



A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

May 16, 2000

Dear Conferee:

As advocates for people with cancer, many of us have been working for the better part of a decade on the issue of coverage of routine patient care costs for enrollees in cancer clinical trials. It is therefore quite disturbing to hear that some Members of the Conference on the Patients' Bill of Rights are taking the position that no clinical trials provision would be a better outcome than a provision that was specific to cancer as in the Senate version. The undersigned organizations write to take strong exception to that view.

Cancer advocacy groups have been the primary—and often the only—advocates for clinical trials coverage since the issue first emerged as part of the health care reform debate in 1993. While we support coverage for all serious and life-threatening diseases, we certainly do not believe an "all or nothing" attitude should foreclose a more limited approach that addresses cancer specifically. Moreover, the scope of the clinical trials provision—whether limited to cancer or expanded to all serious or life-threatening diseases—should be broadened to include privately sponsored trials that have been reviewed by the Food and Drug Administration (FDA), and not limited only to trials sponsored by the National Institutes of Health or other federal agencies.

From the outset, we have urged that coverage extend to all serious and life-threatening diseases, but it is impossible to deny that the clinical trials infrastructure in cancer is much more fully developed than in any other disease, and there are other valid bases for distinguishing cancer, as the Clinton Administration has recognized by proposing a Medicare demonstration project that would be specific to cancer and would not be extended to other diseases. To our knowledge, when the Administration issued these proposals, advocates for other diseases did not object and in fact have acknowledged that the intensive lobbying of the cancer community paved the way for inclusion of clinical trials provisions in both versions of the Patients' Bill of Rights.

In contrast, we do not believe there is any rational basis for distinguishing between government-sponsored trials, which are included in both House and Senate versions, and privately sponsored trials. The private trials that are reviewed by FDA in order to obtain investigational new drug (or IND) status are subject to scrutiny that is at least as rigorous as that applied to the typical government-sponsored trial, and thus there should be no question of the quality of the trials. People with cancer seek access to investigational new agents, and those are most frequently found in trials conducted by pharmaceutical or biotechnology companies as part of the FDA review process. The companies cover the cost of the research activity and of the investigational new drug, but insurance companies should cover the cost of routine patient care, such as hospital or physician charges or routine diagnostic tests. If insurers fail to do so, then consumers are deprived of the value of their insurance; we can think of no issue more important for inclusion in a true Patients' Bill of Rights.

Once again, we want to emphasize that our preference is for a provision that covers clinical trials for all serious or life-threatening diseases and covers all trials, whether publicly or privately funded. However, if distinctions are to be drawn, on the basis of cost or otherwise, we believe that an approach that includes both government and privately-sponsored cancer trials offers a more rational way of limiting coverage. We strongly urge you to resist the arguments that no coverage at all is better than a cancer-specific provision.

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.
Colorectal Cancer Network
Cure For Lymphoma Foundation
Coalition of National Cancer Cooperative Groups, Inc.
Kidney Cancer Association
The Leukemia & Lymphoma Society
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
The Susan G. Komen Breast Cancer Foundation
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

cc: Patients' Bill of Rights Conferees

PATIENTS' BILL OF RIGHTS (PBR) CONFEREES

The Honorable Bill Archer
The Honorable Michael Bilirakis
The Honorable Thomas J. Bliley, Jr.
The Honorable John A. Boehner
The Honorable John D. Dingell
The Honorable Nancy L. Johnson
The Honorable Frank Pallone, Jr.
The Honorable Charles B. Rangel
The Honorable John B. Shadegg
The Honorable Fortney H. Stark
The Honorable James M. Talent
The Honorable William M. Thomas
The Honorable Ernest Lee Fletcher
The Honorable William L. Clay, Sr.
The Honorable Robert E. Andrews
The Honorable Porter J. Goss
The Honorable Marion Berry
The Honorable Christopher J. Dodd
The Honorable Michael B. Enzi
The Honorable William B. Frist
The Honorable Phil Gramm
The Honorable Judd Gregg
The Honorable Tom Harkin
The Honorable Kay Bailey Hutchison
The Honorable James M. Jeffords
The Honorable Edward M. Kennedy
The Honorable Barbara A. Mikulski
The Honorable Don Nickles
The Honorable John D. Rockefeller