President's Cancer Panel Meeting

January 1, 1996 to December 31, 1996

FIGHTING THE WAR ON CANCER IN AN EVOLVING HEALTH CARE SYSTEM

MISSION STATEMENT

More than a million Americans will be diagnosed with cancer this year; and over 10 million are already living with the disease. At some time in their lives, 4 in 10 Americans can expect to hear their doctor say, "You have cancer." When that occurs, the length and qualty of their survival will depend in large measure on the medical care they receive.

As you are well aware, the health care system in the United States is in the midst of an extraordinary and exceedingly rapid evolution. A principal feature of this evolution is a transition from traditional fee-for-service health insurance to varying forms of managed care. With this transition have come much-needed controls on health care costs, but the Panel believes strongly that as currently implemented, managed care now poses a very real danger to our progress in reducing the burden of cacner on the Nation and threatens the ability if the United States to maintain its world leadership in cancer research and care.

Each person waging a personal war with cancer needs timely access to the diagnostic and therapeutic weaponry best able to fight his or her disease. Because we have yet to develop fully effective weapons for many cancers, the need for continued excellence in cancer research--particuarly clinical research that brings molecular, genetic, and other laboratory discoveries to the patient in the form of new treatments and mechanisms for assessing and monitoring disease--remains as crucial as ever.

Testimony presented to the Panel in 1996 on the impact of managed cancer care and clinical cancer research indicates that short-term considerations, particularly under for-profit managed care mechanisms, are severely reducing funding for research; limiting patients' access to optimal cancer care, incuding clinical trials; and reducing physician and institutional incentives and fiscal capacity to conduct clinical cancer research or train the next generation of cancer researchers and caregivers.

Although the national burden imposed by the more than 100 diseases we call caner remains high, we are reaping the benefit of our investments in cancer research--between 1991 and 1995, overall national mortality due to cancer fell for the first time. Every American is at risk for cancer; therefore, we must ensure that progress toward eradicating these diseases is maintained, and that access to quality care for all segments of the population us not sacrificed for illusory short-term savings or corporate gain. As the attahed report and recommendations detail, this wil require equitable sharing of the costs of research by all to optimal cancer care, including care under clinical trials when that represents the most promising treatment choice.

I was appointed to the Panel in 1991 and currently serve as a member and Chairman. Ms. Frances M. Visco, Esquire, was appointed to the Panel in 1993 and will serve until 1999; Dr. Paul Calabresi was appointed to the Panel in 1995 and will also serve as a member until 1998. The Health Omnibus Extension Act of 1988 requires the

Chairman of the Prwident;s Cancer Panel to report annually to you on the status of the National Cancer Program and barriers to its progress. The Panel feels the potential of managed care, as an industry, to interfere with the progress of the National Cancer Program is tremendous. Therefore, on behalf of the Panel, I respectfully submit the attached report for 1996.

EXECUTIVE SUMMARY

Overview:

The health care system in the United States is experiencing an unprecedented period of evolution, in which managed care in varying forms is rapidly becoming the predominant organizational and fiscal mechanism for the delivery of health services. More than 60 million Americans are now covered by private managed care organizations (MCOs) and both Medicare and Medicaid are rapidly converting to managed care systems as a central strategy for minimizing costs.

Managed care has made positive contributions to the health care landscape-braking runaway health care costs, accentuating the need for evidence-based medical care, and addressing the need for certain preventive services. It appears, however, that these positive influences are not without their costs, and ongoing health care system changes do not affect only those enrolled in private health plans and publicly-sponsored health programs. Over 40 million Americans are uninsured and an even greater number are under-insured, particularly for catastrophic illnesses like cancer. Changes in the financing of health care as we move increasingly from fee-for-service to managed or capitated health care options will disproportionately impact the uninsured and under-insured whose expenses were offset, in part, by fee-for-service revenues. This is not an issue unique to cancer and it will continue to have a bearing on the health and economic stability of this Nation. Acceptable visions of health care for the future must include a concern for all human beings, because catastrophic illness is devastating at all socioeconomic and personal levels.

Testimony provided to the President's's Cancer Panel in 1996 provides strong indications that recent and ongoing health system changes are demanding too high a price from the more than 1.3 million people diagnosed annually with cancer and the remainder of Americans at risk. Short-term and short-sighted cost contaminant can and will impede the progress of the National Cancer Program in reducing the national cancer burden. Stated simply:

> **Evolving mechanisms for financing and delivering health care in the United States have resulted in a drastic loss of funding that traditionally has supported clinical cancer research, cancer care for the indigent, and training of cancer researchers and care givers. These funds must be replaced.**

Specifically, testimony provided to the Panel emphasized that:

- The cost cutting achieved through strict utilization control and bare-bones provider contracting has all but eliminated the patient care surpluses that comprised the primary supplement to Federal research support and that were the mainstay for indigent care in manv institutions. No single organization, at anv level, is financially poised to step into this breach.
- Access to optimal care for cancer patients is being limited by complex treatment approval processes and health plan exclusions of investigational treatments that threaten to restrict state-of-the-art cancer care to those able to manipulate the system and pay out-of-pocket. This situation further estranges the alreadv under-served populations of this country-niinorities, the elderly,the poor--and like the feee-for-service system, fails to consider the uninsured at all.
- Physician participants in managed care systems face growing disincentives-chiefly--pressure to generate revenue, expanding documentation requirements, and lack of organizational support--to conduct clinical cancer research or train the next generation of cancer researchers and care givers.
- Institutional health care providers faced with shrinking revenues in expanding managed care markets, particularly academic medical centers and other clinical research centers, are adopting short-term fiscal survival strategies, some of which threaten the infrastructure, of our health care system including our abitity, as a Nation, to train and nurture future generations of reseachers and care givers.
- The loss of traditional sources of funding for clinical studies also appears to be shifting the balance at some research centers away from investigator initiated research funded by, public or volutitary agencies to research funded by, the pharmaceutical and biotechnology industries. Some research centers are becoming increasingly dependent upon revenues from industry sponsored studies and there is concern that failure to ensure an adequate balance between investigator-initiated research and industry--sponsored studies may result in a failure to explore the full range of scientific questions relevant to reducing the burden of cancer

Recommendations:

The President's Cancer Panel recommends:

- Measures must be taken to ensure that minorities, the poor, the elderIy, the uninsured, and the under-insured are not excluded from access to appropriate cancer care as the health care system evolves.
- Both the importance of and the ability to participate in all phases of clinical trials should be formally incorporated into the standards of care for cancer; appropriate trial participation should be an integral component of clinical guidelines for specific malignancies, anci the ability to access such trials, when appropriate, should be independent of health care provider. Criteria are needed

to define clearly the required review processes, objectives, and other characteristics of clinical trials acceptable for patient care cost reimbursement.

- This coverage should be guaranteed through legislation and/or negotiated agreements at the Federal and state levels.
- The cost, of clinical research must he paid in order for the quality of health care to continue improving. These costs must be paid regardless of the structure and financing of the health care delivery system. All of the beneficiaries of clinical research--managed care and other payers; research sponsors including government, voluntary agencies, and the pharmaceutical and biotechnology industries; employer and employee participants; and other consumers--must bear their fair shares in its cost.
- Given the evolving health care financing and deliverv systems, mechanisms must be established to ensure support for the training of clinical cancer care givers and researchers. This crucial intellectual resource and our Nation's world leadership in cancer research and care must not be allowei to deteriorate in the interest of short-term cost savings.
- Partnerships among the pharmaceutical and biotechnology, industries ind the public and other private (e.g., voluntary) research communities should be encouraged, but as a Nation, we must ensure that the questions with the most scientific potential, as well as those offering the greatest economic return, are addressed.
- The process for appealing coverage decisions made by health plans must be simplified, standardized, and fully disclosed to participants in health plans of all types. Appeal decisions must be Tendered expeditiously.
- Consumer education at all levels--e.g,, employers and the public--is needed to promote an understanding of the importance of clinical cancer research and a realization that the need to access such care can become a reality for any person. This understanding is needed to create public demand for access to effective cancer care and to foster health system competition based on access and quality rather than on cost alone.

The attached full report of the Panel presents in detail these key issues and recommendations. In addition, summaries of the testimony provided at the Panel's four meetings in 1996 are presented as Appendices to the report.

INTRODUCTION

Currently, the health care costs of more than 60 million Americans are insured under a managed care plan, the prevailing organizational and fiscal health care delivery mechanism in our evolving health care system. Though more prevalent in the western United States, managed care enrollment is growing in all regions of the country as employers struggle to maintain ever more costly health coverage for workers in a

climate of fiscal constraint. Employed populations and other individuals covered by traditional fee-for-service plans are increasingly "managed" through a variety of payer rules and restrictions concerning payment for needed health services. Medicare and Medicaid, the Federal health insurance programs for the elderly and the poor, respectively, are rapidity transitioning to managed care in an attempt to minimize costs. Approximately 71 million Americans, though insured, have health insurance inadequate to meet the costs of a catastrophic illness such as cancer; 41 million Americans have no health insurance at all, and therefore little access even to routine care.

The President's Cancer Panel is charged to identify and report promptly, to the President barriers to the successful implementation of the National Cancer Program and reduction of the burden of cancer on the American people. The Panel has become increasingly concerned about the impact of health care system changes, exemplified by the burgeoning managed care industry on patients' access to the most appropriate cancer care, including care under, clinical trials, and the Nation's ability to support and maintains its critical clinical cancer research enterprise.

Early detection, accurate diagnosis, and rapid, appropriate treatment hold the greatest hope for cure or control for those afflicted with cancer. Ensuring access to early, detection services and optimal cancer care for all segments of the population is, therefore, a fundamental goal of the National Cancer Program. In its previous reports, the Panel has emphasized the importance of empowering individuals to safeguard their health through appropriate utilization of health services. It is critical that under any health care delivery system, individuals have access to necessary and effective care, and a readily understandable method of appealing private or public health care provider decisions they believe improperly deny, access to that care.

National support of cancer research over the past 25 years has earned the United States worldwide leadership in the war on cancer, and led for the first time to a 2.6 percent overall reduction (1991-1995) in our national mortality from this most dreaded disease. In cancer, unlike most other medical conditions, the efficacy of diagnostic and therapeutic options--new weapons in the war on cancer--can only be verified in a patient population. Clinical research has always been the pathway, by which laboratory discoveries have become life-saving treatment advances, and many of the standard cancer treatments employed today were the subject of clinical research only a few years ago.

The power of clinical research is amply illustrated by our extraordinary advances in curing childhood cancers. Participation in clinical studies is the standard of care for pediatric cancers--more than two-thirds of children with cancer are treated under clinical trials, and five-year relative survival rates have risen from 28 percent in 1960-63 to 71.4 percent in 1986-92 (SEER data). Only three percent of adults participate in clinical research studies, however, and gains in survival for most adult cancers have been far less satisfactory. In fact, despite important advances in treating some malignancies, for many types of cancer, there is still no standard treatment. In these

cases, the alternative to trying newly developed treatments is certain death.

During 1995, the Panel heard testimony, on a variety of topics (reported in the most recent Report of the Chairman) through which a disturbing theme began to emerge--that the evolving health care system was posing an increasing barrier to cancer, patients' access to state-of-the-art or even appropriate care, and that cost-cutting, particularly under evolving managed care systems, was resulting in air environment that discourages the conduct of clinical cancer research and severly limits funding for clinical investigation of potential cancer care advances. Moreover, this situation appeared to be increasing reliance at some, centers on research studies sponsored bv pharmaceutical and biotechnology, companies relative to those sponsored by public or voluntary sponsors. This shift has raised concerns as to wheather important scientific questions in cancer may fail to be explored if they are unlikely to lead to a commercially viable product.

The Panel believes firmly that patient access to potentially life-saving cancer care, continuing progress in clinical cancer research, and the preservation of our global preeminence in this crucial endeavor, must not be compromised under any health care financing and delivery system. Therefore, in 1996 the Panel focused its inquiry on the effect of health care system changes on the conduct and financial support of clinical cancer research and related training, and associated issues of access to appropriate cancer care. In a series of four meetings held in each quadrant of the Nation, the Panel heard extensive testimony, on regional influences of the changing health care environment on clinical research, and on regional and national issues related to access to clinical trials, the conduct of translational research, maintaining educational opportunities for the next generation of cancer researchers and clinicians, and implementing outreach and information dissemination efforts, particularly to underserved populations. Patient perspectives were heard, as were those of pharmaceutical and biotechnology companies involved in clinical cancer research, and some managed care organizations. In all, testimony was heard from 61 individuals representing the diverse constituencies and beneficiaries of progress in detecting, diagnosing, treating, and preventing cancer.

The Panel recognizes that testimony provided in this forum does not carry the weight of empirical study. It is also important to recognize that some of the issues raised reflect broad health care system issues not restricted to managed care. The frequency and similarity with which these issues have been cited across the Nation--including their personal, institutional, and health system consequences or implications--is so striking that the Panel believes these concerns reflect serious barriers to the success of the National Cancer Program and must not be dismissed as anecdotal.

The remainder of this report sumniarizes key aspects of the testimony presented, and the conclusions and recommendations of the Panel. Summaries of the Panel's four meetings in 1996, held in Seattle, Washington ((July 30, 1996); San Antonio, Texas (September 24, 1996); Providence, Rhode Island (October 25, 1996); and Durham, North Carolina (November 22, 1996) are appended to this report.

The Evolving Health Care Environment: Issues for Clinical Research and Access to Care

Managed care has brought positive changes to the U.S. health care landscape-- most notable, attention to the cost of care, emphasis on treatment with therapeutic intent, and a heightened emphasis on evidence--based medical care--features that should be exploited to the benefit of the health status of the population and the economy of the Nation. The Panel recognizes that a certain level of tension between the need to contain costs and the need to provide evidence--based, quality care is to be expected. Testimony, presented to the Panel raised concerns, however, that in some segments of the health care system, the equilibrium between these forces is shifting too heavily, toward cost containment at the expense of quality care. This shift to cost containment as a predominant system driver appears to be having deleterious effects on both the quantity and diversity of health services available to health plan enrollees.

Many health care plans are competing principally on the basis of cost, particularly upon entry into new markets. Cost competition is supported by the desire of corporate health benefits managers to minimize expenditures on emplovye health care, while still providing what they perceive to be a sufficiently broad range of quality services. Health plans may experience significant annual turnover in their enrolled populations because many employees change plans frequently and because employers are continually shopping for the best deal. These dynamics may exacerbate health plans' emphasis on short-term savings over long-term health maintenance of a stable enrolled population.

Thus, while necessary financial corrections to heretofore spiraling health care costs are occurring, these adjustments have given rise to a new set of problems. As the sections below summarize, testimony provided to the Panel indicates that:

The evolving health care system is resulting in:

- Reduced access to clinical trials and other cancer care
- Reduced funding for clinical cancer research and training
- Intensifying and conflicting financial, productivity, and ethical pressures on physicians and health care institutions, and
- A shift in the balance at many institutions between financially motivated clinical research sponsored by the pharmaceutical and biotechnology industries and clinical studies funded by public or voluntary sponsors.

These problems must be addressed, for whatever the final form of the evolving U.S. health care system, the health care needs of the American public must be met.

The Impact of Health Care System Changes on Funding For Clinical Cancer Research

The Federal investment of tax dollars has been a principal, though never sufficient

source of clinical cancer research support. While voluntary organizations, private donations, and the pharmaceutical and biotechnology industries have made important contributions to cancer research, historically, clinical research funding has been supplemented largely, by shifting dollars from institutional medical practice incomes to offset research and teaching costs. As the health care system evolves to meet our need to provide quality care at affordable costs, those institutional medical practice incomes are dwindling and cost shifting to support clinical research and teaching is no longer possible.

Specifically, testimony provided to the Panel underscored repeatedly that managed care systems and many indemnity plans, bv severely curtailing health service utilization and negotiating provider contracts that scarcely cover providers' costs, have all but eliminated the patient care revenues that supported clinical research and the training of clinical cancer investigators and care givers. The net result of this shift has been a significant decrease in the funds available to continue the national clinical research enterprise. At many institutions in regions of the country with the greatest managed care penetration, the number of clinical cancer research studies, referrals and accruals to trials, investment in research infrastructure, and support for clinical and research fellowships are dropping.

Compounding the research funding problem is the refusal of many managed care plans--and the increasingly managed indemnity plans--to cover the routine patient care costs associated with participation in a clinical study. It must be noted that traditional fee-for-service plans have typicallv excluded payment for costs associated with investigational care, but very frequently covered such care if it was deemed medically necessary by the patient's physician. Speakers acknowledged that data are currently unavailable to confirm or refute pavers' assertion that clinical trials participation is more costly than standard care. Representatives from several of the academic medical and cancer centers indicated that their institutions have implemented or are planning new data systems to capture and analyze these patient care costs. Of particular concern, several speakers suggested that the liklihood of reimbursement is becoming an important factor in deciding which clinical studies can be supported in an institution.

Access to Clinical Trials and other Cancer Care in the Existing Health Care Environment

Testimony provided at the Panel's meetings highlighted significant cancer care access issues in the managed care setting--plans' exclusion of care thev deem "experimental," and "gag rules" restricting physicians from informing patients about all possible treatment options. It was also recognized that to some degree, these issues also affect the insured under traditional fee-for-service plans. Historically, patients also have not been informed about treatment options for other reasons, such as physicians' lic of awareness of clinical trials or geographic barriers. In fact, it is not known how fully cancer patients in any health care setting are informed about treatment options, including clinical trials, through an available mechanism, or the extent to which

patients fully understand the information they do receive.

Public outcry about gag rules and other patients' rights issues his, however, prompted response at several levels. The Health Care Financing Administration has recently reissued a policy statement prohibiting managed care physicians treating Medicare beneficiaries from withholding information about treatment choices. Likewise, the American Association of Health Plans (AAHP), which represents approximately 1,000 managed care plans nationwide, has issued new guidelines stating that participating. physicians must provide complete and objective information on treatment options, even if some such options are not covered bv the plan. Similarly, several bills are being developed in the Congress addressing CO patient protection, and nine state legislatures have proposed model legislation to protect the rights of managed care enrollees.

Cancer patients who are offered or request enrollment in a clinical trial are faced with increasingly complex and sometimes illogical treatment approval processes. As numerous speakers described in detail, these approval processes under managed care continue to grow more lengthy and costly. Both institutional and individual providers participating in clinical research have had to hire full-time case management and reimbursement specialists whose sole job is negotiate with and provide documentation and literature to health plan utilization control personnel to obtain treatment approvals. It has been reported that approval decisions are made by individuals lacking appropriate expertise. In some cases, by the time approval has been obtained, decline in the patient's health status or elapse of allowable time from screening to study entry precludes study participation.

Although health plans of all types are required to have an established appeal process, these mechanisms for challenging coverage decisions mav not be fully or clearly explained in plan benefit summaries or other documentation available to enrollees at the time of plan selection or following enrollment. As speakers noted, appeals are often complicated and time consuming; cancer patients or their families mav be physicallv, emotionally, or intellectually unable or unwilling to navigate this process. This may be particularly true of disadvantaged populations and those with lower literacy levels.

Detrimental influences of managed care on the care of children with cancer were described. These included refusal to pay for participation in clinical trials or tne lifetime follow-up care necessary to evaluate long-term treatment effectiveness, fragmentation of care, restricted access to pediatric oncologists, and insistence that adolescents with cancer be treated by oncologists not specifically trained in pediatric oncology. Research has demonstrated that adolescent cancer patients treated on adult treatment protocols suffer poorer health outcomes. This disruption of the standard of care in pediatric orcology, where the war on cancer can claim some of its greatest ictories, is particularly alarming.

Speakers indicated that personnel and other administrative expenses required to secure

treatment approvals, which can take two to three weeks, are responsible for steeply increasing costs of conducting clinical research. A survey of clinical researchers in a major clinical cooperative group in the Southwest suggested that associated overhead costs were 30-40 percent higher for managed care participants in trials than for those with indemnity coverage. At an Eastern center conducting a bone marrow transplant trial, personnel costs associated with obtaining treatment approval had risen 400 percent, while the cost of the procedure itself had been trimmed by 40 percent. Speakers estimated that in excess of 30 percent of an academic medical center director's time may be spent addressing treatment approval and reimbursement issues. The need to develop a data base on the reasons for non-accrual of medically eligible patients to clinical trials was identified.

Several speakers reported that approval is easily obtained for second-and third-line standard therapies, but not for investigational care that, while not necessarily, proven, has clearly demonstrated therapeutic promise in preclinical or early clinical studies. In addition, reimbursement for routine treatment or tests that would be provided as part of standard therapy relay be denied if they are associated with a clinical trial. For example, the cost of administering established chemotherapy drugs singly is typically reimbursable; however, if such established medications are combined and administered under the auspices of a peer-reviewed trial to determine if their effect is additive or complementary, reimbursement is likely to be denied.

Virtually all speakers reported far greater difficulty obtaining reimbursement for Phase I and II trials than for Phase III trials. Phase I studies of a promising new agent typically are conducted in a small number of patients with advanced disease principally to determine the maximum safe dosage. In Phase II trials, a principal objective is to assess disease response of a larger group of patients with one or a variety of cancer types. Phase III trials are larger still, and are designed to compare the efficacy of the new treatment with standard treatment. Health plans maintain that Phase I studies in particular are designed to assess toxicitn, and do not have therapeutic intent. Clinical investigators and pharmaceutical company representatives indicated, however, that if no positive therapeutic response is observed in Phase I, the likelihood that an Investigational agent will be developed further is negligible. It was noted, however, that testing requirements for the new generation of molecular, biologic, and genetic therapies and rnarkers are vastly different from those used for conventional cyotoxic agents; presenters indicated that the clinical study phases as traditionally defined may no longer be relevant and should be reevaluated by the scientific community.

Presenters also noted that payment for certain treatment trials (e.g., new combinations of approved drugs) is more likely if the new treatment is not readily identifiable as investigational. Payment for some therapies (notably, autologous bone marrow transplant with stem cell rescue for the treatment of breast cancer) is being approved predominantly, because health care companies are fearful of negative publicity. This is an inappropriate reason to provide health care coverage. In many of these cases, treatment is provided, perhaps inappropriately, outside of a clinical trial setting; data

on these patients are often lost or irretrievable and so contribute nothing to resolving questions as to the true efficacy of the treatment.

The testimony of highly sophisticated health system participants about their own difficulties in obtaining health plan approval for entry onto clinical studies suggests that getting access to the best care, particularly approval for out-of-plan treatment when that is necessary, may be all but impossible for patients who do not know how to manipulate the system or personally know someone who can intervene in their behalf. This issue is of particular concern as Medicare and Medicaid transition to managed care arrangements; the elderly and the poor, as well as other disadvantaged populations, are often unskilled at negotiating the health care system and less likely to seek out and demand optimal care. Yet it is these populations that suffer the highest cancer incidence and mortality. Moreover, the disadvantaged and uninsured--whose access to even basic care is tenuo--are in danger of being pushed even further out of the system bv changing Medicaid eligibility rules and institutions' shrinking ability to absorb the cost of indigent care. This population mav also be expected to grow as welfare reforms are implemented.

Taken together, these factors pose the danger of limiting access to trials to those with the resources to pay out-of-pocket, the skills needed to obtain and understand information about their disease and its treatment, or the physical strength, energy, and temerity to fight their health plan. The results of studies conducted in this skewed population may not be generalizable to the population as a whole.

A number of Federal initiatives are underway to improve access to clinical trials. The National Cancer Institute (NCI) and the Department of Defense (DoD) have recently finalized an agreement to enable military personnel and their dependents covered bv CHAMPUS (and its TRICARE managed care program) to participate in NCI-sponsored Phase II and III cancer clinical trials. Discussions are currently underway to establish similar agreements with the Department of Veterans Affairs, the Health Care Financing Administration (for coverage of Medicare beneficiaries), and with Blue Cross/Blue Shield. Questions remain, however, as to which trials should be covered and clearly defined standards are needed to ensure, that only well-designed, rigorously reviewed, and efficiently run studies are reimbursed. Federal legislation proposed by Senators Jay Rockefeller and Connie Mack attempts to define such trials for the purpose of a five-year demonstration program in which routine patient care costs of Medicare beneficiaries participating in trials would be reimbursed. At the state level, legislation has been passed in Rhode Island mandating coverage for participation in Phase II, III, and IV; two years after its enactment, major health maintenance organizations in the state report no adverse financial effects of compliance. Similar legislation is pending in six other states.

Physician Pressures in the Current Health Care Environment

Under the evolving managed care systems participating physicians are increasingly being asked to do more with less--to see a greater volume of patients and provide significantly, more documentation of care with less organizational assistance or support staff. In addition, managed care has dictated a major shift to primary care gatekeepers who are under pressure to limit referrals to specialists and care provided in tertiary care facilities, and may be financially rewarded for their success in doing so. Similarly, despite recent activity to lift "gag rules," primary care gatekeepers may be restricted from informing patients about all possible treatment and support options, and may prescribe only medications listed in the health plan's formulary.

Speakers noted that in some plans, the gatekeeper role is being expanded to the degree that some managed care patients with cancer may never actually see an oncologist. Some health plans are requiring primary care physicians to provide chemotherapy with "cookbook" instructions from a consulting oncologist. The practice of delivery of chemotherapy by physicians untrained in its administration raises serious ethical and medical issues.

Physician-scientists providing testimony to the Panel described strong disincentives to participating in research in the managed care setting. Chief among these were little or no organizational support and little or no staff or infrastructure support in the managed care setting. A clinical investigator at a large HMO in the western United States reported that because enrolling patients on studies and caring for them was viewed by the health plan as a non-revenue generating activity, he was able to conducted these activities only after office hours and at lunch periods and was prohibited from using any health plan staff or resources for research efforts.

Productivity pressures on managed care physicians are also limiting or eliminating time available for patient education or education of family members who will care for the patient after discharge or between outpatient treatments. Oncology nurses and registered nurses who might have taken on some of this role are themselves being replaced by less skilled workers (assistive personnel) who lack an understanding cancer patients' specialized needs.

Similarly, pressure to see more patients per hour is discouraging physicians from devoting time to the education of medical students or research fellows. Many managed care plans are requiring supervising physicians to complete duplicative paperwork documenting care provided by these trainees. Despite added paperwork requirements, however, the loss of assistance from these highly capable fellows exacerbates productivity pressures when, as described below, institutions eliminate fellowships due to dwindling financial support. It also threatens to sever the crucial relationship that supports the replenishment of our front-line troops in the war on cancer--young, talented clinical researchers and care givers.

Institutional Provider Pressures in the Current Health Care Environment

Academic medical centers (AMCS) and cancer centers are the foci of translational research that brings laboratory discoveries to clinical utility. These cornerstones of our clinical research enterprise are especiaily threatened in the managed care environment because care provided at these specialized research and training facilities may be more expensive than care provided elsewhere. As a result, managed care plans may prohibit enrollees from receiving care at these centers (or refuse to reimburse such care). Moreover, enrollees who are treated at these centers may be forced to obtain routine tests (e.g., x-rays or scans, blood tests) at other, sometimes distant, facilities with which the MCO has contracted for the service. The resulting fragmentation of care and frequent difficulties in obtaining test results in a timely manner significantly complicate care and can be extremely hazardous to the patient.

As noted in the previous section, some AMCs and cancer centers are being forced to drop fellowships and other training for clinicians and researchers, in part because the patient care that subsidized fellowships has been reduced or eliminated and because the institution is either unable or unwilling to sustain the additional overhead costs associated with health plans' increased documentation requirements when care is rendered by a fellow. While presenters were cognizant that the long-term impact of these actions would be a declining intellectual resource in cancer research and cancer care, they maintained that the actions were necessary for short-term financial survival.

Presenters described a variety of coping mechanisms AMCS, cancer centers, and other institutional health care providers are implementing to adjust to the changing environment. Speakers from the western part of the country related strategies adopted in response to managed care growth; those from areas with lower managed care penetration are observing the western experience and acting in anticipation of greater managed care enrollment.

Among the strategies discussed were: establishing referral and care networks with providers in the communities surrounding the medical center; merging with other facilities to achieve economies of scale and consolidate capacity in the face of reduced utilization; acquiring nearby primary care facilities to help capture patients; developing detailed cost and outcomes tracking svstems to develop data for use in negotiating with managed care companies and identifying opportunities for cost savings; hiring staff dedicated to securing treatment approvals; increasing reliance on industry funding for trials; and developing clinical care pathways for specific malignancies to define appropriate care and facilitate treatment approval and reimbursement.

The Role of Pharmaceutical and Biotechnology Industries in the Conduct of Clinical Research

The pharmaceutical and biotechnology industries are becoming an increasingly important sponsor of clinical research in the United States. It was noted that a great many of the recent advances in cancer diagnostics and therapeutics have come from the pharmaceutical arili biotechnology industries and have contributed greatly to advances in cancer care. These contributions should not be discounted or discouraged. Presenters emphasized, however, that as traditional sources of clinical research support have evaporated in the managed care environment and government support has remained essentially static or diminished, some academic medical centers, cancer centers, and other sites of clinical research are turning to research funded by pharmaceutical and biotechnology companies to fill the financial void and maintain capacity. At one large cancer center in the Southwest, for example, the total number of clinical studies being conducted has remained stable in recent years, but industry sponsorship and accrual to industry-sponsored trials is growing a greater rate than either institution-sponsored trials or NCI-sponsored trials, on which accrual has dropped precipitously. Such shifts in the balance between industry-sponsored clinical studies and investigator-initiated research funded by public or voluntary sponsors raises concerns that we may eventually fail to pursue the full range of scientific concerns relevant to reducing the cancer burden (such as psychosocial or prevention issues) if such studies are unlikely to have commercial potential.

Industry tends to pay more (though not necessarily all) of patient care costs for individuals on trials compared with cooperative groups or other federally funded mechanisms. The larger pharmaceutical companies are generally able to pay more to support patient care and enrollment in trials than are the smaller biotechnology firms. Still, the difference between industry and government sponsorship is sufficiently great (e.g., $2,500-$5,000 per patient on a drug industry-sponsored trial versus $250 per patient on a cooperative group trial) that it centers a significant selection preference.

The drug development process is enormously costly and protracted; as presenters pointed out, new products must be brought to market in sufficient time to recoup research and development costs before patent protections expire and competing generic compounds are offered at lower prices. As a result, the clinical studies that companies are willing to sponsor may differ markedly from government-sponsored research in which the objectives are public health and knowledge base enhancements (e.g., societal benefits of improved cancer care, health status, and quality of life; expanded knowledge about cancer). For example, industry sponsors are generally hesitant to invest in studies to secure approval for additional uses of agents already approved for treatment of a particular malignancy unless the new use is shown to have significant market potential. Established and potential mechanisms for facilitating government/industry collaborations that may enable industry to participate in a broader clinical research agenda were discussed.

CONCLUSIONS

In 1997, an estimated 1,382,400 Americans will be diagnosed with cancer, and approximately 560,000 will die of cancer. Although our successes in curing, controlling, and preventing cancer has varied among populations, we have made great gains in curing childhood and certain other cancers, and for the first time, overall mortality from cancer dropped by 2.6 percent for the period 1991-1995. These gains have, however, been more apparent in some populations than in others. At the same time, incidence and mortality for some cancers continues to rise--despite our successes, cancer remains a formidable foe.

These statistics engender both frustration and hope. The National Cancer Program has made enormous progress into understanding the rnany distinct diseases collectively called cancer, which have extraordinarily complex and diverse risk factors, rnechanisms that control development and progression, and requirements for care. The public and private investments that have given the American people this knowledge ind global Ieadership in cancer research and care should not be diminished or compromised. But we are at a watershed; rapidly evolving molecular and genetic discoveries about cancer--how it develops, how it grows and spreads, how it is inherited--have led to an explosion of new therapeutic, diagnostic, and preventive possibilities that must be brought to the benefit of people with cancer and those at risk. Our knowledge is of no use if it is does not lead to improved cancer care and prevention.

Unquestionably, clinical research is the pathwav by which new discoveries become treatment advances; for many cancers, the standard care of today, was investigational treatment only yesterday. Improved cancer care means earlier detection of disease, improved monitoring targeted to individuals at risk of specific malignancies, better preventive and supportive care, and treatments that are of shorter duration, less invasive and disabling, and more effective. It means reduced need for repeated treatment, and frequently, lower utilization of health services of all tvpes. Unless we are willing to settle for current preventive, diagnostic, treatment, and supportive interventions, that for many cancers remain seriously and inadequate, our capacity to conduct clinical research and train new clinical researchers and cancer care givers must be safeguarded and expanded.

Managed care systems are fast becoming the major organizational and financial mechanisms for the delivery of health care in the United States. The concern is that some rnanaged care entities currently focus principally, on managed cost and are enerting a damaging influence on the Nation's ability to conduct clinical research without which the burden of cancer on the people will not be alleviated. Undeniably, managed care has made significant positive contributions to stabilizing heretofore spiraling national health care expenditures, but necessary cost controls should not be achieved at the expense of the Nation's ability to advance cancer care and ensure that people with cancer can access the care they need.

Research and development is an accepted cost element in virtually every other industry, and the Panel believes the health care industry should be no exception. Managed care and other payers, research sponsors including government and voluntary, agencies as well as pharmaceutical and biotechnology industries, employer and employee participants, and other consumers who benefit from the advances in cancer care and prevention achieved through clinical research should share its cost in appropriate measure. The principal contribution of patients should remain their willingness to participate in promising, though unproven, therapies. The Federal investment in clinical research should be maintained at the highest possible levels. lndustry, for which clinical research is the stepping stone to FDA approvals and subsequent revenue, should continue to pay the drug and research-related costs of studies it sponsors, including procedures and testing in excess of care that would be provided in conjunction with standard treatment. Policies and mechanisms must be developed to ensure that health care financing entities, including managed care, bear their fair share to the research and development effort from which they benefit. The Panel recognizes that the managed care industry is comprised of both mature and newer plans competing in both mature and emerging markets; participation in clinical research and perceptions of social role among these plans likewise are higher variable.

The Panel believes that immediate steps are needed to ensure both the stability and progress of the National Cancer Program and the continued worldwide leadership of the United States in cancer research, treatment, and training. The Panel thus recommends:

- Measures must be taken to ensure that the uninsured and under-insured are not excluded from access to appropriate cancer care, including clinical trials, as the health care system evolves. It must be recognized that these populations, of whom a disproportionate numberly are elderly, disadvantaged, and minority, suffer the highest cancer incidence and mortality yet generally have the least knowledge and the fewest resources and proponents to advance their interests in the health care system.
- Participation in clinical research should be incorporated into the standard of care for cancer. Clinical guidelines delineating critical pathwavs for specific malignancies, including entry onto clinical studies, should be developed, adopted into standard practice, and updated regularly to reflect advances in treatment and related care.
- Access to peer-reviewed clinical cancer detection, treatment, and prevention trials should be incorporated into the standard of care for cancer and incorporated into coverage provided under managed care and indemnity insurance plans.
    - At the national level, agreements explicitly guaranteeing access to peer-reviewed clinical trials, such as the one recently established between the National Cancer Institute and the Department of Defense, should be developed with other major pavers and purchasers of care, including the Health Care Financing Administration, Department of Veteran's Affairs, Blue Cross/ Blue Shield, other insurers offering indemnity and

managed care products, and managed care companies.
    - Currentiv enacted and pending national and state-level legislative efforts to ensure access to clinical trials should be expanded and extended.
- Measures must be adopted to ensure that the cost of clinical research and training are paid regardless of the structure and financing of the health care delivery system.
    - Clinical research is a legitimate research and development cost in medicine and related health disciplines. These costs should be shared by its beneficiaries:
        - Research sponsors-government, the pharmaceutical and biotechnology industries, and voluntary organizations-should cover the costs of drugs, devices, data management, and research nursing associated with studies. They should also be responsible for the cost of patient care and testing that exceeds what would typically be provided in the course of standard care.
        - Managed care organizations and other payers should reimburse providers for routine patient care (i.e., services and other cost items that would be rendered regardless of treatment choice) provided in association with appropriately peer-reviewed Phase I through Phase IV clinical trials. Procedures are needed to ensure that MCOs and other payers contribute equitably to the clinical research enterprise, from which life- and cost-saving advances are developed. Possible mechanisms for achieving this participation could include establishment of a fund into which all pavers contribute in an equitable manner, tax incentives, or a tax on health plan profits. Participation in any such mechanismshould be legislatively mandated, if necessary.
    - Reimburseability of care provided under clinical trials should be evaluated using specific criteria that clearly define the required review processes, objectives, and other characteristics of clinical trials acceptable for patient care cost reimbursement.
    - Data systems must be developed to facilitate the retrieval and linkage of patient data necessary to evaluate differences in outcomes and costs for cancer prevention, detection, treatment, and support interventions provided to specific populations in diverse practice settings and geographic locations.
- Appropriate clinical cancer research training for investigators and cancer care givers is essential to maintain and replenish our crucial intellectual resource in cancer research and care, to maintain our world leadership in cancer research, and to bring new discoveries to the benefit of patients with cancer and those at risk. Given the evolving health care delivery system, mechanisms must be established to ensure support for clinical cancer research training.
- The process for appealing coverage decisions made by health plans must be simplified, standardized, and fully disclosed to participants in health plans of all types (e.g., private managed care and indemnity plans, and publicly funded

health programs). Materials describing the appeals process should be understandable to people with lower literacy levels and should be made available prior to enrollment in a plan. Appeal decisions must be rendered expeditiously to ensure that appeal-related delays do not preclude treatment opportunities.

- Consumer education at all levels (e.g., employers and the public) is needed to promote an understanding of the importance of clinical cancer research and a realization that the need to access such care can become a reality for an person. Without an understanding of the relationship of clinical research to advances in cancer care, the public is unlikeIy to demand that these services are covered under employer-sponsored, union, and publicIy funded health benefit plans. Public demand for access to trials is needed to foster health system competition on access and quality rather than on cost alone.

PRESIDENT'S CANCER PANEL
JULY 30, 1996
Speaker's List

Frederick R. Applebaum, M.D.
Director, Clinical Research Division
Fred Hutchinson Cancer Center
Professor of Medicine
Univeristy of Washington

Allen B. Bredt, M.D., F.A.C.P.
Assistant to the Associate Medical Director
Kaiser Permanente

Scott M. Browning, M.D.
Principal Investigator
Kaiser Permanente
Community Clinical Oncology Program, San Diego

Robert W. Day, M.D.,M.P.H., Ph.D.
President and Director
Fred Hutchinson Cancer

Laura Esserman, M.D.
Assistant Professor Surgery
UCSF Mount Zion Medical Center
Department of Surgery

Robrt A. Figlin, M.D.
Professor of Medicine
UCLA School of Medicine
Division of Hematology and Oncology

Peter O. Kohler, M.D.
President
Oregon Health Sciences University

Keith S. Lanier, M.D.
Principal Investigator
Columbia River Oncology Program

Peter McGough, M.D.
Family Practice Physician
Medalia Health Care

Franco Muggia, M.D.
Director, Medical Oncology
University of Southern California
Norris Cancer Center

H. Irving Pierce, M.D.
Principal Investigator
Northwest Community Clinical Oncoiology Progtam

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Professor of Medicine and Biological Structure
University of Washington Medical Center
Division of ONcology

Sandra Rorem, M.B.A.
CEO, Medalia Health Care

Simeon A. Rubenstein, M.D.
Medical Director of Corporate Health
Group Health Cooperative of Puget

Frank Senecal, M.D.
Oncologist
Medalia Health Care

Paul L. Weiden, M.D.
Principal Investigator
Virginia Mason

PRESIDENT'S CANCER PANEL
SEPTEMBER 24, 1996
Speaker's List

Joseph Bailes, M.D.
Executive Vice President
Physician Reliance Network

Otis Brawley, M.D.
Assistant Director
Office of Special Populations
National Cancer Institute

Doris Browne, M.D., M.P.H.
Director, Prevention and Standards
Department of Denense
Office of the Assistant Secretary of
Defense for Health Affairs

Charles A. Coltman Jr., M.D.
Director
San Antonio Cancer Institute

Richard F. Corlin, M.D.
Speaker, AMA House of Delegates
Amerian Medical Association

Judy Gerner
Director
Anderson Network
M.D. Anderson Cancer Center

Pamels J. Haylock, R.N., M.A.
President Elect
Oncology Nursing Society

Karen B. Heusinkveld, Dr.P.H., R.N.
Board Member, American Cancer Society
Associate Professor
The University of Texas at Arlington
School of Nursing

Sydney T. Hickey
Associate Director, Government Relations
National Military Family Assoication

David C. Hohn, M.D.
Vice President for Patient Care
U. Texas, M.D. Anderson Cancer Center

Lloyd Kitchens, M.D.
Medical Director
Texas Oncology
American College of Physicians

Jose Lopez, M.D.
Oncologist
San Antonio Tumor and Blood Clinic, PA

C. Philip Steuber, M.D.
Professor of Pediatrics
Baylor College of Medicine
Texas Children's Hospital

Emily Untermeyer, M.P.H.
Executive Director
Texas Cancer Council

Leonard Zwelling, M.D., M.B.A.
Associate Vice President for Clinical and
Translational Research
M.D. Anderson Cancer Center

PRESIDENT'S CANCER PANEL
OCTOBER 25, 1996
Speaker's List

Kirby Bland, M.D.
J. Murray Beardsley Professor and Chairman
Department of Surgery
Brown University School of Medicine
Rhode Island Hospital

Bruce A. Chabner, M.D.
Chief, Hematology Oncology
Clinical Director
Massachusetts General Hospital Cancer Center

Vincent T. DeVita, Jr., M.D.
Director
Yale Cancer Center
Yale Uiversity Scool of Medicine

Emil Frei, M.D.
Richard and Susan Smith Distinguished
Professor of Medicine
Harvard Medical School
Physician in Chief, Emeritus
Dana-Farber Cancer Institute

Arvin S. Glicksman, M.D.
Director
Quality Assurance Review Center

William Kreykes
President and CEO
Lifespan

Michael D. Loberg, Ph.D.
President
Oncology/Immunology
Bristol-Myers Squibb

Donald J. Marsh, M.D.
Dean of Medicine and Biological Sciences
Brown University
School of Medicine

Thomas Mays, Ph.D., J.D.
Director
Office of Technology Development
National Cancer Institute

Marlene McCarthy
Chair
Rhode Island Breast Cancer Coalition

Peter Quesenberry, M.D.
Director, Cancer Center
University of Massachusetts Medical Center

Alan Rabson, M.D.
Deputy Diretor
National Cancer Institute

Seth A. Rudnick, M.D.
hairman and Chief Executive Officer
CytoTherapeutics

Philip S. Schein, M.D.
Chairman and Chief Executive Officer
U.S. Bioscience, Inc

Amy Stansfield, R.N., M.B.A.
Administrative Director
Norris Cotton Cancer enter
Dartmouth-Hitchcock Medical Center

David W. Yandell, Sc.D.
Director
Vermont Cancer Center
University of Vermont

PRESIDENT'S CANCER PANEL
NOVEMBER 22, 1996
Speaker's List

Otis Brawley, M.D.
Assistant Director
Office of Special Populations
National Cancer Institute

O. Michael Colvin, M.D.
Director
Duke Comprehensive Cancer Center
Duke University Medical Center

M. Robert Cooper, M.D.
Professor of Medicine
Comprehensive Cancer Center
Wake Forest University
Bowman Gray School of Medicine

Jeffrey Crawford, M.D.
Associate Professor
Department of Medicine
Duke University Medical Center

Russell F. DeVore, III. M.D.
Assistant Professor of Medicine
Division of Medical Oncology
Vanderbilt University Medial Center
Director, Vanderbilt Cancer Center Affiliate Network

Nancy Weaver Emersin
Director, Major Projects
Duke Comprehensive Cancer Center
Duke University Medial Center

Lynn Erdman
Director
Presbyterian Cancer Center

Gilbert H. Friedell, M.D.
Director
Kentucky Cancer Program
University of Kentucky

Carlan T. Graves
Project Director
Cancer Information Service
Duke University Medical Center

Paul K. Halverson, Dr.P.H.
Senior Fellow
Center for Public Health Practice
Assistant Professor
Department of Health Policy and Administration
School of Public Health
University of North CArolina at Chapel Hill

Margaret Hargreaves, Ph.D.
Imtrim Directot
Drew-Meharry-Morehouse Consortium Center
Meharry Medical College

Robert Krance, M.D.
Interim Chairman, Hematology/Oncology
St. Jude Children's Research Hospital

Edward Partridge, M.D.
Associate Director for Community Research
Professor and Director, GYN-ONC
Comprehensive Cancer Center
University of Alabama at Birmingham

Richarf Payne, M.D.
Professor of Medicine (Neurology)
Chief, Section of Pain and Symptom Management
Department of Neurology
M.D. Anderson Cancer Center

Ralph Snyderman, M.D.
Chancellor for Health Affairs
Dean, School of Medicine
Duke University Medial Center

Edward Trapido, Sc.D.
Associate Director
Sylvester Comprehensive Cancer Center
University of Miami

Georgia B. Vogelsang, M.D.
Associate Professor of Oncology
Clinical Director of Bone Marrow Transplant
The Johns Hopkins University

Robert Warren, M.D., F.A.C.P.
Director for Clinical Affairs
Lombardi Cancer Center

Marion S. White
Executive Director
North Carolina Advisory Committee on Cancer
Coordination and Control

NCI FY 95 EXPENDITURES	NON-AIDS		AIDS		TOTAL	
	Number	*Amount*	*Number*	*Amount*	*Number*	*Amount*
RESEARCH GRANTS						
RESEARCH PROJ:						
Noncompeting	205	$56,243	7	$2,811	212	$59,054
Admin. Supp.						
Competing	141	$55,645	3	$771	144	$56,416
Subtotal	346	$111,888	10	$3,582	356	$115,470
SBIR/STTR	3	$254			3	$254
Subtotal, RPG	349	$112,142	10	$3582	359	$115,724
RESEARCH CENTERS						
Spec/Comp.	11	$22,279			11	$22,279
SPORES	4	$4,964			4	$4,964
Subtotal	15	$27,243	0	0	15	$27,243
OTHER RESEARCH						
Coop. Cl. Groups	151	$74,881	1	$310	152	$75,192
Other	0	0			0	0
Subtotal	151	$74,882	1	$310	152	$75,192
Total RGs	151	$214,882	11	$3,892	152	$218,159
R&D CONTRACTS	10	$6,549	6	44,759	16	$11,308
INTRAMURAL		$28,997		$44,081		$73,078
RMS		0		$1,488		$1,488
CONTROL						
Subtotal, Control		$80,784		0		$80,784
CONSTRUCTION		0		0		0
TOTAL, NCI	**525**	**$330,597**	**17**	**$54,220**	**542**	**$384,817**