Statements from the President's Cancer Panel

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

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

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

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

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

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

Rhode Island has mandated coverage by insurers for certain standards of care, i.e., cancer therapies being provided pursuant to Phase III or IV clinical trials approved by the NCI, Department of Defense, Food and Drug Administration, Veteran's Administration, or "a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants." Significantly, testimony obtained from managed care organizations in that state indicates that compliance with this law has had no financial impact; however, there is continued resistance to covering phase I/II studies.

Per Paul Calabresi, this resistance to reimbursing for phase I trials "is not because of cost...but because [health care organizations] think it is research and don't want to set a precedent of paying for research." As a Nation, we can not accept a health care

mentality that allows us to treat patients only if we gain no knowledge from the experience.

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

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

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

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

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

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

- Regulation of for-profit managed care organizations to assure that they assume their fair share of responsibility for the health of this nation
- Legislation of comprehensive cancer care coverage for children as

representing a unique health care population
- Development of an accreditation standard for managed care organizations which includes clinical research participation
- Additional grant funds provided to the General Clinical Research Centers to allow greater participation in both inpatient and outpatient cancer care.

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

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