



April 24, 2018

The Honorable Richard Shelby
Chairman
Committee on Appropriations
S-128 The Capitol
Washington, DC 25010

The Honorable Patrick Leahy
Vice Chairman
Committee on Appropriations
S-128 The Capitol
Washington, DC 20510

The Honorable Roy Blunt
Chairman
Committee on Appropriations
Subcommittee on Labor, HHS & Education
260 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Committee on Appropriations
Subcommittee on Labor, HHS & Education
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable John Hoeven
Chairman
Committee on Appropriations
Subcommittee on Agriculture & FDA
338 Russell Senate Office Building
Washington, DC 20510

The Honorable Jeff Merkley
Ranking Member
Committee on Appropriations
Subcommittee on Agriculture & FDA
313 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Shelby, Vice Chairman Leahy, Chairman Blunt and Ranking Member Murray and Chairman Hoeven and Ranking Member Merkley:

We sincerely thank you 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) by passing the Fiscal Year 2018 (FY18) omnibus appropriations with a historic funding increase for Alzheimer's research. We applaud your continued determination 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.

As you work to construct Fiscal Year 2019 (FY19) appropriations bills, we respectfully encourage you to continue the momentum toward the National Alzheimer's Plan goals and your own commitment to advancing science, care, and support. **Specifically, we request that the FY19 appropriations bills include at least the following minimum increases:**

- **\$425 million for National Institutes of Health (NIH) research for Alzheimer's disease and other forms of dementia** resulting in an NIH-wide dementia research budget of at least \$2.253 billion in FY19.

- **\$500 million for aging research across the NIH, in addition to the funding for dementia-specific research.** This increase will ensure that the NIH has the resources to address the many other age-related chronic diseases that affect people with dementia.
- **\$2 billion for the NIH, in addition to funds included in the 21st Century Cures Act for targeted initiatives.**
- **\$473 million for the Food and Drug Administration (FDA), in addition to funds included in the 21st Century Cures Act for targeted initiatives.**
- **\$57 million for dementia care and services programs at federal agencies including, but not limited to, the Administration for Community Living (ACL), Centers for Disease Control and Prevention (CDC), and the Department of Justice (DoJ).** These investments are relatively small but crucial complements to vastly larger Medicaid and Medicare expenditures to care for people living with dementia.

There are few more compelling or complex issues to confront our aging society, now and over the coming decades, than Alzheimer's disease and other forms of dementia. These neurodegenerative conditions 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.

The choice before our nation is not whether to pay for dementia -- we are paying dearly. The question is whether we will emulate the investment strategies that have led to remarkable progress in fighting other leading causes of death such as cancer, HIV/AIDS and heart disease and achieve similar breakthroughs, or spend trillions to care for tens

of millions of people. A modernized and more robust research portfolio can help America prevent this catastrophe and move us closer to achieving our national goal of preventing and effectively treating dementia by 2025.^{viii}

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.^{ix} The Food and Drug Administration is encouraging new research avenues and clarifying regulatory approval pathways.^x 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;^{xi} address health disparities among women,^{xii} African Americans,^{xiii} Hispanics,^{xiv} and persons with intellectual disabilities;^{xv} 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.^{xvi} In FY19, 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.^{xvii}

We support the recommendation from the Ad Hoc Group on Medical Research to appropriate at least \$39.3 billion in FY19 for the NIH, including funds provided to through the 21st Century Cures Act for targeted initiatives. This funding level would continue a trajectory of steady and predictable annual increases – allowing for meaningful growth above inflation in the base budget that would expand NIH's capacity to support promising science in all disciplines – and would ensure that the Innovation Account supplements the agency's base budget, as intended, through dedicated funding for specific programs.

We support the recommendation from the Alliance for a Stronger FDA to appropriate at least \$3.32 billion in FY19 for the FDA, including the President's request for \$473 million in additional spending on medical products programs. Funding would strengthen FDA systems that guide and support agency decision-making and stimulate innovation for medical products, including improvements in drug and device manufacturing, advances in the use of real world evidence in medical product development, revisions to the regulatory framework for digital health technology, enhancements to research on rare diseases such as less common forms of dementia, and new systems that could speed the introduction of cost-saving generic drugs.

As urgently as resources are needed to enable scientific breakthroughs, the millions of Americans currently living with dementia and their family caregivers deserve strengthened commitments to programs to protect and enhance their quality of life. We commend your work to provide substantial increases in FY 18 funding for the CDC Alzheimer's disease health promotion program (28.6%), the Lifespan Respite Care program (up 20.6%), the Alzheimer's Disease Demonstration Program (up 20.5%), the National Family Caregiver Support Program (up 19.9%), and Meals on Wheels (up 8.4%). We encourage you to provide for similar increases in FY 19. New funding is

needed to sustain core Older Americans Act services and to develop and disseminate services instrumental to achieving the national plan's goals to enhance care quality, efficiency and expand supports.^{xviii} These programs provide essential respite, training, and support to help family caregivers meet the needs of persons living with dementia. The CDC's Healthy Brain Initiative will launch its 2018-2022 Healthy Brain Aging Roadmap to ramp up the nation's public health capacity in addressing dementia. The Roadmap will advance strategies to reduce lifestyle risk factors, improve detection and diagnosis, strengthen community supports for people with dementia and their families, and redress health disparities. The Department of Justice's Missing Alzheimer's Disease Patient Alert Program is a vital lifeline for people living with dementia who are at risk of wandering. Until an effective treatment to prevent, slow or cure dementia comes to market, families and friends rely on these programs to protect their own well-being while helping persons with dementia to remain independent and in the community while delaying placement in institutional settings.

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 legislation or other policy issues, please contact Ian Kremer, executive director of Leaders Engaged on Alzheimer's Disease (the LEAD Coalition),^{xix} ikremer@leadcoalition.org or (571) 383-9916.

Sincerely,

Abe's Garden Alzheimer's Center
of Excellence

Accelerate Cure/Treatments for
Alzheimer's Disease (ACT-AD)
Coalition

ActivistsAgainstAlzheimer's Network

African American Network
Against Alzheimer's

AgeneBio

Aging and Memory Disorder Programs,
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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 Aging Association

American Association for Geriatric
Psychiatry

American Federation for Aging
Research (AFAR)

American Geriatrics Society

American Medical Women's Association

Argentum | Expanding Senior Living

Association of Population Centers

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Beating Alzheimer's by Embracing
Science

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Caregiver Action Network

CaringKind, The Heart of Alzheimer's
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Center to Advance Palliative Care

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ClergyAgainstAlzheimer's Network

Cleveland Clinic Foundation

Cognition Therapeutics

CorTechs Labs

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Critical Path for Alzheimer's Disease

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Cure Alzheimer's Fund

Darrell K. Royal Fund for Alzheimer's
Research

Dementia Alliance International

Department of Neurology, Washington
University School of Medicine

Diverse Elders Coalition

Drexel University College of Nursing
and Health Professions

Duke (Alzheimer's) Family
Support Program

Eisai Co., Ltd.

ElevatingHOME

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Faith United Against
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Home Instead Senior Care

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Indiana University Center for Aging Research	Mount Sinai Center for Cognitive Health
Janssen R&D	National Alliance for Caregiving
Kathy Jedrzewski, PhD (University of Pennsylvania*)	National Asian Pacific Center on Aging
Johns Hopkins Memory and Alzheimer's Treatment Center	National Association of Activity Professionals
Katherine S. Judge, PhD (Cleveland State University*)	National Association of States United for Aging and Disabilities
Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute	National Center for Creative Aging
Keep Memory Alive	National Certification Council for Activity Professionals
Diana R Kerwin, MD (Texas Alzheimer's and Memory Disorders*)	National Committee to Preserve Social Security and Medicare
Walter A. Kukull, PhD (School of Public Health, University of Washington*)	National Council for Behavioral Health
Bruce Lamb, Ph.D. (Indiana University School of Medicine*)	National Down Syndrome Society
Latino Alzheimer's and Memory Disorders Alliance	National Hospice and Palliative Care Organization (NHPCO)
LatinosAgainstAlzheimer's	National Task Group on Intellectual Disabilities and Dementia Practices
LeadingAge	Neurotechnology Industry Organization
Lewy Body Dementia Association	NFL Neurological Center
Linked Senior, Inc	NYU Alzheimer's Disease Center
Lundbeck	NYU Langone Center on Cognitive Neurology
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Milken Institute Center for the Future of Aging	Piramal Imaging S.A.
Minnesota Association of Area Agencies on Aging	Planetree International
Minnesota Brain Aging Research Collaborative	Population Association of America
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 The Youth Movement Against Alzheimer's
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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>

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- 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 <http://aspe.hhs.gov/daltcp/napa/NatlPlan.pdf>
- ix <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>
- x <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM596728.pdf>
- xi <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/genetics-alzheimers-disease>
- xii http://www.alz.org/downloads/facts_figures_2014.pdf
- xiii http://www.usagainstalzheimers.org/sites/default/files/USA2_AAN_CostsReport.pdf
- xiv <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
- xv http://aadmd.org/sites/default/files/NTG_Thinker_Report.pdf
- xvi <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/advancing-discovery-alzheimers#priorities>
- xvii https://www.nia.nih.gov/sites/default/files/2017-07/FY19-bypass-budget-report-508_0.pdf
- xviii <http://aspe.hhs.gov/daltcp/napa/NatlPlan2014.pdf>
- xix <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.