February 11, 2002

Via Telecopy

The Honorable Tommy Thompson
Secretary, Department of Health & Human Services
200 Independence Avenue, S.W.
Room 615-F - HHH Bldg.
Washington, D.C. 20201

Dear Secretary Thompson:

It has come to our attention that the Centers for Medicare and Medicaid Services (CMS) may be considering a significant retreat from standards of quality cancer care for Medicare beneficiaries by denying coverage for routine patient care costs for beneficiaries who enroll in cancer clinical trials. This reversal of CMS policy would be devastating for beneficiaries with cancer and would engender the strongest opposition from cancer patient advocates across the nation, including the members of the Cancer Leadership Council, listed below.

As announced by the Medicare program in the fall of 2000, current policy makes clear that patients enrolled in clinical trials continue to be entitled to reimbursement for their routine patient care costs, such as physician and hospital charges. These routine charges are not research costs but rather patient care costs, and there is no justification for not covering them. After almost a decade of discussion, including various bipartisan legislative proposals to clarify the policy, the Medicare program finally agreed that routine patient care costs were a program responsibility even when rendered in the context of a clinical trial. A decision by the Department to return to a state of uncertainty about the coverage policy -- or worse yet, to clearly state a noncoverage position -- would be unacceptable.

Although cancer is predominantly a disease of the elderly, Medicare beneficiaries have been significantly under-represented in cancer clinical trials, at least in part because of the historical uncertainty about coverage of patient costs. This under-representation in clinical trials has substantial implications for the applicability of research results to senior citizens. The September 2000 policy clarification was an important step forward in integrating Medicare beneficiaries into the cancer clinical trial system, which is an essential component of quality cancer care in this country. It would be most unfortunate if the Medicare program sought now to retrench from its earlier enlightened action and return to denials of coverage for routine patient care just because the beneficiary accesses care in the context of a clinical trial.
Significantly, the current policy was developed in consultation not only with Medicare officials but also with experts from the National Institutes of Health, the Food and Drug Administration, and the Agency for Healthcare Research and Quality. In addition, the Medicare coverage decision in 2000 was an outgrowth of strong bipartisan support for coverage of these costs by Members of Congress as influential and diverse as Democratic Senators Edward Kennedy and Jay Rockefeller, former Republican Senator Connie Mack, and Republican Representatives Nancy Johnson and Deborah Pryce. We believe they would be as concerned as the cancer community if the agency reversed its enlightened decision to clarify coverage of these important entitlements.

During his campaign and since taking office, President Bush has declared his intention to continue the fight against cancer. Clinical trials are critical to any further advances in this fight. Since our nation’s seniors are the population most affected by cancer, rescinding an existing benefit that holds so much promise for them is unacceptable. We urge you and the Department to reject any suggestion of retreat from the position set forth in the September 2000 coverage decision. Medicare beneficiaries should have the same right as every other American to participate in cancer clinical trials without the threat of random denials of health care to which they are otherwise clearly entitled.

Cancer Leadership Council

Alliance for Lung Cancer Advocacy, Support, and Education
American Cancer Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Foundation for the Children’s Oncology Group
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
US TOO! International, Inc.
The Wellness Community
Y-ME National Breast Cancer Organization

cc: The Honorable Nancy L. Johnson
    The Honorable Deborah Pryce
    The Honorable Edward M. Kennedy
    The Honorable John D. Rockefeller