ACT-AD
Accelerate Cure/Treatments for Alzheimer's Disease

March 6, 2017

The Honorable Robert Aderholt
Chairman
House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
2362A Rayburn House Building
Washington, DC 20515

The Honorable John Hoeven
Chairman
Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
129 Dirksen Senate Building
Washington, DC 20510

The Honorable Sanford Bishop
Ranking Member
House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
1016 Longworth House Building
Washington, DC 20515

The Honorable Jeff Merkley
Ranking Member
Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
190 Dirksen Senate Building
Washington, DC 20510

Dear Chairmen Hoeven and Aderholt and Ranking Members Merkley and Bishop,

Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) is a coalition of 52 national organizations representing patients, caregivers, researchers, health professionals, and other health advocates seeking to advance therapeutic development for Alzheimer's disease. Since 2011, ACT-AD has been working with the U.S. Food and Drug Administration (FDA) to clarify regulatory requirements and remove other obstacles that impede successful intervention in Alzheimer's disease. On behalf of ACT-AD, I urge you to provide the FDA with $2.8 billion in budget authority appropriations in Fiscal Year (FY) 2018. This $78 million increase over the FY 2016 appropriated levels would allow the agency to maintain their active engagement with the Alzheimer's disease community and put us closer to more effective treatments and a cure for this disease.

More than 5 million Americans have Alzheimer's disease. It is the sixth leading cause of death in the United States. The disease claims the lives of nearly 1 in 3American seniors. The disease currently costs the health care system more than $200 billion a year. If no new medicines are found to prevent, delay or halt the progression of Alzheimer's disease, the Alzheimer's Association estimates that the number of people age 65 and older diagnosed in the U.S. will increase to 13.8 million, and cost of care will increase to $1.1 trillion by 2050.

Only five drugs for Alzheimer's disease have made it to the point of approval in the last 20 years. While these drugs can provide some relief to patients of Alzheimer's disease symptoms, there is still great need for more effective treatments. Researchers in the public and private sectors have pursued the development of interventions to treat the most troubling symptoms of the disease and to alter the disease course. For decades

many of the attempts to bring new treatments to market have failed, in large part, due to an inadequate understanding of the underlying disease process and the point at which intervention would be most successful. To better aid researchers, the FDA released a report on targeted drug development in 2015 that identified gaps in knowledge believed to be hindering progress in the discovery and testing stages of new drugs for Alzheimer's disease. Since releasing this report, the FDA has participated in two annual meetings convened by ACT-AD and other scientific meetings to shed light on how industry, the National Institutes of Health (NIH), and other organizations can align to more quickly fill these critical research gaps.

In 2013, the FDA released a draft guidance to guide clinical trials focused on treatment of the disease before the onset of noticeable symptoms. This guidance outlines the FDA's thinking on how trials should be designed for drugs targeting patients at the very early stages of Alzheimer's disease. The draft guidance further highlights conditions under which the FDA would consider the use of Accelerated Approval for drugs demonstrating a clear effect on reliable cognitive tests. The guidance continues to serve as an important focus of discussions between the FDA, industry, researchers and patient advocacy groups who are trying to improve the conduct of Alzheimer's disease clinical trials.

In addition to releasing the report on targeted drug development and the draft guidance on early Alzheimer's disease, the FDA is involved in collaborative efforts to find biomarkers that can identify Alzheimer's patients before they show symptoms, distinguish the rate of disease progression among Alzheimer's patients, and predict the clinical outcomes of treatments. The results of these efforts may allow for improved selection of patients for enrollment in appropriate treatment trials and increase the chances of a drug showing a positive effect. Industry, the NIH and private foundations continue to make significant contributions to research and the development of novel biomarkers to accelerate Alzheimer's disease drug development.

We are fortunate that there are more than 70 compounds in various stages of clinical development for Alzheimer's disease. The FDA must continue to be actively involved at each stage of drug development to enable these compounds to potentially change the course of Alzheimer's disease and allow the U.S. to avert a looming fiscal and public health crisis. The actions taken by the FDA in the Alzheimer's disease space are resource intensive and can only be sustained with adequate funding from Congress each year.

Strong support for the FDA in FY 2018 will show that you acknowledge the important role the agency plays in ensuring that we are better prepared to meet the challenges posed by Alzheimer's disease. Thank you for your leadership and if ACT-AD can be of assistance as you contemplate the appropriate level of funding for the FDA this year, please do not hesitate to contact Ryne Carney at rcarney@agingresearch.org or by phone at 202-293-2856.

Sincerely,

Cynthia A. Bens
Executive Director