



June 14, 2018

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Hatch and Ranking Member Wyden:

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 Senate Committee on Finance to pass the bicameral, bipartisan *Concentrating on High-Value Alzheimer's Needs to Get to an End (CHANGE) Act (S.2387)*.**

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

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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
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ClergyAgainstAlzheimer's Network
Cleveland Clinic Foundation
Cognition Therapeutics
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Critical Path for Alzheimer's Disease
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ElevatingHOME

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Organization of America, Inc.
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Home Instead Senior Care
Huffington Center on Aging
Indiana University Center for Aging
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Janssen R&D
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of Pennsylvania*)

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Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute	Mount Sinai Center for Cognitive Health
Keep Memory Alive	National Alliance for Caregiving
Walter A. Kukull, PhD (School of Public Health, University of Washington*)	National Asian Pacific Center on Aging
Bruce Lamb, Ph.D. (Indiana University School of Medicine*)	National Association of Activity Professionals
Latino Alzheimer's and Memory Disorders Alliance	National Association of Area Agencies on Aging
LatinosAgainstAlzheimer's	National Association of Chronic Disease Directors
Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University	National Association of Counties (NACo)
LeadingAge	National Association of Social Workers (NASW)
Lewy Body Dementia Association	National Association of State Long-Term Care Ombudsman Programs (NASOP)
Allison Lindauer, PhD, NP (Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University*)	National Association of States United for Aging and Disabilities
Linked Senior, Inc	National Certification Council for Activity Professionals
Lou Ruvo Center for Brain Health	National Committee to Preserve Social Security and Medicare
Lundbeck	National Consumer Voice for Quality Long-Term Care
Medicare Rights Center	National Council for Behavioral Health
Michigan State University Alzheimer's Alliance	National Down Syndrome Society
Milken Institute Center for the Future of Aging	National Hospice and Palliative Care Organization (NHPCO)
Minnesota Association of Area Agencies on Aging	National Task Group on Intellectual Disabilities and Dementia Practices
Minnesota Brain Aging Research Collaborative	

Neurotechnology Industry Organization	The Association for Frontotemporal Degeneration
NFL Neurological Center	The Evangelical Lutheran Good Samaritan Society
Noah Homes	The Youth Movement Against Alzheimer's
NYU Langone Health	Geoffrey Tremont, Ph.D., ABPP-CN (Alpert Medical School of Brown University*)
Otsuka Pharmaceutical Development and Commercialization	R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)
Planetree International, Inc.	University of Minnesota School of Nursing, Center on Aging
Prevent Alzheimer's Disease 2020 Program to Improve Eldercare, Altarum	USF Health Byrd Alzheimer's Institute
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ResearchersAgainstAlzheimer's	VeteransAgainstAlzheimer's
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Tatiana Sadak, PhD, PMHNP, ARNP (University of Washington School of Nursing*)	Volunteers of America, LEAD Coalition co-convener
Stephen Salloway, M.D., M.S. (The Warren Alpert Medical School of Brown University*)	Vradenburg Foundation
Quincy Miles Samus, PhD, MS (Johns Hopkins School of Medicine*)	Carol J. Whitlatch, PhD (Benjamin Rose Institute on Aging*)
Second Wind Dreams, Inc./ Virtual Dementia Tour	Nancy Wilson, MA LCSW (Baylor College of Medicine*)
Amanda G. Smith, M.D. (USF Health Byrd Alzheimer's Institute*)	WomenAgainstAlzheimer's
Alan B. Stevens, PhD (Baylor Scott & White Health, Center for Healthcare Policy*)	
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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.