

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

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 Psoriasis Foundation

Osteogenesis Imperfecta Foundation

Parkinson's Action Network

PKD Foundation

Prevent Cancer Foundation

Sjögren's Syndrome Foundation

Tremor Action Network

Us TOO International Prostate Cancer Education and Support Network

The Veterans Health Council

Vietnam Veterans of America

Signature List as of March 16, 2015