Dear Representative DeLauro,

First, we would like to thank you for your steadfast support as a champion of biomedical research and consistently making the National Institutes of Health a national priority.

We, the undersigned patient advocacy organizations and other advocates of accelerated medical progress, representing millions of patients, their families and caregivers, would like to affirm the importance of the U.S. Food and Drug Administration’s ability to fully utilize their expedited approval mechanisms to speed promising drugs to patients suffering from serious illness and life-threatening diseases.

These congressionally created programs, which include accelerated approval, fast track, and breakthrough therapy, are reserved for promising and often life-saving drugs that address unmet medical need. The patients they continue to help have few, if any, other treatment options.

Frequently, expedited drugs employ new biological mechanisms, take advantage of new scientific knowledge, and demonstrate effectiveness early in clinical trials. In recognition of their unique value to patients, the FDA utilizes strategies to compress the standard review process for these drugs without sacrificing safety or efficacy standards.

Expedited approval mechanisms do involve some risk and should be used judiciously. But patients suffering from rare diseases, cancer, HIV/AIDS, or other life-threatening and life-altering disorders are willing to accept risk if it means access to medical breakthroughs that could save or prolong their life. These mechanisms are powerful tools for extreme circumstances, and they make the FDA a more patient-focused institution.

Most therapies are still and will continue to be approved by the traditional clinical trial process. But where a new medicine has unprecedented potential to treat a previously untreatable disease, the FDA must have the ability to be flexible, adaptable, and innovative. This is in the best interest of science, progress against disease and most importantly, saving patients’ lives.

Sincerely,

Addario Lung Cancer Foundation
Adenoid Cystic Carcinoma Research Foundation
Alliance for Aging Research
Alpha-1 Association
Alpha-1 Foundation
American Association for Cancer Research
American Association for Respiratory Care
American Society of Clinical Oncology
C-Change
COPD Foundation
Cutaneous Lymphoma Foundation
Epilepsy Foundation
FasterCures
Friends of Cancer Research
International Cancer Advocacy Network
International Myeloma Foundation
Lymphoma Research Foundation

LUNGevity Foundation
Melanoma Research Alliance
Men’s Health Network
National Alliance on Mental Illness
National Coalition for Cancer Research (NCCR)
National Health Council (NHC)
National Multiple Sclerosis Society
Pancreatic Cancer Action Network
Parent Project Muscular Dystrophy
Prevent Cancer Foundation
Prostate Cancer Foundation
Prostate Cancer International
Research!America
Society for Women’s Health Research
The ALS Association
Treatment Action Group