

# **President's Cancer Panel Meeting**

Meeting Minutes

**The Responsiveness of the Health Care System  
to the Needs of Special Populations  
November 21, 1997  
Tampa, Florida**

## Overview

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. The purpose of this meeting, the last in a series of four meetings focusing on the concerns of special populations in the National Cancer Program, was to consider the responsiveness of the health care delivery system to the needs of these populations.

Fifteen speakers presented testimony to the Panel on the experience of Community Clinical Oncology Programs in providing cancer care to special populations, the perspective of patient advocates for various special population groups, rural cancer care issues, and problems experienced by working Americans. Speakers highlighted recent research and interventions focused on meeting the needs of different special populations for cancer screening, education, early detection, treatment, and supportive care, and offered specific recommendations on improving care for special populations for consideration by the Panel.

## Meeting Participants

**President's Cancer Panel:** Harold P. Freeman, M.D., Chairman; Paul Calabresi, M.D., Frances M. Visco, J.D.

**National Cancer Institute:** Maureen O. Wilson, Ph.D., Assistant Director, NCI; Executive Secretary, President's Cancer Panel

### Speakers:

Dr. Luis Baez, Chief, Hematology/Oncology Section, San Juan Veterans Administration Medical Center and San Juan City Hospital

Mr. John Carney, President, Hospice, Inc.; Chairman, Board of Directors, National Hospice Organization

Ms. Nancy Davenport-Ennis, Founding Executive Director, Patient Advocate Foundation

Dr. Enrique Davila, Mount Sinai Medical Center

Dr. Deborah Duran, Senior Research Advisor/Cancer Project Director, National Coalition of Hispanic and Health and Human Service Organizations

Ms. Nadra Floyd, Assistant Director for Community Action, AFL-CIO Field Mobilization Department

Dr. Charles Given, Michigan State University

Dr. Neel Hammond, Principal Investigator, Community Clinical Oncology Program, Montana Cancer Consortium

Dr. Jay K. Harness, Professor of Surgery, University of California at Davis, Bay Area Tumor Institute

Dr. Javier Kane, Assistant Professor, Division of Hematology/Oncology/Immunology, University of Texas Health Science Center

Dr. Constantin J. Rosenthal, State University of New York Health Center at Brooklyn

Dr. John C. Ruckdeschel, H. Lee Moffitt Cancer Center

Mr. Robert Samuels, National Prostate Cancer Coalition

Dr. Robert Veith, Principal Investigator, Louisiana State University Medical Center; Minority Based Community Clinical Oncology Program

Ms. Susan Wallace, National Ovarian Cancer Coalition

Dr. Maureen O. Wilson, Assistant Director, National Cancer Institute

### **Opening Remarks**

Dr. Harold Freedman, Chairman

In opening the meeting, Dr. Freeman stated that:

- This is the last of four meetings addressing the concerns of special populations in the National Cancer Program. Prior meetings in this series addressed the meaning of race in science and related considerations for cancer research, cancer in the aging population, and the real impact of the reduction in cancer mortality.
- Today's meeting is intended to identify areas of the current health care system that successfully serve the needs of special populations, and areas in which improvement is still needed.
- The health care system in the United States is in the midst of an extraordinary and rapid evolution. A principal feature of this evolution is a transition from traditional fee-for-service health insurance to varying forms of managed care. Health care costs are "managed" using structured service networks, negotiated provider-payer contracts, and common health care delivery guidelines, among other mechanisms. This transition is occurring in both the public and private sectors. More than 60 million Americans are now covered by private managed care organizations; further, both Medicare and Medicaid are rapidly converting to managed care systems as a central strategy for minimizing costs.

- In 1996, the Panel addressed the impact of the evolving health care system on the National Cancer Program, and reported its findings in its annual report to President Clinton. The Panel concluded, based on hearings in each quadrant of the country, that the impact of changes in our health care system has been equated, though not always correctly, with the introduction of managed care. These changes, under whatever organizational auspice (including traditional fee-for-service systems), pose a real danger to our progress in reducing the burden of cancer for all people. Perhaps nowhere will the effects of the changing health care system be as pronounced as among the traditionally underserved populations, who are already disadvantaged by having the fewest resources and fewest proponents to advance their interests.
- One of the Panel's recommendations in 1996 was that measures should be taken to ensure that minorities, the poor, the elderly, the uninsured, and the underinsured are not excluded from access to appropriate health care as the health care system evolves. Every person now waging a personal war with cancer, or who may in the future do so, needs timely access to the diagnostic and therapeutic strategies and tools best able to fight his or her disease, and assurance that medical knowledge and care will be applied appropriately to each person as an individual. Thus, access, cost containment, and quality of care are currently the competing priorities, among which we are struggling to achieve a balance for all populations, and particularly for underserved populations. Today's meeting provides an important opportunity to focus at greater length on the responsiveness of the current health care system to the needs of special populations.

### **Director's Remarks**

Dr. Maureen O. Wilson, Assistant Director, NCI

Representing Dr. Richard Klausner, Director, NCI, Dr. Wilson indicated that:

- Over the past two years, many discussions have taken place at the NCI on the impact of the changing health care system on cancer research, particularly in the area of clinical trials. Many efforts to increase participation in clinical trials research have focused on expanding the populations to whom clinical trials are accessible. These efforts have resulted in agreements forged with the Department of Defense (DoD) and the Department of Veterans Affairs to make NCI-sponsored Phase III and IV clinical trials available to persons receiving health services through those systems. NCI is now working to expand this coverage to Phase I and II trials.
- Likewise, discussions have taken place with the Health Care Financing Administration (HCFA) to expand such coverage to populations eligible for Medicare. The Medicare population is at high risk for cancer, and is growing. These discussions are continuing, but NCI realizes that the populations that can be reached through such agreements (i.e., through Federally-sponsored health programs) are relatively limited compared with the population as a whole. The help of institutions across the Nation is needed to expand interactions with the wide range of populations affected by cancer and those at risk.

- NCI has continued to ask why less than three percent of adults participate in clinical research studies. Lack of health insurance coverage is only one of the many factors contributing to this low participation level. Others include a general mistrust of clinical research among special populations, nonresponsiveness of the clinical trials systems to the needs of special populations, physical barriers such as geographic inaccessibility, fiscally-based reluctance of local physicians to refer patients to clinical trials at major cancer centers, and the lack of an evidence-based system of support for clinical trials reimbursement (an issue related to insurance coverage problems).
- Recent statistics show that while we have succeeded in achieving a reduction in cancer mortality nationally and as a research community, we have not been able to achieve a similar result with respect to cancer incidence. NCI has recently launched several initiatives to address this concern. First, a task force has been established to examine one of the most widely used reporting systems in the country, the Surveillance, Epidemiology, and End Results (SEER) program. By reexamining SEER, we will assess the validity of how we collect data on cancer incidence and mortality, and the populations that are affected. SEER data are also a crucial tool for tailoring cancer-related messages and the delivery of health care.
- Second, NCI has reorganized its Division of Cancer Prevention and Control into two distinct parts--a Division of Cancer Prevention, and a Division of Cancer Control and Population Studies. The extramural epidemiology and genetics program has been incorporated into the latter Division.
- Third, NCI is establishing a health informatics system that will be responsive to consumer needs, and plans to organize a network of cancer Web-masters to ensure that information available to one institution can be made available to all participating institutions.
- Lastly, NCI has recently created a consumer liaison group to bring more consumers and survivors into the NCI decision-making process.
- As Dr. Freeman has previously stated, changes being felt as the health care system metamorphoses threaten to disenfranchise further those who are already at risk in the system--the poor, the underinsured, the uninsured, minorities, and the elderly. Another group not often discussed in this category is much of America's working class. It is our responsibility to ensure that this further disenfranchisement does not occur by removing as many obstacles to access to appropriate cancer care as is humanly possible.

## Welcome

Dr. John Ruckdeschel, H. Lee Moffitt Cancer Center

## Background

The H. Lee Moffitt Cancer Center was established 11 years ago with a single mission-- to contribute to the prevention and cure of cancer. It was designed and constructed on a clinical imperative: Florida ranks number two both in number of new cancer cases, and in cancer mortality. The Center's primary catchment area is on the west coast of Florida. It

has a huge population of retirees who have brought with them to the area their accumulated life experience and exposures.

The state legislature created the institution in 1983, which opened as a cancer hospital in 1986. It was funded by the cigarette tax. In 1986, the facility had 50 beds, about 3,500 outpatient visits, and no funded research. The research program was initiated in 1992, and as a result of an aggressive scientific recruitment program, nearly 80 new faculty have joined the Center in the last three years.

Clinical facilities at the Center currently include a full service, 162-bed hospital with the largest bone marrow transplant unit in the Southeast, and full radiation, surgery, imaging, and pathology services. The Moffitt Clinic is the Center's outpatient facility. Clinical facilities also include the Lifetime Cancer Screening Center that provides full screening, genetic screening, and counseling services. Research facilities are growing rapidly, with one addition under construction and another planned. In 1996, the Center had nearly 2,000 patients entered on cancer control, translational, and clinical trials.

The Center uses a multidisciplinary approach to cancer care. Breast, lung, and prostate cancers make up a significant portion of the cancer cases treated at the Center. Somewhat unique to the Center and geographic area, more melanoma patients are treated at the Center than either lung or colon cancer patients. Special populations in the Center's catchment area include Latinos, the elderly, migrant farm workers, African Americans, and children. To serve its large elderly population, the Center has one of the few multidisciplinary senior adult oncology programs, which also serves as a focus for clinical and basic research on issues related to aging and cancer. Special programs for the underserved, low income migrant population focus on breast health; a breast health initiative is also in place for senior, primarily African American women. Programs for elementary school children and adolescents focus on smoking cessation and sun protection.

The Center has taken an aggressive and innovative approach to attracting patients and working with managed care providers in the area, with positive results. The H. Lee Moffitt Cancer Center has become an NCI-designated Cancer Center.

### Key Points

- Populations with special needs that tend not to be addressed include women with cancer other than breast cancer, and men with cancer other than prostate cancer. In addition, academic health centers and the collective national clinical research effort both have unaddressed important needs.
- Advocacy is a double-edged sword. Focusing attention and funding on specific cancers or conditions is beneficial as long as it is not at the expense of patients with other conditions. Without an increase in overall resources, advocacy and fighting between advocacy groups results in politicians setting specific clinical and research priorities--this is wrong.

- Academic health centers, of which cancer centers are a component, are suffering as a result of unintended consequences. In response to concerns about U.S. health care costs, we have rushed headlong into managed care systems without first testing to determine their effect on quality of care. Marketplace forces that are reducing expenditures have led to inappropriately restricted access to care. The Center maintains a staff whose sole job is to argue with managed care companies about patient access. This is true even for patients with policies in which the Center is a participating institution, and for Center employees covered by the Center's health policy who require cancer treatment.
- Teaching hospitals are also suffering the consequences of actions to reduce government spending--Medicare, residency, capital, and Medicaid reimbursements have all been cut. In addition, student loan program changes that now require repayment to begin upon medical school graduation rather than at the end of training discourage individuals who would be the next generation of cancer researchers and caregivers from pursuing specialty training.
- Academic health centers in medical schools are increasingly dependent on the clinical practice of the faculty to support the institution. At the same time, access to specialists is being limited. This results in a highly precarious situation. Capricious funding of clinical research by managed care companies complicates an already difficult problem. Moreover, financial incentives and data management support provided to community physicians by commercial research firms to enroll patients on industry-sponsored studies are reducing accruals to NCI sponsored research.

#### Additional Research Needed and Other Recommendations

- A general increase in research funding is needed. Doubling the National Institutes of Health (NIH) budget would require only the cost of a single B-1 bomber.
- Access to NIH-approved clinical trials should be legislatively mandated.
- The messages of advocacy groups should be carefully weighed until the overall research budget is increased.
- The current trend toward training primarily generalists without specialty knowledge or training, and curtailing specialty and research training will decimate the Nation's academic health enterprise. This must not be allowed to happen; the rebuilding of research system capacity and its workforce cannot be accomplished rapidly.

#### **Discussion**

Dr. Ruckdeschel

#### Key Points

- To attract and support young translational investigators, the Moffitt Cancer Center provides from its core resources salary support and protection from clinical practice requirements. Core grant development funds are used to provide laboratory equipment and support. This assistance is available for up to five years.

A more difficult group to support are predominantly clinical researchers who also need to know enough basic and translational science to cooperate intelligently in the design and implementation of translational trials. They, too, need general, central support. Deans or center directors need a larger pool of funds for such discretionary support. Without adequate support early in their careers, translational scientists are forced to spend their time writing grant applications for projects judged to be most readily fundable, instead of developing the working relationships with basic and clinical scientists necessary for their professional development.

- The commonly accepted statistic stating that only three percent of adults with cancer are treated on clinical trials may be misleading. Not every patient, because of comorbid conditions, lack of an ongoing study relevant to their disease, or other legitimate reasons (not related to funding) is appropriate for inclusion in a clinical trial. Instead of looking at the participation level of the universe of adult cancer patients, it may be more appropriate to assess the level of participation among patients who would be medically eligible for a study and for whom a relevant study is available; at the Moffitt Cancer Center, a study of lung cancer patients found that about 30 percent met these criteria and of these, about one in three entered a study.
- Cancer centers and other institutions should make extra efforts to reach populations in their areas that have special issues or needs. However, the focus on special populations has allowed policy makers, particularly Congress, to escape dealing with the larger, underlying issues (e.g., lack of access to care including clinical trials, lack of insurance coverage, inadequate research funding) that give rise to targeted programs for special groups.
- The Panel has heard testimony from other Cancer Center representatives indicating a shift toward industry-sponsored research compared with government-sponsored research. Dr. Ruckdeschel indicated that the Moffitt Center also grapples with this issue. In the past six years, the Center has de-emphasized reliance on this form of research support, and enters into pharmaceutical studies only as scientific partners with the company and when the study answers a scientific question of interest to the Center's investigators. He noted that at academic centers in which the faculty have heavy responsibility for generating clinical care income, they are likely to have little time for research other than relatively narrow, industry-sponsored studies.
- Until such time as funding for research is substantially increased, strong leadership at NCI and the NIH is crucial to avoid a conglomeration of programs dictated by advocacy support and political pressure. In the last two years, the benefit of such leadership at the NCI in particular has been evident. This underscores the importance of de-politicizing, to the extent possible, decisions regarding the selection of Institute leaders and of insulating these leaders from the whims and direct retribution of individual legislators so that they can be strong leaders. It was noted, however, that advocacy has been the avenue by which people whose health issues may have been ignored gain access to the system; it would not be desirable to close that avenue entirely or filter the exposure of Congress to pressing health issues.



- Protecting the academic centers from fiscal failure due to the dual forces of government spending cutbacks and managed care may require legislative protection or designation of the academic centers as a "special population." The academic centers need to be saved not just for their own sake, but to ensure that needed research on cancer continues. If the medical schools fail, there will be no influx of new talent to continue research into the next century. This in turn can be expected to lead to failure of the cancer centers. The advocacy community has a vested interest and an important role in ensuring the continued viability of the academic centers. The next generation of cancer research will not be done in private practice, in the HMOs, large insurance companies, or large integrated health systems. It will only be done in the academic centers.
- Dr. Calabresi has noted in the past that currently, 50 percent of cancer patients are saved; another 25 percent could be saved with the knowledge and technology we have now. For the remaining 25 percent (those with still intractable disease like pancreatic cancer and most metastatic disease), the research enterprise holds the only hope for improving survival.
- Reiterating that applying the cost of a single Stealth bomber to cancer research would double NCI's budget, Dr. Freeman suggested that an appropriate slogan might be: "We do not need Stealth, we need health."

## **PRESENTATION HIGHLIGHTS**

### **Community Clinical Oncology Program (CCOP) Perspective**

#### **Mount Sinai Medical Center**

Dr. Enrique Davila

#### Background

Mount Sinai Medical Center, located in Miami Beach, is the largest private not-for-profit hospital in Florida, with the only clinical cancer research program sponsored by the NCI in South Florida other than the Moffitt Cancer Center.

#### Key Points

- Managed care patients often cannot be included in studies because of late referral, and denial of coverage by insurers is a continuing problem. In addition, HMOs and managed care programs resist providing complete work-ups that are necessary if a patient is to be included in a trial. Further, managed care companies require patients to receive tests at the facility with which they have contracted; these facilities are often not of the highest quality.
- Other factors that complicate efforts to include managed care patients on clinical studies are preauthorization requirements, difficulties in locating gatekeeper physicians, unproductive discussions with non-physician managed care personnel, and difficulty in obtaining answers to questions. In addition, many oncologists

- treating managed care patients are forced to substitute chemotherapy drugs included in the plan's formulary for those they believe are most effective.
- Managed care plans could be the ideal setting for large screening trials since they have large patient populations.
  - NCI reimbursement for CCOP patient accrual activities is substantially less than that provided by industry studies, and does not provide any payment for patient follow-up. At the Mount Sinai CCOP, the 1997-98 budget (3.5 full time equivalents, \$180,000) is expected to cover enrollment of 75 new treatment patients (100 credits); however, the CCOP is also following 400 patients on adjuvant trials. Income from the pharmaceutical industry-sponsored studies being conducted at the CCOP is in fact subsidizing almost in full the costs associated with the NCI-sponsored trials. Remaining CCOP costs are covered by the Medical Center and philanthropic gifts.
  - National statistics indicate that the average annual salary for oncologists is \$175,000. Considering that most physicians work approximately 310 days per year, 10-12 hours per day, their hourly wage is less than that of their office managers. In addition, time is spent away from family at professional meetings. It should also be noted that participation in Federally-sponsored meetings may not cover the costs (e.g., travel expenses, slides) associated with attendance, unlike participation in industry-sponsored meetings. However, most oncologists continue to participate in clinical research because of the professional satisfaction it brings.
  - The requirement to recruit a specified percentage of minorities to clinical trials has no scientific basis. It has not been proven that minorities, as currently defined, have cancers that behave differently than those of the majority population. It is more costly to recruit these populations, and the study data may have insufficient statistical power to support conclusions. The current requirement does not take into account important socioeconomic factors that have far more impact on health than race/ethnicity; in addition, the requirement does not acknowledge the difficulties in categorizing self-identified multiracial/multicultural individuals.
  - The special populations of particular interest in Dade and Broward Counties, Florida, because of their greater numbers (compared with state and national percentages) include Hispanics and the elderly; the CCOP has been quite successful in recruiting these populations to trials, though the reasons underlying this success are unclear. It is noteworthy that efforts to recruit minorities have also resulted in an increase in accruals overall.

#### Additional Research Needs and Other Recommendations

- The American College of Surgeons has mandated that two to four percent of all new cancer cases be entered onto research protocols. HMOs and other managed care plans could be required by Federal or state mandate to enter a specified percentage of new cancer cases onto NCI-approved protocols. Such a mandate, which should be enforceable, could also include an informed consent provision that would enable the cancer center to conduct appropriate tests and refer the patient to the center and protocol best able to meet his or her needs.

## Montana Cancer Consortium

Dr. Neel Hammond

### Background

Over the past 20 years, the Montana CCOP, currently made up of three major clinical facilities and seven additional affiliates, has accrued about 2,500 patients to NCI-approved clinical trials. Some 830 trial participants are currently being followed. All 22 medical oncologists in the state participate in the CCOP, which is managed centrally from Billings. The CCOP's goals for the current grant period were to increase accrual onto NCI-approved studies, to improve knowledge diffusion in a remote area, to increase the availability of studies to physicians practicing oncology in this remote area, and to consolidate both data management and institutional review board (IRBs) activities.

Montana's geography is unique; a population of just over 850,000 people is spread over 145,000 square miles, and the weather and terrain are highly unpredictable. The Native American population is reservation-based, and has significantly different lifestyle and access to care issues than many other Native American populations.

### Key Points

- Relative to the CCOP's goals, its most impressive achievement has been in accrual to cancer control studies, particularly the Breast Cancer Prevention Trial (BCPT) and the Prostate Cancer Prevention Trial (PCPT). The more than 200 participants in these studies form a nidus for future prevention trials in the region. From 1996-1997, the CCOP accrued 137 credits to these trials, with a dropout rate on the BCPT that is among the lowest in the country. However, only two men were accrued to the PCPT from the Reservation. The Indian Health Service was notably nonsupportive in the accrual effort.
- The CCOP holds twice-yearly oncology conferences and has both telemedicine tumor boards and tumor boards established in all of the major villages. IRB-approved priority lists are delivered every two to four weeks to all outlying participating physicians.
- Data management centralization in Billings has enhanced data quality. In addition, consolidating the IRB in Billings has provided greater access to legal, social worker, and professional support, and has allowed the IRB to have both regionally and ethnically diverse members.
- Breast cancer is only one quarter as prevalent among Native Americans as it is on average nationwide, but five year survival is 50 percent or less, compared with 62.5 percent among African Americans and 75 percent among Caucasians. Native American women with breast cancer are almost invariably diagnosed with late-stage disease.
- A locally famous Native American woman has been instrumental in increasing trust and participation in the CCOP's breast screening program. As a result, the

clinics are now full, and for the first time, several stage one breast cancers have been detected.

- At the same time, it must be recognized that the medical plight of Native Americans on Montana's Cheyenne and Crow reservations is extreme. These maternally-directed reservation cultures are devastated by alcohol, domestic violence, lack of domestic structure, and a seeking of immediate gratification in a disinherited population. The medical providers are all white male physicians, whom the population does not trust. A survey of Native American women on the Crow reservation showed that 99.4 percent did not want to be examined by a white male doctor. Only half of the reservation population has a high school education; the survey indicated that most did not understand what is meant by "a painless lump" and most were unaware that the Indian Health Service (IHS) provided free mammograms. Most communications about health-related information are by word of mouth.
- In the past, NCI's funding to Native American populations has not been based on need. Native American populations differ substantially, and this must be recognized. Cultural differences among tribal nations are also significant; educational materials must be developed for each distinct culture.
- Similarly, rural populations have unique access and quality of care issues. Trying to maintain quality in outlying areas is difficult, and patients in the region do not travel to major metropolitan centers for care no matter how sick they are.
- The diffusion of medical knowledge into Montana is slower than it is into New York, California, or other more populous and accessible states. This is aptly illustrated by Montana's lumpectomy rates for breast cancer; statewide, the rate is 28 percent, compared with 45-50 percent for all National Surgical Adjuvant Breast and Bowel Project (NSABP) participating states and 87 percent in Pittsburgh. Rural women in Montana would rather have a mastectomy than a lumpectomy and radiation if the latter entails traveling 200 miles for the radiotherapy. Similarly, ductal carcinoma in situ (DCIS) incidence, an indirect measure of mammographic efficiency, is lower in Montana than NSABP-wide.
- Providing hospice care in Montana's remote rural setting also presents problems, and there is no hospice funding for the reservation Native American population or for veterans. It must also be recognized that it costs more to provide hospice services in rural settings.
- Unlike many other health services in Montana, radiation facilities are abundant, but their quality is questionable in some cases. Guidelines are needed to ensure adequate quality of these and other services.
- Managed care provides a unique threat in the rural environment; rural residents are very likely to be intimidated by managed care practitioners from major urban centers.

#### Additional Research Needed and Other Recommendations

- It is important that NCI distinguish between needy and non-needy minorities in its funding decisions and know where the money is going, especially in rural areas.

- Federal agencies including the Veterans Administration (VA) and IHS, should be supportive of NCI and NIH clinical research activities.
- To help involve rural residents in clinical trials, hospitals that support rural clinics should themselves be supported. Rural residents will not travel to Billings to see a medical oncologist and the cost of having the physician travel to the outlying areas is prohibitive.
- Managed care organization should be required to accommodate Montana's unique population and geographic requirements.
- Special efforts should be made to recruit and encourage female and minority physicians, particularly in organizations such as the IHS.

## **Louisiana State University Medical Center**

Dr. Robert Veith

### Background

The Louisiana State University (LSU) Medical Center Minority-based CCOP (MBCCOP) has been operational for three years. Its mission is to enhance cancer control in minority and underserved populations. The Stanley Scott Cancer Center at LSU has participated in the Southwest Oncology Group (SWOG) since 1965, in the Pediatric Oncology Group (POG) since 1980, and in the NSABP since 1974. The population served by the CCOP numbers 2.5 million, of whom about 35 percent are African American. Both community and university-based physicians participate in the CCOP.

To date, the CCOP has had more success in recruiting minority subjects for treatment trials than for prevention trials. Recruitment to the PCPT has occurred largely among the Caucasian population, because recruitment was tied strongly to existing prostate screening programs that were concentrated in areas with small minority populations.

### Key Points

- To help identify areas for improvement in prevention clinical trials recruitment, the CCOP conducted two surveys of its cancer epidemiology group. One survey included 62 African American patients (55 percent female) being treated in the Medicine Clinic at Charity Hospital for a variety of conditions. The second survey included 31 medical residents, of whom 23 percent were minorities; its purpose was to better understand the attitudes and beliefs of primary care physicians about cancer prevention trials. The residents perceived that getting to and from the clinic and taking time off from work were substantial barriers to patient participation. Patients did not indicate that these were significant problem areas, but it was recognized that the survey population may differ in its perceptions from a population not already being treated for a medical problem. Patients ranked altruistic reasons (e.g., helping community, mankind, children, and family) as strong motivators for participating in a trial.

- Residents indicated universally that lack of knowledge about available clinical trials was a major barrier to referral, pointing to the need for a major educational effort by the CCOP.
- At the beginning of its effort to recruit patients for the PCPT, the CCOP conducted a telephone survey of 300 lower income men aged 25-65 years in the New Orleans area; 60 percent were African American and none had a history of cancer. The purpose of the survey was to determine the sources from which these men sought out cancer-related information. Though no strong trends emerged, the African Americans indicated a greater reliance on television for this information that did not vary greatly with income level. The Caucasian men surveyed indicated a slightly greater reliance on print media compared with the African American men, and this preference increased with income (a possible surrogate measure of educational attainment).
- At a recent conference on recruiting minorities to cancer prevention and treatment trials, it was suggested that radio can be an effective tool for reaching African American urban populations; in particular, radio spots aired during the late night and early morning hours can be especially effective in reaching older African American men.
- Recruitment for prevention trials is more difficult because people who are not ill are being asked to interface with the medical system and alter their daily routine. It must be recognized that these recruitment efforts take time.

## **San Juan City Hospital**

Dr. Luis Baez

### Background

The San Juan Minority-based CCOP includes six participating institutions. The largest of these, San Juan City Hospital serves a population of 450,000, of whom 80 percent are medically indigent. Cancer is the second leading cause of death. Primary care is provided at Centers for Disease and Treatment that are distributed throughout the service area. Combined, the six CCOP facilities treat 25-30 percent of the cancer cases on the island of Puerto Rico. The relatively small number of patients who have medical insurance are likely to travel to the U.S. to receive treatment at one of the major cancer centers in Florida. For the remainder, the CCOP represents the only source of state-of-the-art cancer care.

### Key Points

- Participation in the MBCCOP has provided several benefits. It has been possible to conduct pilot studies to improve management of cancer pain, laboratory evaluations and pathology reports have been improved, surgical and oncologic reporting has become more specific, a multidisciplinary approach to care has been adopted, and professional education opportunities have been expanded.
- Barriers to the success of the MBCCOP include those related to socioeconomic factors, ethnic/language differences, data management issues, administration,

protocol availability, pharmacy limitations, physician issues, grant funding constraints, and the Puerto Rico health care reform effort. Perhaps the most problematic of these is the demand for cost-neutral studies. Demonstrating cost neutrality is difficult because no firmly established standards of care exist for activities such as staging studies and follow-up.

- Socioeconomic challenges derive from the limited state funding available to care for a large low income population, the limited educational level of most patients, the high percentage of single parent families, and poor telephone communications complicated by a highly mobile population within San Juan.
- # dialects, have made it difficult to use quality of life assessment instruments or existing educational materials.
- IRB issues are a major challenge. Currently, the CCOP must work with four IRBs; the result is nearly overwhelming paperwork, increased data management time, and delayed trial activation. For each protocol, eight informed consent forms must be approved; this is multiplied by the number of amendments to any given protocol. Informed consents are also needed in both Spanish and English.
- Pharmacy-related problems relate to use of non-formulary drugs, limited pharmacist and pharmacy technician manpower, storage issues, and most importantly, off-label use of drugs on clinical trials.
- Physicians tend to refer patients to trials late in the course of disease and often only as a last resort. They are not compensated for increased documentation associated with trials, and resent the 'fiscalization' and monitoring of their practices associated with managed care. Some community physicians do not strictly follow the trial protocol; patients often have higher morbidity as a result.
- Data managers have difficulty performing their role, since they also serve as patient escorts, and perform scheduling, laboratory, x-ray, pathology, and chart retrieval duties. They are required to cover four hospitals, and their salaries are low.
- Puerto Rico is changing rapidly to a capitated system for providing care to the medically indigent population. The potential impact of this transition has not been adequately assessed and problems are expected.

### **Bay Area Tumor Institute CCOP**

Dr. Jay K. Harness

#### Background

The Bay Area Tumor Institute (BATI) CCOP serves the Oakland-East Bay area; the population in Oakland, however, has a far higher percentage of minority, lower income, and poor residents than San Francisco or the State of California. African Americans comprise the largest racial/ethnic poverty group. One quarter of the Alameda County population is non-English speaking. Ninety percent of the CCOP's treatment trial accruals come from the Oakland area's minority, female, pediatric, or indigent populations.

#### Key Points

- The uninsured now number approximately 41 million in the United States, and should be considered a special population. It is somewhat shocking that 40 percent of working Americans are uninsured. Not surprisingly, a recent study from the Department of Health and Human Services demonstrates that the percentage of people who are insured rises as earnings rise.
- The public hospital sector cares for most of the uninsured in the United States; this is particularly true in urban areas. While community need and demand for services from public hospitals is rising, state and Federal dollars supporting these facilities are shrinking. As a result, care is being rationed in the public sector today.
- The private sector and managed care companies are competing for paying patients, including Medicaid patients, but no one is competing to provide care to the uninsured. Public sector hospitals need these Medicaid dollars to provide care to the uninsured.
- The number of new cancer patients seen annually at the Alameda County Medical Center, which serves a large poor and African American population, half of whom are uninsured, has doubled over the past ten years. These patients present with more unstaged and distant disease, less regional and localized disease, and have a 20 percent poorer five year survival rates compared with patients at other facilities in the county.

#### Additional Research Needed and Other Recommendations

- The social, economic, cultural, educational, and institutional barriers to cancer care for special populations are real and require attention. In particular, the Panel should bring the issues of the uninsured to the attention of the President.
- The loss of Medicaid dollars to private sector providers is crippling the ability of public hospitals to provide care to the uninsured, particularly as it is coupled with the loss of other state and Federal funding. NCI should directly support the public hospital sector cancer programs.
- The NCI should support innovative approaches to cancer control for the uninsured. The multidisciplinary, collaborative, and comprehensive approach used in breast cancer control in the private and university sectors can and should be adopted in the public sector. It can be applied to all cancer sites. This model also can be used to provide cancer control for special populations, focusing on patient education, screening of asymptomatic individuals, early and rapid diagnosis, prompt initiation of treatment, and retaining patients in treatment. In addition, supportive and long-term follow-up services are needed for these populations.



## **South Texas Pediatric Minority-Based CCOP**

Dr. Javier Kane

### Background

The South Texas area covers about 65,000 square miles inhabited by some 3.5 million people in 46 counties. None of the 41 counties in the western area has a population of more than 100,000, but population in this area is growing rapidly due to high birth rates and immigration. It is estimated that the lower Rio Grande Valley population will reach 2.5 million by the year 2025. The population in South Texas has just over one million people under age 18 years; this is the population served by the pediatric minority-based CCOP. There are an average of 141 cases of childhood cancer per year.

The South Texas area is considered medically underserved and a health professional shortage area; with 149 physicians per 100,000 population, compared with 173 per 100,000 in Texas overall, and 210 per 100,000 in the U.S.

South Texas has a large Hispanic population that derives from or has close ties with Mexico. The total population is about 60 percent Hispanic, but is up to 95 percent Hispanic in the border towns. Thirty percent of the population identifies Spanish as their primary language. While some of the population has been in the area for multiple generations, there are also many recent immigrants. It is not uncommon for one parent and some children to be U.S. citizens, while the other parent and other children in the family are Mexican citizens. Families tend to be large, extended, and predominantly Roman Catholic.

Levels of acculturation vary widely. Literacy rates are low, while poverty levels are high. Parts of the population adhere to a migrant work lifestyle and folk concepts of health and disease, which complicates the provision of health care. In addition, patients must travel long distances to access pediatric oncology services, and transportation can be unreliable. Provision of care is also complicated by increased surveillance of this population by the Immigration and Naturalization Service (INS).

The overall goal of the minority-based CCOP is to reduce the incidence, morbidity, and mortality of cancer in the pediatric, primarily Mexican American, age group, and to accomplish this principally by enrolling patients in cancer prevention, cancer control, and cancer treatment protocols of the POG. The MBCCOP institutions care for about 75 percent of all pediatric cancer patients in the region. Of all patients enrolled in treatment protocols at the MBCCOP institutions, 87 percent are minorities (74 percent Hispanic, 13 percent African American).

### Key Points

- The minority-based CCOP supports a clinical research office, data managers, expanded services to rural areas, clinics in medically underserved areas, continuing medical education for primary care physicians on the diagnosis and

supportive care of children with cancer, and maintenance of a research-based affiliation with the POG.

- The pediatric oncologists in the area are located in San Antonio and Corpus Christi; patients in the smaller cities are reached through outreach clinics.
- Acute lymphoblastic leukemia (ALL) and relapsed ALL are the most common pediatric cancers treated in the MBCCOP. For all cancers combined, 80-90 percent of eligible patients are enrolled in clinical protocols.
- Historically, it has been difficult to obtain cancer control credits in pediatrics, since primary prevention of childhood cancer is limited in scope, incidence of many cancers is low, and identifiable risk factors are lacking. Recently, however, several secondary prevention and related prevention protocols have been activated.

#### Additional Research Needs and Other Recommendations

- Minority populations can be enrolled onto treatment and cancer control research protocols, but MBCCOP support is essential. Enrolling these populations requires extra coordinating efforts, and these efforts require funds.
- Additional emphasis on secondary prevention, cancer control, and minority affairs is needed.

### **Kings County Minority-Based CCOP**

Dr. Constantin Rosenthal

#### Background

The Kings County MBCCOP serves the 2.5 million residents who reside on the 500 square mile borough of Brooklyn, New York. The population is approximately half Caucasian; the principal minority groups are African Americans and Hispanics. Median level of educational attainment approximates the national level, but the percent living in poverty is twice the national average. The percent elderly is slightly higher than the national average.

Like many minority and low income populations, the residents of Brooklyn tend to be diagnosed with cancer at later stages of disease. Where screening programs exist, earlier detection has been possible. The African American population has higher than average rates of multiple myeloma and cancers of the esophagus, prostate, cervix, and stomach.

Kings County is medically underserved, with approximately 40-45 physicians per 100,000 population.

#### Key Points

- The rapid and aggressive development of managed care organizations has had a negative impact on the MBCCOP participating hospitals and has resulted in a shift to outpatient cancer care. To maintain accrual of managed care patients, the

CCOP has attempted to establish agreements with the managed care organizations; it has been successful in doing so only with the Health Insurance Plan of New York (HIP), a large, not-for-profit plan.

- In addition to the NCI CCOP grant, support has been received from the nonprofit university hospital. This latter support, however, first declined and will now be terminated, due to reduced institutional income driven by the increasing market share of for-profit managed care organizations. The for-profit plans have been uninterested in collaboration with the CCOP.
- To help increase accruals, the CCOP has distributed informational pamphlets to physicians and the community, published a quarterly newsletter, and employed both radio and newspapers to disseminate screening information. In addition, the CCOP has assembled a team of survivors to help in recruiting new patients.
- Up to 40 percent of patients in clinical trials are lost to follow-up; lack of transportation and telephone communication, both linked to income level, are major contributors to this problem.

#### Additional Research Needs and Other Recommendations

- For-profit managed care operates to the detriment of cancer care for minorities; these plans should be required to participate in clinical research activities as a condition of operation.
- Grant funding should provide for transportation and related services needed by minority populations to enable them to participate in follow-up.
- For cancers in which there is no standard treatment and high mortality, Phase III studies should be incorporated into existing treatment regimens.
- A public relations campaign on clinical trials is needed to inform the public and enable the CCOP and other investigators to compete with managed care companies for patient enrollment.

#### **Discussion**

Drs. Davila, Hammond, Veith, Baez, Harness, Kane, and Rosenthal

#### Key Points

- It is difficult to get consumer input or involve consumers in outreach activities in the smaller villages in Montana. Though IRB representatives distribute informational materials, many communities do not have newspapers. Outreach clinics distribute protocol booklets, and patient education sessions are held. Direct consumer involvement (e.g., a cancer survivor from a particular tribe or community providing information to the community) is possible in some of the larger communities, but small numbers make this impractical in the more remote areas.
- Dr. Kane suggested that the high level of accrual of pediatric patients, including minority patients, to clinical trials is the result of excellent organization and communication in the pediatric oncology groups. This organization has developed out of necessity; there is only one pediatric patient for every 150 adults with

cancer, and institutions have needed to collaborate to ensure that enough patients are accrued to conduct meaningful research. The transferability of this model to adult patients should be explored.

- The MBCCOP support in Texas is necessary to enable outreach to remote areas, some of which can only be reached by air.
- In Montana, smoking prevalence is high, though not tied to cultural or religious ceremonies. A recent survey of reservation Native Americans indicated that more than 40 percent of the women surveyed used smokeless tobacco.
- Dr. Davila reiterated his view that the term "minority" is political and is being inappropriately applied to science. In doing so, the purity of science is being sacrificed. We do not know if the Federally-defined minorities should be applied to science, or if cancer incidence, etiology, or response to treatment differ at all between these groups. Moreover, far more data support the importance of socioeconomic rather than racial factors in cancer outcome. However, these factors are frequently linked; without correcting for socioeconomic factors, it is probably meaningless to apply racial categories in science. It was suggested that if studies are to be conducted to identify racial factors, if any, distinct from environmental or sociologic factors, such studies should involve only individuals whose known heritage is one third or more the minority group of interest. In addition, the possibility of important variations within the white population is seldom explored. Within Federally-defined minority/ethnic groups, differences in living circumstances and migration may be far more important than ethnicity. It was also noted that individuals can and do elect to change their Federally-defined racial/ethnic designation; studies to date have not attempted to control for this reality.
- Studies of minorities should first correct for socioeconomic factors. Recent immigrants should be studied separately as a severely disadvantaged group. Cultural aspects, particularly nutritional factors, may also be of significance in epidemiologic studies.
- Dr. Kane maintained that genetic racial differences may exist and should be explored if they appear to influence response to cancer treatment or disease risk. He believes data on different responses to methotrexate among white and black children with ALL illustrates this possibility. He agreed that social, cultural, and economic characteristics of a population are also important.
- Participants acknowledged that while the CCOPs count minority participation in accruals to comply with Federal requirements for funding, it is unclear if this is of scientific value. It does seem to be true, however, that designation of a group for emphasis leads to greater funding, which permits more outreach and more access for previously underserved populations.
- Though no one in Puerto Rico is denied access to health care because of lack of insurance, the state-sponsored system for the uninsured is underfunded and understaffed, resulting in a dual standard of care. It has a fixed annual budget which has to cover all care; funds for certain procedures may be exhausted before the middle of the calendar year.
- Managed care competition for Medicaid patients is diverting funds from public sector providers that need these funds to provide care to the uninsured. The loss of

these funds has a particular impact on access to cancer care, which tends to be expensive.

## **An Advocacy Voice**

### **Coalition of Hispanic and Health and Human Service Organizations**

Dr. Deborah Duran

#### Background

The Coalition of Hispanic and Health and Human Service Organizations works with community-based organizations across the country; it does not accept either tobacco or alcohol industry funding.

The Hispanic population in the United States is the fastest growing population group. It is highly heterogeneous, and relatively young (average age 26.4 years). Two-fifths report that they do not speak English well.

#### Key Points

- Advocacy is needed by and for specific populations. Until they are afforded the same data coverage, the same quality of cancer care, the same opportunity to experience quality of life with and after a cancer diagnosis, and until language differences and cultural meanings of illness are integrated into programs, research projects and treatments (instead of as add-ons or dismissed as unimportant), advocacy will be needed to secure designated funding for these populations.
- Overall funding for health care and research should be increased, but it should not occur without concomitant increases in funding for special populations, for whom a disparity of data, care, and quality of life persists. If increased funding does not also occur for special population programs, these groups will remain invisible, and will continue to have limited tools and resources to fight cancer as a disease, or to fight disparities in research and health care systems.
- Only those who have not experienced discrimination and bias would negate the need for targeted cancer funds for special populations. If a special population representative is not at the decision making table, their issues are not included in funding or study design decisions. What comes out of a meeting depends on who is invited to participate.
- It is less important to know whether or not biological race exists; it is more important that there are racial disparities in treatment, care, and the collection of data.
- Hispanic populations have many of the high risk behaviors and characteristics (e.g., tobacco and alcohol use; different diets; low levels of exercise; low education, screening, SES, and insurance levels) associated with higher cancer rates. Yet Hispanics overall have low incidence rates for most cancers, and low mortality in general. Their cancer survival rates, however, are relatively low.

- In 20 years the rapidly growing Hispanic population will reach the ages at which cancer incidence escalates; an epidemic of cancer in this population may be the result and we must be prepared.
- Currently, only 50 percent of Hispanic children complete high school. Because of lower educational levels, Hispanics are concentrated in lower income occupations; however, Hispanics earn less at every educational level than the general population. In addition, Hispanics tend to be in jobs that do not offer health insurance benefits; at least one third of working, documented Hispanics have no health insurance.
- Hispanics visit the doctor less than the average. Since 81 percent report a preference for speaking Spanish, a lack of Spanish-speaking providers may be a cultural barrier to care.
- Cancer data on the Hispanic population is badly lacking. As a result, important questions about cancer prevention, intervention, treatment, and genetic differences cannot be answered either for Hispanic subgroups or the Hispanic population as a whole. The Surveillance, Epidemiology, and End Results (SEER) program did not begin collecting data on Hispanics until 1992, thus no trend data exist at this time. The Centers for Disease Control and Prevention (CDC) registries are relatively new, and have a distinct set of problems. In addition, the population growth denominators from the Census Bureau are problematic. In research studies, sample sizes of Hispanics are so small that conclusions cannot be drawn from the data.
- The National Hispanic Leadership Initiative on Cancer (NHLIC) began a focus on population-specific studies, but its funding has been cut. The only current national study on Hispanic women with breast cancer (sponsored by UNIDOS) has identified important differences in patterns of follow-up care, number of procedures and elapsed time to diagnostic completion, barriers to care, and treatment options offered. The five most frequently cited barriers to health care were: cost, long waits in medical offices, inconvenient hours, long waits for appointments, and long distances to travel for care. Of the 98 percent of women studied for whom surgery was recommended, 66 percent received radical mastectomy; 59 percent indicated that they were not given a choice on type of surgery.

#### Additional Research Needs and Other Recommendations

- Population-specific studies are needed, and Hispanics should also be included in all national studies.
- Extramural programs that include community-based research collaborations should be supported, since community-based organizations can best assess population needs and facilitate communication of research findings to Hispanic communities.
- Culturally competent cancer education, outreach, prevention, and screening programs should be fostered. Tailored community messages enhance the likelihood of behavior change.

- The Department of Health and Human Services= (DHHS) Hispanic Agenda and Office of Management and Budget (OMB) Directive 15 should be more fully implemented. More Hispanic professional and scientific staff are needed; the development of Hispanic researchers and scientific professionals should be fostered. Hispanics currently are underrepresented in these areas.

## **National Ovarian Cancer Coalition**

Ms. Susan Wallace

### Background

The National Ovarian Cancer Coalition (NOCC) is a grassroots effort envisioned and created by Gail Hayward, an ovarian cancer survivor, approximately one year ago. Its mission is to raise awareness about the disease, and to promote education for health professionals and the public on the facts and issues of ovarian cancer. The Coalition hopes to reduce morbidity from the disease. It operates a toll-free information line and a Web site. Volunteers distribute educational brochures and symptom cards.

A related organization, the Ovarian Cancer National Alliance, has as its mission to unite organizations and individuals to fight to overcome ovarian cancer. Based in Washington, D.C., its goals are communication and coordination of local, state, and national efforts, with an emphasis on public policy development and strategy, education of women and health care providers, and increasing research attention to ovarian cancer. The Alliance now acts as an umbrella organization for a wide variety of support organizations for ovarian cancer. One of the Alliance's board members was recently chosen to participate in NCI's consumer liaison group.

The main goal of the NOCC and the Alliance is to save women's lives.

### Key Points

- Ovarian cancer is the fifth leading cause of cancer death among women, and the deadliest of the gynecologic cancers. More than 50 percent of women diagnosed die within five years because 70 percent of cases are not diagnosed until they are advanced and incurable. In these advanced cases, the fatality rate is 80 percent. However, when diagnosed at stage 1 (less than 25 percent of cases), the five year survival rate is over 90 percent.
- Ninety percent of women who have had surgery for early stage ovarian cancer did not have tissue samples taken throughout the abdominal cavity to determine if the disease had spread. The knowledge gained from these biopsies can mean the difference between life and death. In addition, women whose initial surgery was performed by a gynecologic oncologist have been demonstrated to have longer survival; unfortunately, most women do not know these specialists exist.
- Awareness of ovarian cancer in the medical community is extremely limited. Because it affects only one in 55 women by age 60 years, it is not on the screening list of many obstetricians, gynecologists, internists, or family

- physicians. Symptoms can be vague (e.g., bloating, abdominal discomfort, menstrual problems, fatigue, painful intercourse, constipation); many women are told their symptoms are common to middle age or are referred to gastroenterologists while their ovarian cancer continues to advance.
- Another reason for the low five year survival rate for this disease is that middle aged and older women, who are at greatest risk, are relatively unaware of the disease. Even those with more explicit risk factors (e.g., women without children, those with a family history of breast, ovarian, or colon cancer) are not alert to the disease.
  - The imperfect status of diagnostic tools for ovarian cancer and the lack of cost effective, simple, and reliable screening methods is the third problem that dooms so many women to late stage diagnosis. The CA-125 blood test for ovarian cancer has limited sensitivity.

#### Additional Research Needs and Other Recommendations

- Dramatically expanded awareness of ovarian cancer and resources devoted to improving early detection are urgently needed. A screening test with better sensitivity than the existing CA-125 test must be developed. The lower incidence of ovarian cancer relative to breast or cervical cancer is no excuse to delay developing a reliable screening test that will prevent thousands of women from dying.
- Vital research on ovarian cancer is taking place and has resulted in treatment improvements, but far more research is needed. Research funding for ovarian cancer should be increased in both the public and private sectors; research is needed on all aspects of the disease, including psychosocial issues.
- Challenges in the fight against ovarian cancer are to provide greater public and professional education, and to ensure that women are aware of the availability of CA-125 and transvaginal ultrasound, and the need for an annual bimanual rectovaginal pelvic examination. Further, better access to clinical trials is needed, and the trials need to be made understandable to patients.
- Ovarian cancer screening should be piggybacked onto breast and cervical cancer screening schedules, since women have become accustomed to receiving these tests.
- Medical school curricula should include more in-depth education on ovarian cancer.
- A Federal information program on ovarian cancer is needed to disseminate prevention, detection, and treatment information.

#### **National Prostate Cancer Coalition**

Mr. Robert Samuels

#### Background

The National Prostate Cancer Coalition was formed in 1996 in recognition of the need for a unified voice to the Nation on the issues of prostate cancer. Made up of organizations



both specifically and more broadly related to fighting prostate cancer, the Coalition's mission is the elimination of the disease as a serious concern for men and their families.

In 1997, 209,000 men will be diagnosed with prostate cancer, and 41,800 men will die from the disease; this means that a man is diagnosed with prostate cancer approximately every 2.5 minutes, and a man dies from prostate cancer every 12.5 minutes.

### Key Points

- Prostate cancer accounts for 25 percent of all non-skin cancer cases annually, yet only 3.5 percent of cancer research funding is devoted to prostate cancer research.
- Prostate cancer has a particularly severe impact on minority populations. African Americans have the highest prostate cancer rates in the world; some 66 percent higher for African American men compared with white men. African American men die of prostate cancer at twice the rate of white males. African American men are often diagnosed at later stages of disease, but research is needed to identify other factors contributing to these disparities.
- Twenty percent of new prostate cancer cases are now diagnosed in men under age 65, dispelling the myth that this is an old man's disease. However, our ability to diagnose the disease has outpaced our ability to treat it. Earlier diagnosis in men at the peak of their professional and earning capacities also has serious economic implications.

### Additional Research Needs and Other Recommendations

- The national financial commitment to AIDS research has made a major difference in the lives of those affected by that disease. A similar all-out attack on prostate cancer is needed. Research priorities in five major areas have been identified:
  - Identifying the causes of prostate cancer and its progression
  - Predicting the stages of prostate cancer
  - Eliminating the pain associated with prostate cancer
  - Determining the risk of recurrence
  - Determining why men under age 65 years are increasingly at risk for prostate cancer
- Addressing these research needs requires at least an additional \$250 million annually. The Federal government must play a more aggressive role in prostate cancer research funding.
- A more accurate and useful diagnostic test is needed for prostate cancer. In addition, a test is needed to identify which prostate cancers are aggressive and which are not.
- Early detection must be accompanied by treatment advances and assurance of access to competent therapy.
- In the African American community, research is needed to determine if prostate cancer differs biologically by race; what factors are hindering early detection and the delivery of adequate therapy for black men; and what cultural, economic, or

other issues impact the development of an African American patient support system.

- The research funding pie is too small. Rather than divert resources from other diseases, the relative funding levels of defense and cancer should be re-examined. While we should not weaken our national defenses, arguably, the real war is against cancer. If we expect to prevail in that war, we must commit sufficient resources to it.

### **Patient Advocate Foundation**

Ms. Nancy Davenport-Ennis

#### Background

The Patient Advocate Foundation assists cancer patients nationwide in the areas of managed care interface, legal support, and access to and funding for care. Patients are referred to the Foundation by cancer centers, research facilities, and national voluntary health agencies that have exhausted all avenues available to them to assist the patient.

#### Key Points

- Americans previously accustomed to indemnity insurance with major medical benefits are struggling to transition to managed systems of health care. Competent individuals, corporations, providers, policy makers, medical device, and pharmaceutical entities are increasingly confused by the requirement to conform to ever-changing sets of rules which they have not endorsed.
- The drive to contain health care costs has resulted in health care that serves fewer citizens and is delivered by less qualified medical personnel. Medical decisions are being made by computer specialists at managed care organizations rather than by the physician in consultation with the patient. Patients and providers are weary--their energies are no longer directed at battling disease; instead, they are expended in negotiations with providers for access to and funding for cancer care as prescribed by the treating physician.
- Physicians are demoralized by the closing of hospitals that cared for the underserved and, enforced by the threat of being deleted from the approved list of providers, by restrictions on the treatment options that can be offered to patients. Likewise, primary care physicians are reluctant to make referrals to specialists, since they are at direct financial risk for the cost of the referral, or subject to practice profiling that may have an impact on an end-of-year bonus. Capitation rates create even more restricted access to care.
- Clinical trials funding is threatening our Nation's leadership in health care. Cutbacks in hospital reimbursements have resulted in data collection cutbacks; thus, we are making patient management decisions based on less data. In addition, fewer patients are being enrolled on clinical trials, as fewer insurers are willing to participate in the costs. Patients are at risk of losing access to evolving therapies, while physician practices, hospitals, and research centers are at risk of closing.

Many major pharmaceutical companies have chosen to conduct new drug trials in other countries.

- The Foundation's experience suggests that health plans are inconsistent in their interpretation of what constitutes investigational or experimental therapy; moreover, there often is inconsistency in coverage within a given plan.
- Every American diagnosed with cancer becomes a member of a special population. The insured are endangered by a lack of minimum standards for insurance coverage, the lack of an expedited appeals process, lack of or poor adherence to quality performance or standards, and limited input in selection of physician, hospital and/or protocol for care. Special populations defined by age, socioeconomic, or ethnic factors share these concerns. Insured population concerns also include a lack of preventive care.
- Employed, lack health coverage. The uninsured population also faces delays in support from medical public assistance, and delays and denials in obtaining Social Security and other benefits. As they struggle with these problems, their cancer is progressing.
- Senior citizens have cancer rates in excess of rates in the general population. The Medicare population is burdened by reimbursement reductions within the Medicare system. Physicians are restricted in the treatment options they can offer, and there are financial incentives to undertreat the elderly. This population is especially stressed by disruptions in continuity of care, particularly in the face of severe illness. Home health care funding is lacking. The elderly also are facing increasing copayments and deductibles, while living on fixed incomes. Transportation is a key issue for this population.
- Medicaid provides medical care coverage for more than 35 million Americans; of these, 10 million are enrolled in Medicaid managed care. Low income working adults do not qualify for Medicaid; they are the population that "falls through the cracks" if a serious illness occurs in the family. Medicaid eligibility requirements are rigid, and the enrollment process is extremely slow. Lower provider reimbursements for Medicaid patients cause these patients to be shifted to public hospitals, but these facilities are closing. The shift to Medicaid managed care means greater variation in coverage across this population.
- Delayed decisionmaking by insurers can lead to emotional and psychological distress, disfigurement, or death for patients. Insurers deny care prescribed by the physician, or refer the patient to a distant location, effectively deterring many from accessing needed services. Referral to specialists is restricted by gatekeepers, and there is no universal, consistent and timely appeals process for coverage decisions. Policy language describing benefits, exclusions, restrictions, and financial responsibility is confusing. Terms such as experimental, medically necessary, investigational, adequate, and peer review--pivotal terms in decisions made by insurers--are defined inconsistently.
- New technology assessment processes also vary and contribute to uneven access to innovative therapies.
- By the year 2000, one in 900 adults in the U.S. will be a survivor of a childhood cancer. The mean annual out-of-pocket cost of having a child with cancer now represents 52.4 percent of gross family income. Families are told that the only

- way their child can receive needed medical care through Medicaid is for the child to become a ward of the state; we must find a better solution than this.
- Children with cancer need access to psychological counseling. As they mature, they need information about possible late effects of their childhood cancer treatment. They also need assistance in securing health and life insurance.
  - Among Hispanic Americans, 54 percent have no insurance, 32.6 percent of those employed have no insurance, and only 17 percent receive Medicaid health services.
  - Employer-sponsored, or employer self-funded ERISA health plans are subject to little Federal regulation, and are immune from state regulation. In some cases, different categories of employees are offered varying levels of coverage. Appeals processes and utilization review may be particularly arbitrary or uneven.

#### Additional Research Needs and Other Recommendations

- Specific standards for health plan and technology evaluation processes are needed. Legislation recently passed in Maryland may serve as a useful model.

### **National Hospice Organization**

Mr. John Carney

#### Background

The mission of the National Hospice Organization (NHO) is to be the voice of dying Americans. NHO is a national organization serving approximately 2,600 hospices across the country. The focus of hospice is on care rather than cure. Annually, one-half million Americans receive hospice care; about 80 percent have cancer. Thus, hospice providers care for nearly half of all Americans who die annually from cancer.

Most hospice care is provided in the patient's home; about 90 percent of hospice patients die at home. However, 60 percent of all Americans die in the hospital, most without benefit of hospice services.

In 1983, Congress adopted a benefit allowing a Medicare patient to elect hospice care for a terminal disease, in effect disenrolling from traditional Medicare for care for that terminal disease. However, regular Medicare part A coverage remains in force for treatment of other conditions. This hospice benefit provides payment for items not normally covered under Medicare, including palliative and comfort measures, supplies, and equipment. Payment under this benefit is prospective, and averages about \$100 per day. This covers all needed services at virtually no cost to the patient. The eligibility period is up to six months, however, the median length of stay for hospice patients is currently 36 days, reflecting a pattern of late referral to hospice care.

## Key Points

- NHO has been working with the IHS and VA to develop agreements on models for hospice care for their covered populations. Funding mechanisms have yet to be established.
- Though not a research organization, NHO has established medical guidelines for determining prognosis in nine non-cancer diagnoses; these have been adopted by the Health Care Financing Administration (HCFA) for determining hospice eligibility of Medicare patients. Similar guidelines for cancer patient prognosis are under development. Recognizing that prognosis as currently defined by physicians may not be the best way of establishing readiness for hospice care, the NHO has established a Medicare task force to determine how prognosis should be redefined.
- Dying Americans do not want to be abandoned, and they do not want to die in pain. To date, we have not been able to meet these needs. The most comprehensive study of dying Americans, sponsored by the Robert Wood Johnson Foundation, was completed two years ago. A two-phase study conducted over eight years, found that despite a number of interventions with the study population (e.g., discussions with patients about their impending death, intervention of psychiatric nurses with families, discussion with physicians about advanced directives and living wills, additional assistance to patients and families), there was virtually no change in key outcome measures. Forty percent of the patients died in what their family members considered to be intolerable pain. One third spent their entire life savings paying for medical care. One half reported that their physician were not informed nor did the physician report knowing the wishes of the dying patient.
- We lack adequate language about dying in this culture, and we have not rejected the notion that death is a failure of medicine. Death will occur for every person at some point, but we cling to the notion that death is an optional event, and that the primacy of medicine is paramount. We are unable to distinguish between hope and expectation in discussing death with patients and families. We do not understand the importance and dignity of dying and the work that a patient does in the final stages of life.
- While the typical activities or duties of a well person or a sick person are clear to most people, few understand that the duties of a dying person include reconciliation, saying "I love you," and completing one's life story. These tasks take time. We tend to see death as an interruption rather than a completion. We have always viewed illness and death in this country as a disease or biological process rather than as part of a biography. Regardless of the age of the patient, death is still a completing event and families need time to discuss what they need and want relative to this completion.
- When we leave the world, disease is not necessarily the enemy; most of us will need a disease to make our exit. Therefore, while prevention and treatment of disease are important, at the time a patient is dying, the disease is a necessary component of the process.

- The American Medical Association is beginning to recognize and address the need for physicians to understand and develop language about dying.
- In this country, we do not usually view rituals of separation that are (or could be) sacred for most families as being an important health care issue in the final days of life. Honoring and conducting such rituals could be of significant preventive value to the loved ones of the person who dies by enabling them to deal authentically with the death before it occurs.
- For 20 years, hospice has prided itself on being separate and discrete from the medical system, and has not engaged in serious conversations or collaborations with the medical community. NHO now recognizes that to change the way most Americans die, these collaborations and conversations are necessary.
- Mr. Carney's local hospice organization participates in outcomes research in collaboration with the local CCOP, but study patients often do not complete participation in the trial. There is a need to find another model for conducting research on patient outcomes.
- A major challenge for hospice is to become more fully integrated into the health care continuum in this country.

#### Additional Research Needs and Other Recommendations

- We must teach that it is possible to die well; to be healthy in a terminal status. Accepting this idea would allow critical aspects of preventive care to be provided to family members.
- NHO has identified three key outcomes on which descriptive research in clinical trials is needed: effective grieving, safe and comfortable death, and self-determined life closure.

#### **Discussion**

Dr. Duran, Ms. Wallance Mr. Ssmuels, Ms. Davenport-Ennis, and Mr. Carney

#### Key Points

- Cost effectiveness analyses of hospice care may not lend themselves to prospective randomized clinical studies, since patients cannot be randomized to not die. A retrospective study completed in 1995, however, suggests that for every dollar spent by Medicare on care for dying patients, hospice saves \$1.52. The Institute of Medicine had planned a study of futile treatment at the end of life, but did not pursue this part of the study since acceptable definitions of futile treatment is retrospective determination. Instead the IOM focused on end of life decision making processes.
- An Annenberg Foundation physician education program, Care Beyond Cure, recommends that at the time of diagnosis, the physician should begin discussion about the possibility of dying from the disease. In this way, conversation about dying is begun well before the event is imminent.
- Mr. Carney noted that the research on symptom management conducted to date by hospice organizations has consisted of small, focused studies. These tend to be

- discounted as anecdotal by insurers. In some areas, such as bereavement care, little data exist to demonstrate what hospice providers know from experience--that family members surviving hospice-involved patients are less sick after the death of the patient, and socialize more quickly after the death of the patient if they have been involved in the patient's care in the home setting prior to death.
- Twenty-eight percent of Medicare dollars are spent in the last year of life. Physicians are trained to prolong life, and families may demand heroic measures, when both may know that the patient cannot be cured and is dying. Physicians and nurses feel compelled to do everything possible for the patients because they have been trained to do so. Hospice maintains that you can always care for the patient, but the focus is on comfort and support rather than cure. One of the biggest fears of patients= and families' is abandonment, including abandonment by their doctor.
  - Physicians are only beginning to address the needs of the dying patient and learn to have discussions with patients about death. This includes seeing the patient as a whole (that includes his/her family) rather than focusing only on the disease. These physician education efforts need to be initiated in medical school; we are good at teaching the science of medicine, but do a poor job of teaching the art of the practice of medicine.
  - The Hastings Center (New York) in collaboration with the World Health Organization has recently adopted its New Goals of Medicine. One of these goals is the avoidance of premature death and the pursuit of a peaceful death.
  - It was suggested that all of the advocacy organizations might be well served to unite under a single umbrella organization with sections devoted to specific diseases, a structure parallel to medical professional organizations. It was noted that this structure does not necessarily foster productive communication or collaboration among physicians (even those treating the same disease); therefore, this may not offer the best model for other, more disparate groups.
  - Studies on specific minorities should be designed and funded as such and should be conducted by facilities that can attract those populations. Lumping unrelated or marginally related population groups under the term "minority" results in minority individuals being placed on studies that do not address issues specific to them. In addition, some "minority" programs have been heavily focused on African Americans; the result has been that other population groups are left to fight over an even smaller portion of funds than were allocated. The various groups should be studied individually, so that differences among them--whether genetic, biologic, behavioral, environmental--can be identified, if they exist, and beneficial or protective factors applied to other population groups when possible. More funding, not reallocation of funds, is needed.
  - In the same way that Japanese-U.S. migration studies have shown increases in cancer rates within a very few generations to levels found in the U.S. white population, similar studies of Hispanic populations show that the more Hispanics are acculturated, the more their cancer rates approach those of U.S. whites. Similar trends have been demonstrated for depression rates among Hispanics.
  - The most relevant research questions vary among populations; we do not necessarily need to ask every question about every group. It is essential to involve

the communities in study design and implementation; the communities know best what are the relevant questions.

- We still have the dilemma that resources are allocated based on racial and ethnic classifications that have been socially and politically determined; they are not based on science or anthropology. Recognizing that there are historic social and economic injustices that require correction, it remains unclear how to obtain scientific truth from studies based on social and political classifications of individuals who may share little more than certain cultural practices and social pride.
- Regardless of what actual biologic or genetic differences may exist, at this point in this country, health care access is determined substantially by phenotype. Populations experiencing discrimination in health care access or research attention need data to support their claim to resources. For some populations, such as Hispanics, these data do not yet exist.
- It is inappropriate to try to correct health care access problems through the research mechanisms, such as the MBCCOPs.
- A crucial difference between previous fee-for-service care and the current systems of managed care is the feeling of essential security and well-being that people had under indemnity care. People felt reasonably sure that if they became ill and went to a doctor or hospital, that care would be provided and would be provided as prescribed by the physician. This is no longer the case; insurance intermediaries now determine what protocol is appropriate and how long hospitalizations should be. Patients and physicians are demoralized and frustrated with attempts to deal with insurers in the current environment. It was also noted, however, that under the fee-for-service system, many patients probably received more services than they needed because there was the assurance that their cost would be reimbursed.
- At this time five Federal bills are pending on ERISA reform; each has a component dealing with the issue of patient access to reasonable care. Requiring health plans to define reasonable care is an important first step in restoring integrity and morality to the health care system and in relieving the frustration currently felt by patients, medical providers, and advocates. Advocates face strong opposition from health industry and corporate lobbies in this matter; Congressional action will be needed to resolve the problems now faced by the more than 60 percent of Americans covered by ERISA plans.
- Dr. Calabresi cited the Rhode Island legislation guaranteeing access to Phase II, III, and IV trials approved by the NIH, DoD, or FDA. Last year, 19 states introduced clinical trials funding legislation.



## Rural Research Issues

### Rural Linkages

Dr. Charles Given

#### Key Points

- The National Commission on Quality Assurance (NCQA) and the HEDIS guidelines have had significant positive effects on screening and early detection in rural areas, particularly in mammography, prostate, and colorectal cancer screening in the past few years. Another aid to screening in rural populations has been the availability of computer-generated reminder notices that can be produced from desktop computers using off-the-shelf software. Digitized data transmission (e.g., mammography images) has afforded people in rural areas access to high standards of care, since images can be transmitted for evaluation by experts at major medical centers. Standards for rural laboratories have also improved.
- Despite these improvements, the single greatest problem remains the number of rural families who are outside any system of continuous care; these vulnerable populations tend to receive only episodic care. Barriers to rural cancer care include travel distances to sites of specialty care; concentrations of poor, elderly, and less educated citizens; fragmented community services; lack of access to the full range of cancer services; inability to recruit and retain cancer specialists in rural areas; and reliance on informal systems of care.
- Rural America is an aging population, and therefore is at high risk for cancer. Lower education makes this population less likely to be engaged in preventive, screening, and early detection services. The rural population also suffers from low income and a poor economic base. Those who are insured are not usually covered for screening or preventive services.
- A 1992 study of cancer care in rural areas concluded that once rural residents became involved in cancer care, they generally were able to access high quality services in their locales; however, problem areas identified included a lack of supportive care for chemotherapy side effects, difficulties contacting oncologists, and a lack of integrated palliative care.
- A multi-community study was conducted to assess the impact of educational interventions for rural oncologists, primary care physicians, nurses, and pharmacists on cancer diagnosis and staging, treatment, and support. The data suggested that even in the non-intervention communities, patients were receiving appropriate care, as measured by cancer management scores devised for the study. The investigators in this study are now analyzing the data to determine if there were important differences in stage at diagnosis.
- Dr. Given and colleagues developed a nurse-centered intervention to deliver supportive care to rural cancer patients in four targeted communities. The intervention was linked with and developed in collaboration with community oncologists, rural surgeons, local family physicians, and the CCOP. Patient histories, treatment plans, and other study data were maintained on laptop computers; in addition, on-line access to PDQ and the Cancer Information Service

enabled the nurses to locate and print needed information for patients. The nurses were heavily involved in early detection and management of treatment side effects, evaluating and monitoring patient health, educating families and patients, and provided other nursing services such as dressings and venous access maintenance. In addition, they facilitated referral and coordinated care including drug assistance programs, working with social service agencies, arranging transportation, and helping patients with Medicaid eligibility paperwork. Through this intervention, patients were better able to care for themselves, and family members and primary care givers became more active in patient care throughout treatment and follow-up. Among the strengths of the program were the relational database used, the development of quantifiable data on the nursing interventions, the use of procedure (CPT) and International Classification of Diseases (ICD) codes that permitted assessment of treatment complexity and billing for nursing services in one of the study locations, and improved care for these patients.

#### Additional Research Needs and Other Recommendations

- We need to find ways to extend state-of-the-art cancer care to rural populations. It is important to link patients with suspicious screening findings to definitive care, and to provide supportive care in the rural communities.

#### **On Behalf of Working America**

#### **AFL-CIO**

Ms. Nadra Floyd

#### Key Points

- The American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) is greatly concerned about the problems faced by uninsured and underinsured workers. According to the National Institute on Occupational Safety and Health (NIOSH), of the half million cancer deaths occurring annually in the United States, four percent (20,000 deaths) are due to occupational exposures. While this figure reflects remarkable progress in reducing the effects of recognized carcinogens in the work place, it remains clear that far too many Americans are still being killed slowly by the work they do.
- As many as five million American workers are exposed to substances classified by the International Agency for Research on Cancer (IARC) as human carcinogens. NIOSH estimates that 10 percent of lung cancers and up to 27 percent of bladder cancers result from occupational exposures. In workers with documented exposure to established carcinogens, close to 100 percent of angiosarcomas of the liver can be traced to occupational exposure to vinyl chloride. As much as 50 percent of lung cancers in these workers can be attributed to asbestos exposure.
- By the late 1970s, when compelling epidemiologic evidence existed demonstrating that asbestos exposure caused cancer, 27 million American

workers had already been exposed. Since then, some 8,000 asbestos-related deaths have occurred annually and can be expected to continue occurring into the next century.

- Advances in microbiology and genetics have opened new fields of research that could reduce the death toll from occupational exposures, particularly concerning the interaction of chemical agents with human genetic material.
- Too few employees are being screened for important occupational exposures. The lack of accurate and cost effective screening methods has been an obstacle to collecting the level of exposure data that will prompt the deployment of effective controls and efforts to measure whether controls have been effective in reducing exposures.
- Worker compensation systems are largely irrelevant for workers who develop cancer as a result of long-term exposures because the linkage between exposure and disease is often impossible to establish, especially without adequate screening methods. These workers are left at the mercy of the Medicaid and/or Medicare systems. Even in cases where causation is established, worker compensation benefits are often woefully inadequate, and reflect the politics of a community. Many states are moving to managed care systems for worker compensation programs, limiting quality and choice for workers, reducing or eliminating screening programs, and hampering research efforts.
- The AFL-CIO and other larger unions maintain occupational health and safety staffs, and provide funding both for the worker's health fund and to relevant research and advocacy organizations. The staffs provide guidance to elected officials and government staff at state and Federal levels, identify member concerns, and design programs to help workers negotiate work place improvements. The United Auto Workers (UAW), as part of their active participation in the National Prostate Cancer Coalition, has launched a prostate cancer awareness program. Three occupations--welders and electroplaters working with cadmium, farm workers, and rubber and tire manufacturing workers--appear to be at particular risk for prostate cancer. New research suggests that workers exposed to mineral spirits, diesel fuel, and lubricating oils may also be at risk. The UAW gathers research data on such exposures for use in public and worker education efforts, and in efforts to encourage greater cancer research funding.
- The UAW and American Federation of Teachers (AFT) have worked to publicize breast cancer risk. A 1993 NIOSH death certificate study of 2.9 million women who died from 1979 through 1987 correlated cause of death and occupation. It showed that teachers have a higher breast cancer death rate than the general population. White teachers had a 62 percent higher rate of breast cancer death than the general population; the death rate among African American teachers was nearly double that of the general population. A follow-up study by the CDC suggested that deferred childbearing, or choosing to have no children, might be among the factors contributing to the findings.
- AFT focus groups identified several barriers to breast cancer screening among its membership: lack of knowledge about breast cancer, lack of time for screening, and viewing a breast cancer diagnosis as a death sentence. A three-year education

- program was developed; the pilot programs are to be evaluated and results published in the 1998-99 school year.
- A study by the Laborer's International Union found that laborers were 13 percent more likely than the general population to die of cancer. Incidence of cancers of the lung, stomach, rectum, and thyroid were all higher than those of the general population. The union has established agreements for worker education, training and research projects with two major academic health centers.
  - As an individual currently being treated for cancer, Ms. Floyd emphasized the crucial value of a comprehensive medical plan and employer sick leave policies that enable patients to obtain needed care and maintain economic stability while being treated for a major illness.

### Additional Research Needs and Other Recommendations

Through well-funded, comprehensive research, we must develop better methods for identifying potential carcinogens among the four million chemical products with commercial U.S. applications, and develop more extensive and effective models for extrapolating results from animal research to the human experience.

- Research on the relationships between chemicals with human genetic susceptibility to cancer must be vigorously funded and pursued.
- Occupational safety and health research should focus on reducing or eliminating worker exposure to carcinogens. This research should encompass administrative policies (e.g., work practices, worker education, training), work place engineering (e.g., equipment design, selection of materials, work methods modification), and protective equipment and techniques (e.g., respirators, protective clothing).
- Innovations and adaptations in these three areas have been achieved through the collective bargaining process; in environments in which workers have no union voice, responsible public policy and regulation is needed to require employers to adopt best practices, and provide the best level of personal protection available.
- Exposure assessment research is essential to create convenient and low cost exposure measurement tools.
- Public policy leadership on the issue of cancer in the work place and in the community at large must come at the national level. In addition, we need more public education, a stronger public commitment to funding lifesaving research, and the political will to enforce work place standards and industry screening programs that we know will save lives.

### **Discussion**

Dr. Given and Ms. Floyd

### Key Points

- Dr. Given indicated that clinical outcomes of the patients involved in the rural linkage study are now being analyzed and will be compared with outcomes in a patient population matched for age, gender, cancer site, and stage of disease. The

transferability of this model of care may depend in part on variations in state rules as to how master's level nurse practitioners are permitted to practice under the direction of a physician. It should be possible to adopt or adapt the model not only in other rural areas, but in any area in which there is a vulnerable population that requires extra case management support in order to stay in screening and treatment programs.

- Workers compensation systems are primarily designed to address workplace injuries, not diseases. In addition, claims for workers compensation must be filed within specified time periods; workers who develop a disease as a result of an exposure that occurred 10 or 15 earlier will not qualify for these benefits. The problem is complicated by a lack of recordkeeping that would enable workers to prove the link between exposure and disease.
- Experience thus far with managed care systems for workers compensation suggests that patients are faced with increased paperwork, limited choice of provider, and limited services.

### **Closing Remarks**

Dr. Freeman

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- Testimony on the impact of managed care on special populations underscores the continuing debate on the evolving health care system.
- The definition of special populations remains unclear; methodologies for studying these populations and the value of doing so remains a key question in cancer research.
- The role of advocacy in addressing special population needs in cancer research was a recurrent theme.
- The input of the presenters will be of significant value as the Panel formulates its recommendations to the President in these important areas.

I certify that this summary of the President's Cancer Panel meeting on Concerns of Special Populations in The National Cancer Program, The Responsiveness of the Health Care System to the Needs of Special Populations, held on November 21, 1997, is accurate and complete.

Certified by:

Harold P. Freeman, M.D.  
Chairperson  
President's Cancer Panel  
Date: July 29, 1998