

Advisory Council

March 26, 2012

Alliance for Aging Research

The Honorable Herb Kohl
Chair

Alzheimer's Foundation of America

Senate Appropriations Subcommittee on
Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
184 Dirksen Senate Office Building
Washington, DC 20510

American Society on Aging

National Alliance for Caregiving

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

National Association of Area Agencies on Aging

National Consumers League

Dear Chairman Kohl and Ranking Member Blunt:

Research!America

Society for Women's Health Research

The coalition to Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) is comprised of 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. To this end, we strongly urge you to include \$2.656 billion for FDA in your FY 2013 appropriations bill.

There are numerous compounds currently in development for Alzheimer's disease. Several of these are demonstrating promise at various stages of development. However, in the currently regulatory environment many of the discoveries made today cannot provide a cure 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 increased focus, expertise, and manpower devoted to Alzheimer's disease at the FDA.

For more than two decades Congress has charged FDA with a growing number of responsibilities without providing adequate appropriations to execute them. Some initiatives that have suffered the most are those that allow FDA to foster innovation by investing in training and research. During this time the agency was also unable to give proper attention to how it defined and applied consistent standards for medical product review across its various centers.

In recent years, you and other congressional champions have begun to put FDA back on a sound fiscal footing. We appreciate the investment that has been made in strengthening the FDA and we urge you to continue this investment. FDA is actively pursuing strategies for improving its ability to help advance biomedical innovation. As you know the majority of FDA's budget is devoted to maintaining a highly-skilled workforce. Boom and bust funding patterns will lead the agency to a place where inflation and growing operation costs can supersede their desire to support important priorities to more rapidly allow patients access to new treatments in the development pipeline.

To ensure that the FDA has the flexibility to pursue worthy initiatives, particularly those in the area of Alzheimer's disease, ACT-AD recommends funding the FDA at \$2.656 billion in FY 2013. This is an increase of \$150 million, or 6% more than was appropriated in FY 2012. This level of funding would allow FDA to continue fulfilling its mandated responsibilities and begin their own work to advance new tools with potential to revolutionize the way diseases like Alzheimer's are detected and treated.

The members of ACT-AD and the millions of Americans we represent are grateful for your attention to this issue and your consideration of this important request. If we can be of assistance to the subcommittee as it contemplates the appropriate level of funding for the FDA this year, please contact Cynthia Bens on the coalition staff at cbens@agingresearch.org or (202) 293-2856 x116.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel Perry", with a horizontal line extending to the right from the end of the signature.

Daniel Perry
Chairman

CC. The Honorable Daniel Inouye, Chairman, Senate Appropriations Committee
The Honorable Thad Cochran, Ranking Member, Senate Appropriations Committee