



June 14, 2018

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
United States House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
United States House of Representatives
1139E Longworth House Office Building
Washington, D.C. 20515

The Honorable Peter Roskam
Chairman
Committee on Ways and Means
Subcommittee on Health
United States House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
Subcommittee on Health
United States House of Representatives
1139E Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Brady, Ranking Member Neal, Chairman Roskam and Ranking Member Levin:

We sincerely thank you and your colleagues for recognizing and decisively responding to the challenges of Alzheimer's disease and other forms of dementia (including vascular, Lewy body dementia and frontotemporal degeneration). Congressional determination to make dementia a national priority has been evident, powerful, and effective. From passage of the National Alzheimer's Project Act, to historic funding increases for Alzheimer's research, and legislation that improves quality of life for those facing dementia while strengthening the scientific enterprise, Congress is changing the trajectory of Alzheimer's disease and other forms of dementia. We applaud your continued commitment to seize the enormous opportunities for America if we invest in the science, care, and support required to overcome these challenges and for recognizing the consequences if we fail to act. Doing so is a national priority, an economic and budgetary necessity, a health and moral imperative. In that same spirit, **we encourage House Committee on Ways and Means to pass the bicameral, bipartisan *Concentrating on High-Value Alzheimer's Needs to Get to an End (CHANGE) Act (H.R.4957)*.**

The CHANGE Act will advance systemic changes required to strengthen care for millions of American families currently facing dementia while helping to maximize the value of our national investments in science to deliver prevention, disease modifying treatments and an eventual cure. In particular, the CHANGE Act makes clear that Medicare should adopt and cover uniformly accepted assessment and diagnostic tools for Alzheimer's disease and other forms of dementia. As research increasingly focuses on intervening at the earliest point in the disease trajectory, shortcomings in disease

detection impede progress toward breakthrough therapies. The lack of uniform Alzheimer's tools delays cognitive impairment detection and diagnosis at the earliest possible point, resulting in decreased opportunities for people to access timely treatment options, including clinical trial participation.

When people receive a timely and accurate diagnosis, they are better able to make informed decisions about participating in research. They also have improved opportunities to make productive medical, financial, legal, and spiritual choices to improve both their own quality of life and that of their family caregivers. Delaying diagnosis or receiving an inaccurate diagnosis significantly complicates and all-too-often prevents research participation and undermines efficacy of quality of life decisions.

The CHANGE Act would encourage early assessment and diagnosis, improve care, and accelerate scientific progress:

- **Diagnosis / Clinical Research:** Would require the Centers for Medicare and Medicaid Services to identify a uniform, reliable cognitive impairment detection tool or set of tools and to incentivize clinicians to detect, refer, and diagnose Alzheimer's disease and other forms of dementia in their earliest stages. Earlier diagnosis would allow for increased clinical trial participation and contribution by the patient in health care decision making, and validated tools would make it much easier for physicians to provide earlier diagnoses.
- **Care:** Would use Medicare authority to test a comprehensive continuum of care addressing care needs for people living with Alzheimer's disease and other forms of dementia along with their caregivers, modeled on the Programs of All-Inclusive Care for the Elderly (the PACE Program). It also would create a coverage and payment model that offers family caregivers evidence-based training and certification specific to dementia care that qualifies them to provide certain medically necessary services that society relies upon them to provide.

The CHANGE Act comes at a time of deepening urgency and expanding opportunity. While the need never has been greater, Congress and federal agencies are taking unprecedented action build comprehensive, integrated and transformative solutions.

Alzheimer's disease and other forms of dementia impose enormous costs to our nation's health, prosperity, and social fabric, costs that are skyrocketing.ⁱ Based on the National Institute on Aging's Health and Retirement Study (HRS), we know that the health system costs of caring for people with dementia in the United States are comparable to, and perhaps greater than, those for heart disease and cancer.ⁱⁱ A recent analysis of HRS data revealed that average per-person health care spending in the last five years of life for people with dementia was more than \$250,000 -- 57 percent greater than costs associated with death from other diseases including cancer and heart disease.ⁱⁱⁱ

Today, more than 5.7 million Americans are living with dementia at an annual cost to our economy exceeding \$259 billion.^{iv} An estimated 16 million Americans provide unpaid care for someone with dementia, resulting in additional healthcare and economic costs for the family caregiver. Alzheimer's disease contributes to the deaths of approximately 500,000 Americans each year. Alzheimer's disease is the third leading cause of death in the United States^v and the only one among the top 10 for which there is no proven means of prevention, disease modification or cure.^{vi}

Today, another person develops the disease every 65 seconds; by 2050, someone in the United States will develop the disease every 33 seconds. This explosive growth will cause Alzheimer's costs to increase from an estimated \$277 billion in 2018 to \$1.1 trillion in 2050 (in 2018 dollars).^{vii} The federal government, through Medicare and Medicaid payments, shoulders an estimated 70 percent of all such direct care costs. These mounting costs threaten to bankrupt families, businesses and our health care system.

Due to leadership and direction from Congress, the Department of Health and Human Services (HHS) continues to increase prioritization of Alzheimer's disease and other forms of dementia. The publicly-appointed members of the Advisory Council on Alzheimer's Research, Care, and Services have generated their most thoughtful and catalytic recommendations for the annual update to the National Plan to Address Alzheimer's Disease. There is heightened focus on improving care for people with advanced dementia.^{viii} The Food and Drug Administration is encouraging new research avenues and clarifying regulatory approval pathways.^{ix} Your committee and NIH have moved mountains to create additional resources, public-private partnerships, and a culture of urgency. Across the NIH, institutes are supporting promising research into Alzheimer's disease and other forms of dementia to: understand genetic risk factors;^x address health disparities among women,^{xi} African Americans,^{xii} Hispanics,^{xiii} and persons with intellectual disabilities;^{xiv} understand Down syndrome's relationship to Alzheimer's disease; and pursue cutting-edge trials aimed at preventing or substantially slowing disease progression by administering treatments much earlier in the disease process.^{xv} In the coming year, the National Institute on Aging (NIA) plans to increase its research focus on Molecular Pathogenesis and Pathophysiology of Alzheimer's Disease; Diagnosis, Assessment, and Disease Monitoring; Translational Research and Clinical Interventions; Epidemiology; and Care and Caregiver Support.^{xvi}

The CHANGE Act is essential to unlocking the transformative potential made possible by Congress and federal agencies. The CHANGE Act will improve access to timely and accurate diagnosis, in turn catalyzing better informed decisions about participating in research; simultaneously, the CHANGE Act will offer access to evidence-based care and services to improve quality of life for both the person living with dementia and family caregivers.

Please support passage of this important legislation to advance diagnosis, treatment, research progress, and support for individuals living with dementia and for family caregivers.

Thank you for considering our views and for your commitment to overcoming Alzheimer's disease and other forms of dementia. For any questions or additional information about this or other policy issues, please contact Ian Kremer, executive director of Leaders Engaged on Alzheimer's Disease (the LEAD Coalition),^{xvii} ikremer@leadcoalition.org or (571) 383-9916.

Sincerely,

Abe's Garden Alzheimer's Center of
Excellence

ActivistsAgainstAlzheimer's Network
Aging Life Care Association®

African American Network Against Alzheimer's
 Paul S. Aisen, MD (Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute*)
 Alliance for Aging Research
 Alliance for Patient Access
 Alzheimer's & Dementia Alliance of Wisconsin
 Alzheimer's Disease Resource Center, Inc. (ADRC)
 Alzheimer's Drug Discovery Foundation
 Alzheimer's Foundation of America
 Alzheimer's Greater Los Angeles
 Alzheimer's Mississippi
 Alzheimer's New Jersey
 Alzheimer's Orange County
 Alzheimer's San Diego
 Alzheimer's Tennessee
 Alzheimer's Texas
 AMDA – The Society for Post-Acute and Long-Term Care Medicine
 American Academy of Neurology
 American Association for Geriatric Psychiatry
 American Federation for Aging Research (AFAR)
 American Medical Women's Association
 Argentum | Expanding Senior Living
 Laura D. Baker, PhD (Wake Forest University Health Sciences*)
 David M. Bass, PhD (Benjamin Rose Institute on Aging*)
 Baylor Scott & White Health
 Beating Alzheimer's by Embracing Science
 Benjamin Rose Institute on Aging
 Biogen
 B'nai B'rith International
 Soo Borson MD (Minnesota Brain Aging Research Collaborative*)
 James Brewer, M.D., Ph.D. (UC San Diego and Alzheimer's Disease Cooperative Study*)
 Bridge Builder Strategies
 BrightFocus Foundation
 Christopher M. Callahan, MD (Indiana University Center for Aging Research*)
 Caregiver Action Network
 Caregiver Voices United
 CaringKind, The Heart of Alzheimer's Caregiving
 Center for BrainHealth at The University of Texas at Dallas
 Center to Advance Palliative Care
 Sandra Bond Chapman, PhD (Center for BrainHealth at The University of Texas at Dallas*)
 Joshua Chodosh, MD, MSHS, FACP (New York University*)
 ClergyAgainstAlzheimer's Network
 Cleveland Clinic Foundation
 Cognition Therapeutics
 Suzanne Craft, PhD (Wake Forest School of Medicine*)
 Critical Path for Alzheimer's Disease (CPAD)
 Jeffrey Cummings, MD, ScD (Cleveland Clinic Lou Ruvo Center for Brain Health*)
 Darrell K. Royal Fund for Alzheimer's Research
 Dementia Alliance International
 Department of Neurology, Washington University School of Medicine
 Drexel University College of Nursing and Health Professions

Duke (Alzheimer's) Family Support Program	Katherine S. Judge, PhD (Cleveland State University*)
Eisai Co., Ltd.	Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute
ElevatingHOME	Keep Memory Alive
Eli Lilly and Company	Walter A. Kukull, PhD (School of Public Health, University of Washington*)
Gary Epstein-Lubow, MD (Alpert Medical School of Brown University*)	Bruce Lamb, Ph.D. (Indiana University School of Medicine*)
Faith United Against Alzheimer's Coalition	Latino Alzheimer's and Memory Disorders Alliance
Sam Gandy, MD, PhD (Icahn School of Medicine at Mount Sinai*)	LatinosAgainstAlzheimer's
Joseph E. Gaugler, PhD (School of Nursing, Center on Aging, University of Minnesota*)	Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University
Daniel R. George, Ph.D, M.Sc (Penn State College of Medicine*)	LeadingAge
Georgetown University Medical Center Memory Disorders Program	Lewy Body Dementia Association
Gerontological Society of America	Allison Lindauer, PhD, NP (Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University*)
Laura N. Gitlin, PhD (Drexel University, College of Nursing and Health Professions*)	Linked Senior, Inc
Global Alzheimer's Platform Foundation	Lou Ruvo Center for Brain Health
Global Coalition on Aging	Lundbeck
Lisa P. Gwyther, MSW, LCSW (Duke University Medical Center*)	Medicare Rights Center
Hadassah, The Women's Zionist Organization of America, Inc.	Michigan State University Alzheimer's Alliance
David M. Holtzman, MD (Washington University School of Medicine, Department of Neurology*)	Milken Institute Center for the Future of Aging
Home Instead Senior Care	Minnesota Association of Area Agencies on Aging
Huffington Center on Aging	Minnesota Brain Aging Research Collaborative
Indiana University Center for Aging Research	David G. Morgan, PhD (Michigan State University*)
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Kathy Jedrziwski, PhD (University of Pennsylvania*)	Mount Sinai Center for Cognitive Health
The Jewish Federations of North America	

National Alliance for Caregiving	Peter Reed, PhD (Sanford Center for Aging, University of Nevada Reno*)
National Asian Pacific Center on Aging	ResearchersAgainstAlzheimer's
National Association of Activity Professionals	David B. Reuben, MD (David Geffen School of Medicine at UCLA*)
National Association of Area Agencies on Aging	Tatiana Sadak, PhD, PMHNP, ARNP (University of Washington School of Nursing*)
National Association of Chronic Disease Directors	Stephen Salloway, M.D., M.S. (The Warren Alpert Medical School of Brown University*)
National Association of Counties (NACo)	Quincy Miles Samus, PhD, MS (Johns Hopkins School of Medicine*)
National Association of Social Workers (NASW)	Second Wind Dreams, Inc./ Virtual Dementia Tour
National Association of State Long-Term Care Ombudsman Programs (NASOP)	Amanda G. Smith, M.D. (USF Health Byrd Alzheimer's Institute*)
National Association of States United for Aging and Disabilities	Alan B. Stevens, PhD (Baylor Scott & White Health, Center for Healthcare Policy*)
National Certification Council for Activity Professionals	Rudolph Tanzi, PhD (Department of Neurology, MGH/Harvard Medical School*)
National Committee to Preserve Social Security and Medicare	The Association for Frontotemporal Degeneration
National Consumer Voice for Quality Long-Term Care	The Evangelical Lutheran Good Samaritan Society
National Council for Behavioral Health	The Youth Movement Against Alzheimer's
National Down Syndrome Society	Geoffrey Tremont, Ph.D., ABPP-CN (Alpert Medical School of Brown University*)
National Hospice and Palliative Care Organization (NHPCO)	R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)
National Task Group on Intellectual Disabilities and Dementia Practices	University of Minnesota School of Nursing, Center on Aging
Neurotechnology Industry Organization	USF Health Byrd Alzheimer's Institute
NFL Neurological Center	UsAgainstAlzheimer's, LEAD Coalition co-convener
Noah Homes	VeteransAgainstAlzheimer's
NYU Langone Health	
Otsuka Pharmaceutical Development and Commercialization	
Planetree International, Inc.	
Prevent Alzheimer's Disease 2020	
Program to Improve Eldercare, Altarum	

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** Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of affiliated institutions.*

ⁱ <http://www.nejm.org/doi/full/10.1056/NEJMsa1204629>

ⁱⁱ <http://www.nejm.org/doi/full/10.1056/NEJMsa1204629>

ⁱⁱⁱ <http://annals.org/article.aspx?articleid=2466364#>

^{iv} https://www.alz.org/documents_custom/2018-facts-and-figures.pdf

^v <http://www.neurology.org/content/early/2014/03/05/WNL.0000000000000240>

^{vi} <http://www.neurology.org/content/early/2014/03/05/WNL.0000000000000240>

^{vii} https://www.alz.org/documents_custom/2018-facts-and-figures.pdf

^{viii} <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>

^{ix} <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM596728.pdf>

^x <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/genetics-alzheimers-disease>

^{xi} http://www.alz.org/downloads/facts_figures_2014.pdf

^{xii} http://www.usagainstalzheimers.org/sites/default/files/USA2_AAN_CostsReport.pdf

^{xiii} <http://www.nhcoa.org/wp-content/uploads/2013/05/NHCOA-Alzheimers-Executive-Summary.pdf> and
http://www.usagainstalzheimers.org/sites/all/themes/alzheimers_networks/files/LatinosAgainstAlzheimers_Issue_Brief.pdf

^{xiv} http://aadmd.org/sites/default/files/NTG_Thinker_Report.pdf

^{xv} <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/advancing-discovery-alzheimers#priorities>

xvi https://www.nia.nih.gov/sites/default/files/2017-07/FY19-bypass-budget-report-508_0.pdf

xvii <http://www.leadcoalition.org> Leaders Engaged on Alzheimer's Disease (the LEAD Coalition) is a diverse national coalition of member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and home and residential care providers, large health systems, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation's strategic attention on dementia in all its causes -- including Alzheimer's disease, vascular disease, Lewy body dementia, and frontotemporal degeneration -- and to accelerate transformational progress in detection and diagnosis, care and support, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.