

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

July 10, 2001

The Honorable Thomas H. Allen U.S. House of Representatives 1717 Longworth House Office Bldg. Washington, D.C. 20515

Dear Representative Allen:

It has come to our attention that you may be considering a proposed amendment to the Appropriations bill for the Food and Drug Administration (FDA) that would bar the agency from approving any new drug application that was not accompanied by prior written disclosure of the cost of the drug's development. According to your amendment, itemization of the drug's development cost must include data with respect to each stage of drug development, as well as specific information related to research funding from federal or state sources.

As a community of organizations advocating for quality cancer care, we are concerned that your amendment constitutes a recipe for stalemate with industry and will cause delays in the approval of new medications for cancer. For people with cancer, stalemate and delay are unacceptable. The Congress has worked very hard to make the FDA approval process more accountable and more efficient. As a result of these changes and the dedication of the FDA's oncology review staff, a new life-extending anti-cancer drug for a rare blood cancer was recently approved in record time. Your amendment could place at risk the improvements in FDA procedures for reviewing new drugs.

Being very familiar with the processes for funding and carrying out cancer research, we understand that basic science research funded by the federal government most often results in generalized information that could potentially make contributions to many medical advances, including cancer. While we believe reporting of research funding dollars and how they are spent in pursuit of these new therapies is desirable, we believe your amendment, as written, would not achieve that outcome and would have the unintended consequence of a chilling effect on public/private research collaboration. We strongly urge you to reconsider your proposed amendment and instead find some alternative approach to achieving your goals with respect to reporting of research funding.

Thank you for your attention to our concerns. 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 Kidney Cancer Association The Leukemia & Lymphoma Society National Alliance of Breast Cancer Organizations National Coalition for Cancer Survivorship National Patient Advocate Foundation National Prostate Cancer Coalition Ovarian Cancer National Alliance Pancreatic Cancer Action Network