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ACCC Presidents' Retreat brings together oncology's leadership

It was a remarkable attempt to bring together the leadership of seven major national oncology organizations and all of the state medical oncology societies with the leadership of key federal agencies, Congressional policy makers, legislative analysts, and leadership from the pharmaceutical industry. In the last days of January, at a circular table for 70 people, the presidents or their designees and the senior staff of oncology's leading organizations rolled up their shirt sleeves for two days and looked at the future of cancer treatment and research under the new administration.

Along with ACCC leadership, ASCO, national ACS, ASH, MGMA, ONS, NCCS, and more than 30 state societies held lengthy discussions at the Presidents' Retreat. The outcome was a vow to work together more closely on health care reform and other key legislative and regulatory policies affecting the profession.

"There was an enormous amount of give and take between all of the folks sitting at the table," said David K. King, M.D., the meeting's chairman, "The idea was to tap into some of the tremendous expertise available throughout the nation and through the national organizations in D.C. and to make certain that we were all getting the same information at the same time. The reaction was very positive."

Among the presidents presenting at the meeting were Dr. David Regan on the Oregon plan, Dr. Irving Lerner with Dr. Burt Schwartz on managed care in Minnesota, and Dr. Jim Wade on the Illinois Society's legislative success on off-label. Congressional staffers involved with the formulation of the managed competition bill also addressed the group, answering key questions about pre-existing conditions, off-label, and experimental trials. ASCO and ACCC legal counsels discussed some of the likely impacts of health care reform on physicians and hospitals.

"It was a real opportunity to share our knowledge and successes as well as some of the problems we confront at the state and federal levels," said Dr. Jim Wade, President of the Illinois Medical Oncology Society and a member of both the ASCO Clinical Practice Committee's Executive Committee and the ACCC Board. "While there has been a history of friction between some members of this group, none of that was present at this meeting. Getting away from the usual brief meeting format made an enormous difference. This was a chance for us all to get to know each other better and to see how many common goals we really share."

During the first day of the conference, representatives from key Congressional committees, senior staff from HCFA, GAO, NCI, and FDA and analysts from two D.C. based law firms supporting ASCO and ACCC discussed the current health care legislative and regulatory environment. The president of a major U.S. biotechnology firm also spoke with the group.

On the second day, presidents from a number of states discussed health care reform measures in their areas and the impact on clinical oncology. A member of the Illinois legislature described the process by which ACCC's off-label legislation was developed and passed with the assistance of the state medical oncology society. The President of the Illinois Hospital Association and this year's ACCC President discussed the impact of managed competition on hospitals.

The meeting concluded with an interest expressed by all of the participants in continuing to work together on these types of pressing legislative issues. Several state presidents requested that ACCC consider serving as a coordinator for the informal efforts of the group to continue.

Meeting highlights

Discussion during the meeting included:

- Mr. Dave Kendall, Legislative Director to Congressman Michael A. Andrews and one of the prominent authors of current managed competition legislation discussed three basic ideas that underpin the bill: standardized benefits; a tax cap and, required outcomes reporting.

  Kendall noted that he was aware of the interests of the oncology community with regard to experimental trials and planned to include coverage for the patient care costs of patients on clinical trials. He also noted that the legislation eliminates pre-existing conditions and has global budgeting aspects. In response to questions, Kendall noted that oncology will have to be part of the basic benefits package, as will prescription drugs. He also suggested that he was not in favor of heavily regulating prescription drug development, but that Senator Pryor may have other plans.

- Dr. Mike Miller, Legislative Assistant for Health Care to Congressman Sander M. Levin, discussed some of his views on managed competition, and noted that there may be other ways to pay than global budgeting. Miller noted the *New England Journal of Medicine* estimate that 29 percent of the U.S. population reside in rural areas where it is unlikely that there are sufficient providers to actually establish a competitive environment.

  Miller noted that they hoped the Administration would alter Medicare policy on off-label, instructing the carriers to use the three compendia, and the Rockefeller-Levin bill will be re-introduced as a back up. Miller noted that a Congressional Budget Office analysis of the legislation indicated that it had a zero impact on the budget, and expressed the opinion that the legislation would have little difficulty passing.

- Mr. George Silberman from the General Accounting Office reviewed

three oncology-related studies which he has directed: one on off-label, a second on transfer of oncology patients to the hospital setting, and a third ongoing study that analyzes bone marrow transplantation in 10 countries and compares the quality of care received. Mr. Silberman indicated that results from the last study will be available in 7 months.

- Two representatives from the FDA discussed the agency's current approval process and the ACCC's recent comments about the agency's proposed regulations on off-label drug promotion. Dr. Peter Rheinstein, Director, Medicine Staff, Office of Health Affairs, stated that the regulations are intended to govern sole sponsor, sole purpose meetings, rather than the multi-purpose, multi-sponsor meetings that concerned the oncology community.

- Ms. Anne Marie Hummel, Director, Division of Medical Services Coverage Policy, Health Care Financing Administration, noted that HCFA had worked closely with the oncology community and that Drs. King and Mortenson had discussed off-label coverage with several advisory committees. She pointed out that Section 2050.5 of the carriers manual stated that carriers should pay for all FDA approved drugs except when they are "not medically reasonable and necessary," thus shifting the burden of proof to the carrier, rather than the physician.

  While she recognized that many carriers were not acting in this spirit, she said that the agency intended to work with the carriers on coverage policy. In response to audience questions, Ms. Hummel stated that there was still significant carrier discretion mandated by law and in regulation.

- Dr. Michael Friedman, Dr. Jim Wade, and Dr. B.J. Kennedy discussed some of the emerging problems with reimbursement for patient care costs of patients on clinical trials during a session chaired by Ms. Diane Van Ostenberg. The participants noted that this was just the onset of the problem.

  Dr. Friedman noted that a number of investigators had already expressed considerable concern that studies of off-label uses of Taxol were being denied. Dr. Kennedy noted the need to address lower frequencies of tests during trials. Dr. Wade suggested that trials may require cost effectiveness components. Ms. Van Ostenberg indicated problems with patients and the potential skewing of results.

- Mr. Samuel Turner, ASCO Legislative Counsel discussed federal regulation and research. Public policy and health care reform was discussed by Mr. John Hoff, ACCC Legislative Counsel. Dr. A. Collier Smyth discussed the perspective of a practicing oncologist to health care reform.

- Mr. Dennis Longstreet, President of Ortho Biotech, discussed the potential innovations under development by the biotechnology industry and some of the significant risks and costs associated with new biological development. He invited the group to work with members of the national biotechnology community on issues which will affect the ability of the industry to continue rapid development of new innovations in cancer care. (See article on page 13.)

- Illinois State Senator Penny Severns joined Dr. Wade and Jamie Young, ACCC's Director of Public Policy, and Mr. Alan Mills, ACS's Senior Manager for Public Issues, in a discussion of off-label legislation and how it can be passed in many states. The participants noted that federal legislation will focus on the Medicare population and state legislation will affect other local insurers, HMOs, and PPOs.

- In a panel chaired by Dr. Albert Einstein, Drs. Kennedy and Wade discussed the growing shortage of medical oncologists and the prospect that other health care providers will need to supplement some of the functions currently managed by oncologists.

  Mr. Robert T. Clarke, ACCC's current President, indicated that the role of community hospitals will shift under managed competition, from one of a revenue producer to a cost center. Mr. Hoff discussed current changes in the interactions between hospitals and physicians. Dr. Charles Nash, President of the Oklahoma Medical Oncology Society, described some of the impacts of RBRVS on practices in his state. Dr. Dave Regan, President of the Oregon Medical Oncology Society, discussed the Oregon Plan and noted that a companion bill with a larger population of patients is likely to go into effect with or without federal waivers.

  Managed care restrictions on oncology care in Minnesota were described by Dr. Irving J. Lerner, President, Minnesota Society of Clinical Oncology and Dr. Burton S. Schwartz, Vice President and Chairman of the MSCO Scientific Technology Review Committee.

- Dr. Daniel Rosenblum, Chairman, American Society of Hematology Clinical Practice Committee; Dr. Thomas A. Bensinger, Co-Chairman; and Mr. Clarke discussed the need for studies on cost and quality.

- Representatives from ACS, Dr. Reginald C.S. Ho; ONS, Ms. Sandra Lee Schafer; MGMA, Ms. Carole Erickson and NCCS, Ms. Ellen Stovall expressed interest in working together in this and other forums.

Other developments

In open discussion the participants suggested several different strategies for moving forward:

- The development of an informal working group of leadership from interested societies to consider how these national and state organizations might work together on common issues.

- The development of a white paper or strategic plan on several key issues of concern, such as payment for clinical trials and off-label, patients rights, and the insurability of survivors.

- Backing from the organizations of patient groups, such as NCCS, that is in the process of developing a national white paper on health care reform from the patient's perspective.

ACCC leadership have taken a number of steps to follow the group's recommendations subsequent to the meeting. A full report on the progress of this effort will be available at the National meeting in March.