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

August 20, 2012

The Honorable John Boehner
Speaker
U.S. House of Representatives
H-232 The Capitol
Washington, DC 20515

The Honorable Harry Reid
Majority Leader
U.S. Senate
522 Hart Senate Building
Washington, DC 20510

Dear Speaker Boehner and Majority Leader Reid:

The coalition to Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) is comprised of more than 50 national organizations representing patients, caregivers, researchers, health professionals, and other health advocates. Our mission is to support efforts to expedite the development, review, and approval of transformational therapies for Alzheimer's disease. We are committed to collaborating with the U.S. Food and Drug Administration (FDA) to achieve this goal, but in order for FDA to be an active partner they must be provided with sufficient funding. On behalf of the coalition, I am writing to express deep concern over the looming threat of sequestration on overall funding at the FDA. We appreciate the fiscal pressures Congress and the nation faces, however we urge members of both parties to work aggressively toward a budget solution that avoids these cuts.

There are numerous potential treatments currently in development for Alzheimer's disease. However, in the current regulatory environment many of the discoveries made today cannot provide relief in time to reach the 14 million Americans expected to suffer from the devastating effects of Alzheimer's by the middle of this century. An improved process for the evaluation of new breakthroughs to detect, slow, and reverse the effects of Alzheimer's disease is needed to avert a national crisis. Such a process requires sustained focus, expertise, and manpower devoted to Alzheimer's disease at the FDA.

The House and Senate have taken action in recent years which acknowledge the important role FDA plays in ensuring that we are better prepared to meet the challenges posed by Alzheimer's disease. With the passage of the National Alzheimer's Project Act (NAPA) in 2011, Congress set all agencies under the umbrella of the Department of Health and Human Services on a course to develop a national plan to fight Alzheimer's disease. The plan that was released on May 15, 2012 includes a number of action items requiring significant participation from the FDA. These actions fall under Goal 1 of the National Plan, "Prevent and Effectively Treat Alzheimer's Disease by 2025." This is not a goal that we can afford to fall short of, but in order to achieve it Congress must commit necessary resources to the federal agencies that are involved in bringing about solutions to revolutionize the way Alzheimer's disease is detected and treated.

In June Congress successfully delivered legislation to President Obama that modernizes the FDA and reauthorizes the agency's drug and device user fee programs. This Food and Drug Administration Safety & Innovation Act (FDASIA) was the culmination of two years of work between the FDA, industry, Congress and patient groups including ACT-AD to help the agency facilitate the development of novel therapies while maintaining high standards for product approval. Throughout the reauthorization process congressional champions on both sides of the aisle supported an investment in FDA that would foster innovation. As a result, activities authorized under in FDASIA could accelerate the development and review of much-needed therapies and cures for patients who are facing serious, life-threatening conditions, but only if commensurate resources are made available.

Should sequestration occur, FDA's budget would fall by as much as $250 million in FY 2013. This painful reduction will affect important priorities like those described above to more rapidly allow patients access to treatments in the development pipeline. FDA will struggle to continue fulfilling its mandated responsibilities, as well as to carry out commitments that were incorporated into FDASIA that are not paid for by user fees.

The members of ACT-AD and the millions of Americans we represent are grateful for your leadership and attention to this issue. If we can be of assistance to the Congress as it contemplates an alternative budget plan to stop sequestration, please contact Cynthia Bens on the coalition staff at cbens@agingresearch.org or (202) 293-2856.

Sincerely,

Daniel Perry
Chairman

CC. The Honorable Eric Cantor, Majority Leader, U.S. House of Representatives
The Honorable Nancy Pelosi, Minority Leader, U.S. House of Representatives
The Honorable Mitch McConnell, Minority Leader, U.S. Senate
Margaret Hamburg, M.D., Commissioner, U.S. Food and Drug Administration