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

February 3, 2014

The Honorable Barbara Mikulski
Chairwoman
Committee on Appropriations
United States Senate

The Honorable Hal Rogers
Chairman
Committee on Appropriations United States House of Representatives

The Honorable Richard Shelby
Ranking Member
Committee on Appropriations
United States Senate

The Honorable Nita Lowey
Ranking Member
Committee on Appropriations
United States House of Representatives

The Honorable Mark Pryor
Chairman
Subcommittee on Agriculture, Rural Development and Food & Drug Administration
United States Senate

The Honorable Robert Aderholt
Chairman
Subcommittee on Agriculture, Rural Development and Food & Drug Administration United States House of Representatives

The Honorable Roy Blunt
Ranking Member
Subcommittee on Agriculture, Rural Development and Food & Drug Administration United States Senate

The Honorable Sam Farr
Ranking Member
Subcommittee on Agriculture, Rural Development and Food & Drug Administration United States House of Representatives

Dear Chairs Mikulski, Rogers, Pryor, and Aderholt and Ranking Members Shelby, Lowey, Blunt, and Farr:

The coalition to Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD), www.act-ad.org, 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 FDA must be provided with sufficient funding to do its' part. On behalf of ACT-AD, I want to thank you and your colleagues for making the Food and Drug Administration (FDA) a priority during the Fiscal Year 2014 appropriations process. The $175 million increase over FY 13 appropriated levels you provided, and the restoration of $78 million in sequestered user fees, will help the Agency maintain high standards for medical product approvals while at the same time ensuring that it can help facilitate the delivery of novel therapies to patients in a more timely manner.

There are more than 80 compounds currently in various stages of clinical development for Alzheimer's disease. Unfortunately, because of the current drug

development paradigm, many of the discoveries made today cannot provide relief in time to reach the 16 million Americans expected to suffer from the devastating effects of Alzheimer's by the middle of this century. Now whole again, FDA can return to the level of focus and expertise needed to continue as active partners in the fight against Alzheimer's disease and evaluate promising interventions to detect, slow, and reverse the effects of the disease in the future.

In recent years the FDA has undertaken resource-intensive initiatives like issuing draft guidance for industry further clarifying requirements for testing early-stage Alzheimer's treatments, expressing the conditions under which they would consider the use of Accelerated Approval for an AD treatment. Representatives from the Agency also routinely participate in national and international meetings with patient advocates, the scientific community, and industry focused on improving AD clinical trials. While ambitious, we cannot afford to let the FDA abandon these ongoing activities.

Thank you for your leadership. Your commitment to the FDA is an acknowledgement of the important role it plays in ensuring that we are better prepared to meet the challenges posed by Alzheimer's disease. If we can be of assistance moving forward, please contact Cynthia Bens on the coalition staff at cbens@agingresearch.org or (202) 293-2856.

Sincerely,

Daniel Perry
Chairman