June 15, 2012

The Honorable Tom Harkin  The Honorable Mike Enzi
Chair HELP Committee
HELP Committee United States Senate
HELP Committee United States Senate

The Honorable Fred Upton  The Honorable Henry Waxman
Chair Committee on Energy & Commerce
Committee on Energy & Commerce United States House of Representatives
United States House of Representatives

Dear Chairman Harkin, Chairman Upton, Ranking Member Enzi, and Ranking Member Waxman:

The undersigned cancer patient, provider, and research organizations are writing to commend your leadership in developing a Food and Drug Administration (FDA) user fee package that will provide the agency the resources necessary to support an efficient and effective review program. We also applaud the decision to reauthorize on a permanent basis the pediatric research laws – the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA) – as this action signifies the strong Congressional commitment to the laws. Finally, we appreciate the reauthorization of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee, which has provided important advice to industry and FDA about pediatric cancer drug development.

As you consider the minor differences in the House and Senate bills related to PREA and BPCA, we urge that you accept two important provisions related to pediatric cancer research. These are: 1) the requirement that the Secretary of Health and Human Services (HHS) hold a public meeting on the impact of BPCA and PREA on the development of new therapies for children with cancer, and 2) the requirement that the study completed by HHS four years after enactment of the user fee law (and every five years after) include an assessment of the impact of PREA and BPCA on the study of drugs for children with cancer. The evaluation of the laws’ impact on pediatric cancer research is to be accompanied by recommendations for modifications of the programs that would lead to new and better therapies for children with cancer.

The pediatric research laws have encouraged pediatric research in many diseases, but the promise of the laws has not been fully realized in cancer. The laws encourage or require research on adult diseases in children, and that model is not fully applicable in cancer, where adult and pediatric cancers may differ and adult cancers may not occur in
children. The public meeting and report may identify modifications in the laws that will improve their impact on pediatric cancer research.

The organizations below include groups that focus primarily on pediatric cancer research and care and many more that dedicate their efforts to the issues confronting adults with cancer. However, BPCA and PREA are of concern to all of us. We wish to ensure that research incentives and requirements that are administered by the federal government are effective in accomplishing their mission of fostering research on all diseases, including pediatric cancer, and that federal resources are used to optimal impact to help children with cancer and their families and caregivers. In addition, cancer research advances related to adult cancers inform research on pediatric cancers, and lessons from pediatric research are useful to those researchers focusing on adult cancers. It is critically important to all of us that research incentives are effective and barriers to research are removed.

Thank you in advance for considering these requests that will foster research on new therapies for all Americans with cancer.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVESTRONG
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Prevent Cancer Foundation
Sarcoma Foundation of America