



Accelerate Cure/Treatments for Alzheimer's Disease

Advisory Council

December 15, 2014

Alliance for Aging  
Research

Richard J. Hodes, M.D  
Director

Alzheimer's  
Foundation of America

National Institute on Aging  
National Institutes of Health  
31 Center Drive, MSC 2292  
Bethesda, MD 20892

American Society  
on Aging

National Alliance for  
Caregiving

**RE: *Ageing Well in the 21<sup>st</sup> Century*: Strategic Directions for Research on Aging  
Draft**

National Association  
of Area Agencies on  
Aging

Dear Dr. Hodes,

National Consumers  
League

Research!America

Society for Women's  
Health Research

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. For the past nine years we have supported efforts to expedite the development, review, and approval of transformational therapies for Alzheimer's disease (AD). On behalf of ACT-AD, we would like to thank you for the priority you have placed on advancing Alzheimer's disease research at the National Institute on Aging (NIA) and the commitment NIA has shown to collaborating with other NIH institutes and centers, as well as other public and private sector partners to more quickly translate research findings into new treatment options for people living with Alzheimer's disease. ACT-AD appreciates the opportunity to suggest ideas that should be considered as part of NIA's recently-released draft strategic directions document, *Ageing Well in the 21<sup>st</sup> Century*. In the NIA's final plan, we encourage you to include greater emphasis on research to develop improved tools for measuring cognition and function in early stage AD and on advancing combination drug therapy for Alzheimer's disease.

Goal D of *Ageing Well in the 21<sup>st</sup> Century* is dedicated to improving our understanding of the aging brain, Alzheimer's disease and other neurodegenerative diseases and to developing interventions to address Alzheimer's and other age-related neurological conditions. With growing knowledge of Alzheimer's disease, it is widely hypothesized that in order for treatments to have the greatest impact, they may need to be administered earlier in the disease course. This knowledge has set the field on a path toward earlier intervention in patients with very early signs of disease where cognitive symptoms are developing, but functional impairment may not be overt. Current tools are not sensitive enough to capture subtle deficits in these earlier stages of disease that include MCI due to AD, prodromal AD and preclinical AD. Objective D-3 under Goal D deals with expanding research to improve assessment and diagnostic tools for distinguishing people with normal brain aging from those who will develop mild MCI, AD, and related conditions. This objective places a heavy emphasis on gathering biomarker data and on developing cognitive assessment tools for the purposes of diagnosis. Biomarkers to better identify people who are likely to develop Alzheimer's

disease and those that predict the likelihood of a response to treatment are going to continue to be an essential piece of therapeutic development. However, there is also still a need for tools in drug development that can be used to measure cognition and function in all stages of the disease. It would be useful for NIA to create a separate objective under Goal D that promotes research that can be applied in the development of cognitive and functional assessment tools for use in clinical trials for early stages of AD. Such research would be valuable to pursue in the five-year period covered by the strategic directions document, given the paucity data currently available in the public domain to support the development of novel tools.

Objective D-4 under Goal D references studies conducted by NIA that combined cognitive training and drug treatment, emphasizing that there should be a continued focus on clinical trials testing drug, behavioral and non-pharmacologic interventions in combination for Alzheimer's disease. We agree that both pharmacologic and non-pharmacologic interventions for Alzheimer's disease are important to explore, however, we stress that combination drug therapy should be explicitly considered as part of research under objective D-4. In 2012 and 2013 ACT-AD co-convened two pivotal meetings looking at the potential for a combination approach to treating Alzheimer's disease. Participants at the meetings discussed the possible benefits and challenges associated with combining multiple pharmacologic treatments for AD, from basic mechanisms through regulatory approval. Advocates, industry, the scientific community, and regulators have coalesced around AD combination therapy in theory, but it is slow to take root in reality. A lack of research into what Alzheimer's targets should be pursued in combination and the absence of a platform to conduct the adaptive-style trials necessary to test multiple treatments are obstacles we identified to moving combination therapy to the forefront of AD drug development. We applaud efforts that the NIA has taken on since 2012 to eliminate barriers to data sharing and analysis and to take target validation for Alzheimer's disease through proof of concept in a multi-stakeholder, pre-competitive environment. We think NIA should build on these initiatives and we feel that it is uniquely positioned to lead efforts to facilitate more aggressive testing of compounds in combination. We would suggest additional language under objective D-4 asserting NIA's leadership in this area. Without leadership the community stands to lose many years when it could be capitalizing on an opportunity that was crucial to the success in turning lethal diseases like HIV/AIDS, forms of cancer and tuberculosis into treatable conditions.

We understand all too well that many breakthrough made today will not provide relief in time to reach the millions Americans expected to suffer from the devastating effects of Alzheimer's disease in the next decade. Thank you for the work you, your staff and NIA-supported investigators do to provide hope to these patients and their families by endeavoring to change the course of Alzheimer's treatment in the future. We appreciate your careful consideration of the views expressed above. If we can be of assistance as the Institute finalizes *Aging Well in the 21<sup>st</sup> Century*, please feel free to contact us at (202) 293-2856.

Sincerely,



Daniel Perry  
Chairman



Cynthia Bens  
Vice President, Public Policy