

The Honorable Rosa DeLauro  
U.S. House of Representatives  
2262 Rayburn House Office Building  
Washington, DC 20515

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

LUNGeivity 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