



May 7, 2012

The Honorable Joe Pitts  
Chair  
Subcommittee on Health  
Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health  
Committee on Energy and Commerce  
United States House of Representatives  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the Alzheimer's Association, thank you for your leadership on issues important to the 5.4 million Americans living with Alzheimer's disease and their 15 million caregivers. We applaud the Committee for enhancing accelerated patient access to new medical treatments through bipartisan legislation to reauthorize user fee programs for prescription drugs and medical devices, establish user fee programs for generic drugs and biosimilars, and reform Food and Drug Administration (FDA) programs. The reauthorization of the FDA user fee programs are vital to ensuring patient access to safe and effective new therapies and devices.

The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease and other dementias through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer's.

As you know, Alzheimer's disease is the sixth leading cause of death in the U.S. and the only cause of death among the top ten in America without a way to prevent, cure or even slow its progression. Unfortunately, insufficient understanding of the basic biology of Alzheimer's, lack of development tools, such as biomarkers, and slow disease progression make clinical development of innovative treatments a long and, in many cases, prohibitively costly process. A disease-modifying or preventative therapy would not only save millions of lives but would save billions of dollars in health care costs. Specifically, according to the Alzheimer's Association report *Changing the Trajectory of Alzheimer's Disease: A National Imperative*, if a treatment became available in 2015 that delayed onset of Alzheimer's for five years (a treatment similar to anti-cholesterol drugs) savings would be seen almost immediately with Medicare and Medicaid spending reduced by \$42 billion in 2020.

Finding ways to further accelerate the review process without compromising the scientific rigor of the process remains an important priority for the Alzheimer's Association. We are pleased the legislation includes key provisions to expedite drug approval and access to safe and effective treatments. In particular, we appreciate the Committee's focus on accelerating patient access to new medical treatments through enhancement of accelerated approval for drugs for serious or life-threatening disease or condition by clarifying the types of evidence and endpoints on which the Secretary can rely. In addition, we appreciate the inclusion of the provision to expedite the development and review of a drug designated a "breakthrough therapy." To achieve this designation, a drug must be intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate

that it may demonstrate substantial improvement over existing therapies. Neurodegenerative diseases, like Alzheimer's, are the longest in the pipeline, averaging 15-20 years of development. Without advances in the science and increased incentives, we may see a decline in tackling tough-to-crack diseases.

The Alzheimer's Association appreciates your leadership on correcting barriers that discourage the aggressive pursuit of breakthrough treatments for complex diseases, like Alzheimer's. We look forward to seeing the reauthorization of the FDA user fee programs before the September 30 deadline. If you have any questions, please contact Rachel Conant, Director of Federal Affairs, at [Rachel.Conant@alz.org](mailto:Rachel.Conant@alz.org) or 202.638.7121.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Richards", written in a cursive style.

Mary Richards  
Senior Director, Public Policy