Statements from the President's Cancer Panel

to Assess Managed Care's Role in the War on Cancer

Issues of Access in Today's Health Care System

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

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

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

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

Two of the leading cancer centers in the State of Texas--The San Antonio Cancer Institute (SACI) and M.D. Anderson Cancer Center (MDACC)--presented to the Panel that managed care penetration has not has not caused a noticeable decline in the number of patient's able to access clinical trials, however, maintaining access is becoming increasingly difficult. Both institutes agreed that, as a result of movement toward a managed care health system, substantially more resources are required to enroll patients into research protocols, leaving less resources to devote to performing research, patient care, and education. In a SACI survey of 27 in-house and Southwestern Oncology Group (SWOG) physicians, 83 percent reported increases in the cost and time to obtain reimbursement and referrals due to managed care, with an average increase in overhead costs of 30-40 percent. MDACC has had to invest in new infrastructure processes in order to maintain its patients' access to clinical trials

and quality medical care. Case management program personnel now work with faculty and staff to make sure that clinical therapies will be paid for and that necessary paperwork is completed.

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

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

The responsibility of "for-profit" managed care was raised. Dr. Richard Corlin of the AMA, questioned who should profit from delivering health care services, pointing out that "[i]nsurers used to provide value by spreading risk," however under capitated reimbursement that risk is now passed to physicians and hospitals. An inherent problem was seen in a health care community. Dr. Harold Freeman, Panel Chair, acknowledged that conflict between medical ethics and fundamental business principles, and expressed concern that medical ethics not be overshadowed by business motivation as health care becomes a profit-driven enterprise.

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

Many patients perceive their access to care is directly related to their ability to challenge the decision of their health care plan. One presenter called it the "survival of the fittest" of those who will fight the hardest to obtain care. More patients are turning to litigation to obtain access to desired treatment protocols, which is seen as a "no-win" situation for all. In an informal survey presented by The Anderson Network of its membership, comments included, "We have such a fight to live. Please quit making us fight for our care." Another patient asked the Panel, "Please don't cut

funding. Let us have access to clinical trials. This is our future. That will win the war [on cancer]."

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

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

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

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

Increasingly industries, such as pharmaceutical and biotechnology companies, are

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

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

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

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

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