October 13, 2000

VIA TELECOPY

John M. Eisenberg, M.D.
Director, Agency for Healthcare Research & Quality
2101 East Jefferson Street
Suite 600
Rockville, Maryland 20852

Dear Dr. Eisenberg:

The undersigned national cancer organizations have been intimately involved in the development of Medicare policy for coverage of routine patient care costs in clinical trials. We are writing to express our objections to the lack of adequate and timely notice from the Agency for Healthcare Research and Quality (AHRQ) in connection with your proposed public meeting to discuss this vital issue. The notice published October 11, 2000, in the Federal Register indicated that this public meeting would occur on October 20, thus giving only eight days notice. We believe that this notice period is entirely insufficient to enable advocacy groups to plan to attend and to prepare their comments on a matter of considerable complexity.

Although the recent National Coverage Decision on this issue applies to all diseases, it will likely have the greatest impact on cancer clinical trials, and there can be no doubt that it was the cancer community that drove the decision by the President to issue the June 7, 2000, executive memorandum extending coverage. Moreover, it was representatives of the cancer community who engaged in extensive negotiations concerning the proposed National Coverage Decision with officials from different agencies of the Department of Health and Human Services (HHS) with the Health Care Financing Administration (HCFA), with the National Cancer Institute (NCI), with the Food and Drug Administration (FDA), and with the Assistant Secretary for Legislation, but unfortunately not including AHRQ.

When the final version of the National Coverage Decision was released, we were quite concerned that, contrary to assurances given to us by the Administration, the so-called “IND-exempt” trials had been removed from those “deemed” covered. This decision appears not to have been made in response to comments and certainly was not a result of discussions with our organizations. We believe it unnecessarily places at risk a category of trials that has been influential in the post-approval development of many important cancer therapies--i.e., investigator-initiated trials of already marketed drugs.
Our organizations are spread across the United States and find it difficult to arrange travel and other schedules on such short notice. In addition, with legislative and other public policy activities ongoing at this time of year, many of us already have irreconcilable conflicts with the proposed date. While the notice asserts that the recommended 15 days of notice was not provided “due to time constraints,” there is no explanation of what such constraints might be. No one wants resolution of these issues more than the cancer community, but the stakes are too high to rush to a judgment that may undermine, at least in part, the very good intentions of the President when he issued his June 7 executive memorandum.

Given these circumstances, we strongly urge that you reschedule the meeting, providing ample notice and opportunity for contributions from the many interested parties in the cancer community and beyond. Thank you for your prompt attention to this matter. We look forward to your response.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer Advocacy,
  Support, and Education
American Society of Clinical Oncology
Association of American Cancer Institutes
Cancer Care, Inc.
Cancer Research Foundation of America
The Children’s Cause, Inc.
Colorectal Cancer Network
Cure For Lymphoma Foundation
International Myeloma Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
The Susan G. Komen Breast Cancer Foundation

cc: The Honorable Donna E. Shalala, Secretary, HHS
    Michael Hash, Acting HCFA Administrator
    Jane E. Henney, M.D., Commissioner, FDA
    Richard Klausner, M.D., Director, NCI
    Kevin Thurm, HHS/OS
    Richard Tarplin, HHS/OS
    Nilam Patel, MPH, AHRQ
    Shana Olshan, HCFA