C L C CANCER LEADERSHIP COUNCIL

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

February 7, 2000

The Honorable Orrin G. Hatch
United States Senate
131 Russell Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Hatch:

It has come to our attention that you have recently convened representatives of both research-based and generic pharmaceutical industries to discuss possible revision of the 1984 Hatch-Waxman legislation. The 1984 legislation played a critical role in defining the benefits available to companies willing to invest in original drug development research, but there are no doubt ways in which that law could be refined to enhance the ability of patients to access potentially life-extending therapies. Therefore, we welcome your dedication to possible reform of this landmark legislation to ensure that patients continue to benefit optimally from the fruits of biomedical research.

We are also aware that a number of diverse groups calling themselves the Patients and Consumers Coalition has asked to be included in any working group reexamining Hatch-Waxman. We concur with the notion of having patient and consumer groups involved and urge that any such representation be sufficiently expansive to include the full range of patient and consumer opinion on the complex issues raised by Hatch-Waxman reauthorization. Specifically, we want to ensure that the issues relevant to drug development for anticancer interventions are adequately addressed.

As you may know, cancer poses special problems with respect to drug development. Notably because of their heterogeneity and complexity, all but a few common cancers are orphan disorders where relatively small numbers of patients are available to participate in clinical trials. In this environment, there is a high premium on research sponsors willing to dedicate substantial resources to investigation of new agents. Advances in treatment are incremental, and we believe no incentive to research should be ignored in order to take advantage of every conceivable opportunity to make progress against the disease. Therefore, our sense of the balance between research incentives and generic availability of drugs may be somewhat different from that of other patient or consumer representatives.

Cancer is one of the leading causes of morbidity and mortality in this country, and its toll on human suffering and lives lost is predicted to worsen in the coming years. The pharmaceutical industry has made great strides over the past two decades in developing new treatments for cancer, but much remains to be done. Incentives to research are essential, and none is more powerful that the promise of marketing exclusivity, such as that provided by Hatch-Waxman. We believe our perspective is invaluable in your reassessment of the current legislation, and we respectfully request that you include our input in any effort to move forward with any revisions to it.

We are eager to work with you and your colleagues in the Congress to preserve, enhance and extend the benefits of Hatch-Waxman to encourage development of new therapies to prevent or treat cancer. Thank you for consideration of our request and we look forward to hearing from you.

Sincerely,

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
Cure For Lymphoma Foundation
Kidney Cancer Association
Leukemia Society of America, Inc.
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
North American Brain Tumor Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
Susan G. Komen Breast Cancer Foundation
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

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