (3/29/96 and 10/27/96). We recommend that the White House build on the success of those events with a day in Los Angeles that combines (1) a visit and remarks at UCLA -- an academic health center that is also an NCI-supported comprehensive cancer center -- and (2) a dinner and brief remarks with the leaders of the entertainment industry to encourage a significant public education effort they are prepared to undertake. The purpose of this memo is to request a commitment to a date in February for this event.

Cancer is a disease which touches almost all Americans. In the next few years it will surpass heart disease as the leading cause of death in the U.S. Over our lifetimes, more than 40 percent of us will develop cancer, and more than 20 percent of us will die of it. However, recent data show we are beginning to turn the corner on cancer mortality. 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.

This is the 25th anniversary year of the National Cancer Act, which was signed into law on December 23, 1971. To mark that anniversary, the nation's major cancer organizations have joined together under the banner of Friends of Cancer Research to raise public awareness and support for cancer research. Rick Klausner, the energetic and able Director of the National Cancer Institute, has supported this effort and participated with keynote speeches at two kickoff events in October, as well as the President's Rose Garden announcements October 27.

Years of intensive research and collaboration have taught scientists that there is no single cure for cancer. They have discovered instead many different ways to contain and destroy some forms of cancer. Researchers are experimenting today with innovative procedures that will equip doctors with more means of successfully treating patients than ever before. Excitement is growing over recent progress in fields like genetics -- progress that has already begun saving lives and will keep researchers' hands full with promising opportunities to turn radically new and successful treatments into general practice in the coming years.

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The leaders of the nation's television industry are in a position to convey that message of hope, and Sherry Lansing, Chairman of Paramount, is committed to making it happen. After meeting with Klausner, she offered to host (either at her home or at Paramount) approximately 100-150 of the leading figures in the entertainment industry -- major stars, producers, and studio heads -- to hear from Dr. Klausner directly. She will appeal to them to speak out personally on the importance of cancer research and to integrate the theme into their programs' story lines. Ms. Lansing, the Entertainment Industry Chair for Friends of Cancer Research, is one of the most powerful studio executives in Hollywood and the first woman to hold such a position.

She has asked that the President or Vice President participate in this event, and **we strongly recommend it.** Both the President and Mrs. Clinton and the Vice President and Mrs. Gore have strong personal connections to the topic of cancer research. This would also be an opportunity to reinforce the Administration's position on tobacco and youth. Finally, this is a chance to interact with the movers and shakers in this important industry in something other than a fundraising event. The cancer community is very well organized and would also notice and appreciate their participation.

To maximize the attendance of the key figures and thus the impact of the event, a commitment in advance to a specific date is urgently needed. We recommend February 13 or 14 but will schedule the event on the basis of your availability.

To frame the issue properly for the press, we recommend that the President make a late morning or early afternoon visit to UCLA's Jonsson Comprehensive Cancer Center for an event that would be hosted collaboratively with USC's Norris Comprehensive Cancer Center and the City of Hope National Medical Center. The UCLA and USC centers are two of just 26 centers in the U.S. designated as comprehensive for their support of basic and clinical research. We would assemble an audience of researchers and cancer survivors to hear remarks by the President and Dr. Klausner. The theme: We will find the answers to cancer in the 21st century with the research we are supporting today. This would also provide an opportunity to show support for academic health centers, which are threatened by the cost containment imposed by managed care.

As a follow-up to the Lansing dinner, we will also have a substantive conference of writers and producers -- identified by the participants at the dinner -- at which Dr. Klausner or appropriate surrogates will present some of the stories of courage and hope that we believe could be adapted for television, taking advantage of the medium's power to educate Americans about the warning signs of cancer and the options available to combat it. **The President's involvement in this initiative will catalyze broad interest and support in the industry and help bring it to fruition.**

For more information, call me or Reid Detchon at 393-1010, or Ellen Sigal, Chair of Friends of Cancer Research, at 944-6710.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002. memo	Martie Kendrick to Jerry Mande re Intercultural Cancer Council (partial) (1 page)	01/27/1998	b(6)

COLLECTION:
Clinton Presidential Records
Office of Science and Technology Policy
Jerold Mande
OA/Box Number: 13033

FOLDER TITLE:
Cancer Panels: Cancer Panels

2008-1524-F
kc1217

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.
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RR. Document will be reviewed upon request.

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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]

[002]

PATTON BOGGS, L.L.P.

MEMORANDUM

VIA FAX 466-6027

TO: Jerry Mande

FROM: Martie Kendrick and Kate Boyce

DATE: January 27, 1998

SUBJECT: Intercultural Cancer Council

Following is the information you requested on potential ICC participants for Vice President Gore's January 29, 1998 session.

Armin Weinberg
Co-Chair, Intercultural Cancer Council
Phone: (713) 798-4614
DOB:
SSN: (b)(6)

Pam Jackson
Outreach Director
Phone: (713) 798-4617
DOB:
SSN: (b)(6)

Lovell Jones, PhD
Co-Chair, Intercultural Cancer Council
Phone: (713) 794-5550
DOB:
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Kate Boyce, Esq.
Washington Counsel
Phone: (202) 457-6094
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Elin Greenberg
Intercultural Cancer Council
Phone: (214) 750-8350
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Martha Kendrick, Esq.
Washington Counsel
Phone: (202) 457-6520
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PRESIDENT'S CANCER PANEL

National Cancer Program ◆ National Cancer Institute

Executive Secretary
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WEB Site: http://156.40.252.246/advisory/boards.htm

January 30, 1998

The Vice President
Old Executive Office Building
Room 276
Washington, D.C. 20500

Dear Mr. Vice President:

The purpose of this letter is to make you aware of observations and conclusions of the President's Cancer Panel regarding the meaning of race in science, which I have already forwarded to the President, and to request the opportunity to personally brief you on these findings. I read with great interest your remarks on the occasion of Martin Luther King Jr. Day and your subsequent statements regarding genetics during the James D. Watson Lecture and can not help but think that our recommendations will aide you in the course you and the President are charting for America in the 21st Century.

On April 9, 1997, the President's Cancer Panel convened a meeting on *The Meaning of Race in Science*. Its purpose was to discuss frankly how we classify people for purposes of scientific study, the basis on which these classifications have evolved, and how these classifications influence scientific inquiry, access to health care, and ultimately, health status and survival. Foremost among the points made at that meeting are:

- **Race as used in the United States is a social and political construct derived from our Nation's history. It has no basis in science or anthropology.**

- **Biologically distinct races do not exist. Indeed, there is no evidence that they have ever existed in the recorded history of the human community.**

- **Neither is there a genetic basis for racial classification.** Modern technologies for measuring and conceptualizing human variation reveal that approximately 85% of all variation in gene frequency occurs within populations or races and only 15% occurs between such populations.

- **Racism, rooted in the erroneous concept of biological racial superiority, has powerful societal effects and continues to influence science.** The cultural framework of societal, institutional, and civilizational values in which science is conducted, and the role science has played in constructing and legitimizing race and racism must be recognized and addressed.

The Panel concludes that race does not exist from a biological perspective, but that racism, rooted in the social concept of race, does exist. As you so well indicated, in your discussion of the "sin of racism," the consequences of having an identified race and the racism inherent in such categorization have been associated with lower socioeconomic position, greater exposure to stress and unsafe environments, and reduced access to quality health care for some racial groups. These are areas traditionally addressed by civil rights reform, but we can not fail to recognize that socioeconomic position, environment, and access to care have also become significant indicators of health outcomes. If the power of science can be used to eliminate public perceptions of racial superiority and inferiority that are believed to be the basis of racism itself, and if we can better characterize the variables leading to health outcomes that have been erroneously associated with race, then science can help us "transcend race." I look forward to discussing this with you.

Sincerely,

Harold P. Freeman

Harold P. Freeman, M.D.
Chairman

Attachment

PRESIDENT'S CANCER PANEL

National Cancer Program ◆ National Cancer Institute

Executive Secretary
Maureen O. Wilson, Ph.D.
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Phone: 301-496-1148/FAX: 301-402-1508
E-mail: PRESCAN@nih.gov
WEB Site: http://156.40.252.246/advisory/boards.htm

January 30, 1998

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The purpose of this letter is to make you aware of observations and conclusions of the President's Cancer Panel regarding the meaning of race in science and to request the opportunity to discuss with you personally the ramifications of these findings for your initiative on race relations. We are aware that in June 1997, the President's Advisory Board on Race was formed and charged to provide counsel on your initiative to promote forthright national dialogue on controversial issues of race, to improve understanding of the history of race relations, to help bridge racial divides and work toward a common future for all races, and to propose actions to address issues in critical areas, including education and health care. Our findings, we believe, will be crucial to the Board's deliberations and I would request the opportunity to share our findings with them.

On April 9, 1997, the President's Cancer Panel convened a meeting on *The Meaning of Race in Science*. Its purpose was to discuss frankly how we classify people for purposes of scientific study, the basis on which these classifications have evolved, and how these classifications influence scientific inquiry, access to health care, and ultimately, health status and survival. Foremost among the points made at that meeting are:

- **Race as used in the United States is a social and political construct derived from our Nation's history. It has no basis in science or anthropology.**

- **Biologically distinct races do not exist. Indeed, there is no evidence that they have ever existed in the recorded history of the human community.**

- **Neither is there a genetic basis for racial classification.** Modern technologies for measuring and conceptualizing human variation reveal that approximately 85% of all variation in gene frequency occurs within populations or races and only 15% occurs between such populations.

- **Racism, rooted in the erroneous concept of biological racial superiority, has powerful societal effects and continues to influence science.** The cultural framework of societal, institutional, and civilizational values in which science is conducted, and the role science has played in constructing and legitimizing race and racism must be recognized and addressed.

Mr. President, we conclude that race does not exist from a biological perspective, but that racism, rooted in the social concept of race, does exist. In our society, the consequences of having an identified race and the racism inherent in such categorization have been associated with lower socioeconomic position, greater exposure to stress and unsafe environments, and reduced access to quality health care for some racial groups. If the power of science can be used to eliminate public perceptions of racial superiority and inferiority that are believed to be the basis of racism itself, then science could prove pivotal in discussions on matters involving race and racial reconciliation.

Now, more than ever before, we have the opportunity to promote a more meaningful dialogue among people of America and throughout the world. Science can be a crucial element in the Nation's most important mission of building one America. We can begin by teaching every first grader the simple truths that science has now shown us--that we are more alike than we are different. We can not fail to take advantage of this window of opportunity to provide generations of young Americans with an education that dispels the notion of biological race and the societal implications it engenders. I look forward to engaging in personal dialogue with you on this critical issue for the American public.

Sincerely,

Harold R Freeman

Harold P. Freeman, M.D.
Chairman

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[003]

310-828-5268

Judith C. Gasson, Ph.D.

Curriculum Vitae

DATE OF BIRTH: (b)(6)

SOCIAL SECURITY NO:

EDUCATION:

B.S.	1973	Microbiology, Colorado State University
Ph.D.	1979	Physiology, University of Colorado
Post-Doctoral	1979-1982	Genetics, Salk Institute

PROFESSIONAL POSITIONS:

9/95 - present	Director, Jonsson Comprehensive Cancer Center
7/1/93 - present	Professor of Medicine and Biological Chemistry, UCLA School of Medicine.
6/92 - present	Full Member, Molecular Biology Institute.
7/91 - 8/95	Associate Chief for Basic Research, Division of Hematology-Oncology.
8/1/89 - 6/30/93	Associate Professor of Biological Chemistry UCLA School of Medicine
7/1/87 - 6/30/93	Associate Professor of Medicine Division of Hematology-Oncology, Department of Medicine, UCLA School of Medicine. Member, Jonsson Comprehensive Cancer Center.
7/1/84 - 6/30/87	Assistant Professor of Medicine Division of Hematology-Oncology, Department of Medicine, UCLA School of Medicine. Member, Jonsson Comprehensive Cancer Center.
1/1/83 - 7/l/84	Assistant Research Biologist Division of Hematology-Oncology, Department of Medicine, UCLA School of Medicine.
1979 - 1982	Postdoctoral Fellow, Regulatory Biology Laboratory, The Salk Institute, San Diego, CA. Advisor: Dr. Suzanne Bourgeois.
1975 - 1979	Predoctoral Fellow, Physiology Department, University of Colorado. Advisors: Drs. Betty Eipper and Dick Mains.
1973 - 1975	Research Assistant Denver General Hospital, Department of Surgery.

AWARDS:

1985-1988	Recipient, American Cancer Society Junior Faculty Award
1987	Richard F. Dwyer-Eleanor W. Dwyer Fund for Excellence at the Jonsson Comprehensive Cancer Center
1988-1993	Recipient, Leukemia Society of America Scholar Award
1991	Inducted into Glover Gallery, Colorado State University
1991	UCLA "Woman of Science"
1991	Stohlman Memorial Scholar Award, Leukemia Society of America
1994	American Society for Clinical Investigation

PUBLIC SERVICE:

1988 - 1992, NIH Hematology-2 Study Section
1993, American Society of Hematology Advisory Board
1993 - 1995, Chair, Institutional Biosafety Committee
1993 - present, Cancer Research Coordinating Committee Grant Review Committee
1995 - 1999, American Society of Hematology Subcommittee on Hematopoietic Growth Factors (Chair, 1996)
1996, NCI, Cancer Centers Working Group
1996 - 1999, Board of Directors, American Association of Cancer Institutes

EDITORIAL BOARDS:

Oncogene
Stem Cells
Blood, Associate Editor, 1993-1995

RECENT RESEARCH SUPPORT RECEIVED:

9/95-9/2000	NIH "SCOR in Hematopoietic Stem Cell Biology"; Project 1 (PI), "Role of Homeobox Genes in Hematopoietic Differentiation and Maturation"
7/85-11/98	NIH, R01 CA40163, "Mechanism of Action of a Human Granulopoietin: GM-CSF"
6/86-7/00	NIH Program Project, P01 CA32737, J. Gasson, Co-PI and Project 1 PI, "Role of c-Fes in Normal and Neoplastic Hematopoieis"
7/91-6/94	Tobacco-Related Diseases Research Program, "Smoking and Leukemia: A Molecular Genetic Approach"
7/88-6/93	Leukemia Society of America Scholar Award, "Mechanism of Action of a Human Granulopoietin, GM-CSF"

PUBLICATIONS:

1. Gasson JC: Steroidogenic activity of high molecular weight forms of corticotropin. Biochemistry 18:4215-4224, 1979.

2. Gasson JC: Forms and activity of high molecular weight adrenocorticotropin in guinea pig. Peptides 1:223-229, 1980.

3. Huet-Minkowski M, Gasson J, Bourgeois S: Induction of glucocorticoid resistant variants in a murine thymoma line by antitumor drugs. Cancer Res 41:4540-4546, 1981.

4. Huet-Minkowski M, Gasson J, Bourgeois S: Glucocorticoid resistance in lymphoid cell lines. In Drug and Hormone Resistance in Neoplasia, vol 1, Bruchovsky N, Goldie JH, eds. CRC Press, Boca Raton, FL, 1982, pp. 79-94.

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12. Wachsman W, Gasson JC, Golde DW, Chen ISY: HTLV-II and human leukemia. In Biology and Therapy of Acute Leukemia. Proceedings of the 17th Annual Detroit Cancer Symposium, Baker L, Valeriote F, Ratanatharathorn V, eds. Martinus Nijhoff, New York NY, 1985, pp. 53-64.

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