April 16, 2012

The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

The Honorable Michael B. Enzi
Ranking Member
Senate Committee on Health, Education, Labor & Pensions
835 Senate Hart Office Building
Washington, D.C. 20510

Dear Chairman Harkin & Senator Enzi:

The under signed organizations, representing patients, advocates, physicians, caregivers, consumers and researchers strongly support the establishment of a Breakthrough Therapy designation for new drugs that show a high magnitude of clinical activity early in their development.

This idea was included in the bipartisan “Advancing Breakthrough Therapies for Patients Act of 2012” that was introduced on March 26, 2012, by Senators Bennet (D-CO), Hatch (R-UT), and Burr (R-NC). We support legislation on this important issue and commend the bipartisan effort that will help ensure the most promising new treatments reach patients as safely and efficiently as possible.

The Breakthrough designation would initiate an “all hands on deck” approach for FDA to collaboratively work with the sponsor to design the most efficient development program for the very promising therapy. Designation as a Breakthrough Therapy would encourage use of strategies to expedite getting new, more targeted drugs to patients who desperately need them, as well as avoid giving large numbers of patients potentially harmful or ineffective drugs as part of a control arm. This approach that could include the use of a variety of innovative clinical trial designs, or specific strategies for accumulating further evidence on the breakthrough drug after it is approved.

The under signed groups respectfully ask that a Breakthrough Therapy designation be included as part of the upcoming reauthorization of the Prescription Drug User Fee Act (PDUFA).

Sincerely,

Accelerate Brain Cancer Cure (ABC2)
Accelerate Cure/Treatments for Alzheimer’s Disease
Adenoid Cystic Carcinoma Research Foundation (ACCRF)
AHAF Alzheimer’s Disease Research
Alliance for Aging Research
ALPHA-1 ASSOCIATION
ALPHA-1 FOUNDATION
Alzheimer’s Association
American Association for Cancer Research
American Association for Respiratory Care (AARC)
American Society of Clinical Oncology
Association of American Cancer Institutes
Cancer Support Community
C-Change
COPD FOUNDATION
Facing Our Risk of Cancer Empowered (FORCE)
FasterCures
Fight Colorectal Cancer
Friends of Cancer Research
Intercultural Cancer Caucus (ICCC)
JDRF
Kidney Cancer Association
Lung Cancer Alliance
LUNGevity Foundation
Lupus Research Institute National Coalition
Mental Health America
National Alliance for Caregiving
National Alliance on Mental Illness
National Brain Tumor Society
National Coalition for Cancer Research (NCRR)
National Comprehensive Cancer Network
National Organization Against Rare Cancers (NOARC)
National Organization for Rare Disorders
National Patient Advocate Foundation
Oncology Nursing Society
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Sjögren’s Syndrome Foundation
Society for Women's Health Research
Society of Gynecologic Oncology
U.S. Pain Foundation
United Cerebral Palsy
USAgainstAlzheimer's
VITAL OPTIONS INTERNATIONAL