

March 17, 2015

The Honorable Fred Upton  
2183 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
2368 Rayburn House Office Building  
Washington, DC 20515

RE: 21st Century Cures Discussion Draft

Dear Chairman Upton and Representative DeGette:

We, the undersigned organizations, wish to express our sincere gratitude for the inclusion of the Dormant Therapies Act into the 21st Century Cures discussion draft bill and offer our support to ensure passage of the legislation. The dormant therapies provisions contained in Title I, Subtitle L of the discussion document create a truly vital pathway for the development of cures and new treatments that have the potential to improve the lives of millions of Americans living with chronic diseases and disabilities.

We endorse and support the creation of the dormant therapies pathway.

Millions of Americans live with diseases and disabilities that currently have few or no treatments to affect the course of the illness. The people with these conditions are desperately in need of therapies that will stop or slow the progression of the disease or offer a cure. With this legislation, Congress can provide the incentive for researchers to pursue innovative therapies that would otherwise be abandoned for reasons having nothing to do with efficacy or safety.

The dormant therapies provisions will provide a fixed period of protection from generic competition, which begins when a medicine is approved by the Food and Drug Administration (FDA). Certainty regarding a medicine's patent protection can be a significant driver of whether or not a company develops a promising therapy, despite the medicine's potential benefit to patients. The risk of not having enough patent term left when a product gets approved discourages companies from pursuing new treatments that take a long time to develop – such as medicines that prevent diseases, treat early-stage disease, or treat a disease that has no existing treatments, is not well understood, or progresses slowly.

The dormant therapies provisions will remove this barrier and accelerate the development of promising new medicines that treat an unmet medical need, regardless of patent protection. Further, the legislation's unique patent waiver provisions will create a predictable timeline for generic or biosimilars manufacturers to bring their products to market, giving patients and their providers realistic expectations of when these lower-cost alternatives will be available.

The dormant therapy designation is only granted to a treatment if the FDA determines that it meets an unmet medical need.

While the undersigned organizations understand that Congress must thoroughly debate the length of the period of protection, we believe that this debate must occur to realign incentives to ensure that products that treat the most challenging conditions come to market. We believe that creating a time-

certain period of protection that starts at the date of FDA approval will allow science, not patents, to drive biopharmaceutical manufacturers to develop products for patients with the greatest need.

We look forward to working with Congress to ensure passage of this urgently needed legislation to speed new treatments and greatly improve existing care for millions of Americans living with chronic conditions.

Sincerely,

Alpha-1 Foundation  
The ALS Association  
Alzheimer's Association  
American Association for Respiratory Care  
American Association on Health and Disability  
American Autoimmune Related Diseases Association  
American Brain Coalition  
American Foundation for Suicide Prevention  
American Kidney Fund  
Amputee Coalition  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
Caregiver Action Network  
COPD Foundation  
Epilepsy Foundation  
Global Liver Institute  
HealthHIV  
Huntington's Disease Society of America  
Hydrocephalus Association  
Immune Deficiency Foundation  
International Cancer Advocacy Network  
International Essential Tremor Foundation  
Lupus Foundation of America  
The Marfan Foundation  
National Alliance on Mental Illness  
National Alopecia Areata Foundation  
National Eczema Association  
National Health Council  
National Hemophilia Foundation  
National Kidney Foundation  
National Osteoporosis Foundation  
National Psoriasis Foundation  
Osteogenesis Imperfecta Foundation  
Parkinson's Action Network  
PKD Foundation  
Prevent Cancer Foundation

Sjögren's Syndrome Foundation  
Spina Bifida Association  
Tremor Action Network  
Us TOO International Prostate Cancer Education and Support Network  
The Veterans Health Council  
Vietnam Veterans of America

\*Signature List as of April 8, 2015\*