

Advisory Council

March 16, 2015

Alliance for Aging Research

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 Jerry Moran
Chairman
Senate Appropriations Subcommittee
on Agriculture, Rural Development,
Food and Drug Administration, and
Related Agencies
190 Dirksen Senate Building
Washington, DC 20510

Alzheimer's Foundation of America

American Society on Aging

National Alliance for Caregiving

National Association of Area Agencies on Aging

National Consumers League

Research!America

Society for Women's Health Research

The Honorable Sam Farr
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
129 Dirksen Senate Building
Washington, DC 20510

Dear Chairmen Aderholt and Moran and Ranking Members Farr and Merkley,

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. On behalf of ACT-AD, I urge you to prioritize the U.S. Food and Drug Administration (FDA) during the Fiscal Year (FY) 2016 appropriations process and increase the agency's appropriated funding from \$2.6 billion to \$2.8 billion this year.

ACT-AD's 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 FDA to achieve this goal, but the agency must be provided with sufficient funding to do its part. In order to ensure that that the FDA can maintain high standards for medical product approvals and help facilitate the delivery of novel therapies to patients in a timelier manner, FY 2016 appropriations for FDA should be increased by \$200 million over FY 2015 levels.

Currently, there are more than 80 compounds 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 disease by the middle of this century. FDA must sustain the level of focus and expertise needed to continue to serve as an active partner in the fight against Alzheimer's disease.

In recent years the FDA has undertaken crucial resource-intensive initiatives like issuing draft guidance for industry further clarifying requirements for testing early-stage Alzheimer's treatments and expressing the conditions under which they would consider the use of Accelerated Approval for AD treatments. Representatives from the agency also routinely participate in important national and international meetings with patient advocates, researchers, and industry focused on improving AD clinical trials. Their participation in these discussions is essential. We cannot afford to let the FDA abandon these ongoing activities. In fact, the agency has made finalizing its draft guidance on early Alzheimer's disease a priority for 2015. Having this final guidance will provide transparency and stability for those developing drugs to intervene in the earliest stages of the disease when they may have the greatest impact.

Your strong support of the FDA in FY 2016 would acknowledge the important role it plays in ensuring that we are better prepared to meet the challenges posed by Alzheimer's disease. Thank you for your leadership. If we can be of assistance to the subcommittee as it contemplates the appropriate level of funding for the FDA this year, please do not hesitate to contact me at cbens@agingresearch.org or (202) 293-2856.

Sincerely,

A handwritten signature in black ink, appearing to read "Cynthia Bens". The signature is fluid and cursive, with the first name being more prominent.

Cynthia Bens
Executive Director