May 27, 2021

The Honorable Patrick Leahy
Chair
Committee on Appropriations

The Honorable Richard Shelby
Vice Chair
Committee on Appropriations

The Honorable Patty Murray
Chair
Subcommittee on Labor, HHS & Education

The Honorable Roy Blunt
Ranking Member
Subcommittee on Labor, HHS & Education

The Honorable Tammy Baldwin
Chair
Subcommittee on Agriculture & FDA

The Honorable John Hoeven
Ranking Member
Subcommittee on Agriculture & FDA

The Honorable Jeanne Shaheen
Chair
Subcommittee on Commerce, Justice, Science, and Related Agencies

The Honorable Jerry Moran
Ranking Member
Subcommittee on Commerce, Justice, Science, and Related Agencies

by electronic delivery

Dear Chairman Leahy, Vice Chairman Shelby, Chairman Murray and Ranking Member Blunt, Chairman Baldwin and Ranking Member Hoeven, Chairman Shaheen and Ranking Member Moran:

We sincerely thank you for recognizing and decisively responding to the challenges of Alzheimer's disease and other forms of dementia (including cerebrovascular disease, Lewy body dementia, frontotemporal degeneration and Creutzfeldt-Jakob disease) by passing the Fiscal Year 2021 (FY21) appropriations package 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 continue acting with the required urgency. Doing so is a national priority, an economic and budgetary necessity, a health and moral imperative. We also are deeply grateful for Congress taking swift and robust action during the COVID-19 pandemic to address the needs of older Americans who are among the most vulnerable both to the disease and to the unintended consequences of social distancing, stay-at-home orders, and other public health necessities that exacerbate already precarious living conditions.

As you work to construct Fiscal Year 2022 (FY22) 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, and public health. **Specifically, we request that the FY22 appropriations bills include at least the following minimum increases:**

- **a $289 million increase for National Institutes of Health (NIH) research on Alzheimer's disease and other forms of dementia to accelerate progress as articulated in the Bypass Budget Proposal for FY22**

- **a $500 million increase for aging research across the NIH, in addition to the funding for dementia-specific research,** to ensure that the NIH has the resources to address the many other age-related chronic diseases that affect people with dementia

- **a $3.2 billion increase for the NIH's current institutes and operations, including funds from the 21st Century Cures Act for targeted initiatives**

- **$6.5 billion to launch the Advanced Research Projects Agency for Health (ARPA-H)**

- **$560 million for the BRAIN Initiative**

- **$200 million for the FDA, in addition to funds included in the 21st Century Cures Act for targeted initiatives**

- **double funding for Older Americans Act programs and services**

- **a $7.5 million increase for the ACL Alzheimer's Disease Program**

- **an $8.263 million increase for the HRSA geriatrics workforce programs**

- **a $2 million increase for the DoJ Missing Alzheimer's Disease Alert Program**

- **$60 million for the CDC's Alzheimer's Disease and Healthy Aging Program (ADHAP) to continue BOLD Act implementation, expand the CDC Healthy Brain Initiative road map for state and national partnerships, and reduce dementia risk through brain health promotion**

- **a $500 million increase for the Federally Qualified Health Centers (FQHCs)**

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 2015 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] Those costs continue to climb and are unsustainable for families, public and private insurers, and our nation's economy.

Currently, more than 6.2 million Americans are living with dementia, with combined healthcare and long-term care costs of $355 billion.[iv] Taxpayers foot about two-thirds of that

bill -- $239 billion – directly through the Medicare and Medicaid programs. Individuals with dementia and their families pay out of pocket for another fifth of the cost, $76 billion. More than 11 million Americans provide unpaid care for someone with dementia, resulting in additional healthcare and economic costs. Today, as another person develops the disease every 65 seconds, Alzheimer's and other forms of dementia impose an economic cost exceeding $600 billion in public and private expenditures along with uncompensated caregiving. By 2050, someone in the United States will develop the disease every 33 seconds with as many as 12.7 million Americans living with dementia. This explosive growth will cause direct costs to increase from an estimated $355 billion in 2021 to $1.1 trillion in 2050 (in 2021 dollars) and the hidden costs of uncompensated caregiving to become even more staggering.[v]

Alzheimer's disease contributes to the deaths of more than 500,000 Americans each year. Alzheimer's disease is the third leading cause of death in the United States[vi] and — despite a powerful body of evidence for risk-reduction strategies,[vii] which is being expanded with significant NIH investments[viii] — the only one among the top 10 for which there is not yet a proven means of prevention, disease modification or cure.[ix] As the Alzheimer's Association reported in March, one third of older Americans dies with Alzheimer's disease or another form of dementia.[x]

Advancing Science

We support a $289 million increase for National Institutes of Health (NIH) research on Alzheimer's disease and other forms of dementia to accelerate progress as articulated in the Bypass Budget Proposal for Fiscal Year 2022,[xi] and a $500 million increase for aging research across the NIH in addition to the funding for dementia-specific research, to ensure that NIH has resources to address other age-related chronic diseases that affect people with dementia. 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.[xii]

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 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.[xiii] The Food and Drug Administration (FDA) is encouraging new research avenues, clarifying regulatory approval pathways,[xiv] and reviewing products to address some of the most heart-breaking symptoms of dementia along with what would be the first disease modifying therapy. Congressional appropriations committees and NIH have moved mountains to create additional resources, public-private partnerships, and a culture of urgency. Across NIH, institutes are advancing promising research into Alzheimer's disease and other forms of dementia to: understand genetic risk factors; address health disparities among women, African Americans, Hispanics, and persons with intellectual and developmental disabilities; understand Down syndrome's relationship to Alzheimer's disease; pursue cutting-edge trials aimed at preventing or substantially slowing disease progression by administering treatments much earlier in the

disease process; and improve quality of life for people with dementia and their caregivers.[xv] NIH is demonstrating strong progress as reflected in the AD+ADRD (Alzheimer's Disease and Alzheimer's Disease-Related Dementias) Research Implementation Milestones database.[xvi] NIH and its partners are hard at work implementing the *National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research*,[xvii] engaging broad segments of the public in the Alzheimer's and related dementias research enterprise, with a particular focus on making research participants more accurately reflect intended beneficiaries of breakthroughs. The progress has been important but incomplete in diversifying the scientific workforce, the pool of clinical trial participants and the nature of the specific research projects to remedy the deep and disturbing health disparities that drive Alzheimer's disease and other forms of dementia. In FY22, the National Institute on Aging (NIA) plans to advance research to improve the diagnosis, treatment, and care of those living with dementia by identifying and testing new drug candidates, advancing comprehensive models of care, developing novel biomarkers for use as screening tests and to monitor treatment response, exploring disease risk and protective factors, and improving the understanding of the role of genetics and other disease mechanisms.[xviii]

We support the recommendation from the Ad Hoc Group on Medical Research to appropriate at least $46.1 billion in FY22 for the NIH's current institutes and operations, including funds provided 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 an additional $6.5 billion to launch the Advanced Research Projects Agency for Health (ARPA-H). Modeled on the Defense Advanced Research Projects Agency (DARPA), ARPA-H would leverage existing public sector basic science research programs along with private sector efforts to overcome the innovation "valley of death" and accelerate development of new capabilities for disease prevention, detection, and treatment and overcome the bottlenecks that have historically limited progress.

We support the recommendation from the American Brain Coalition for at least level funding of $560 million for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Originally created in 2013, the BRAIN Initiative is revolutionizing our understanding of the human brain to better develop treatments and cures for neurologic diseases, including Alzheimer's and other forms of dementia. This multidisciplinary collaboration (including the NIH, FDA, DARPA and IARPA,[xix] along with private partners) is working to map circuits of the brain, measure electrical and chemical activity, and understand how their interplay creates unique cognitive and behavioral capabilities. To date, the BRAIN Initiative has supported more than 900 awards totaling approximately $1.8 billion,[xx] resulting in research that has made significant advances in important technologies such as brain imaging. The ongoing commitment to fund this program will continue to advance our knowledge, and help launch three large projects including a brain cell census, a brain micro connectivity mapping project, and new methods to allow cell type-based manipulation of brain activity.[xxi]

We support the recommendation from the Alliance for a Stronger FDA to appropriate at least $200 million in additional funding for the FDA to meet the most pressing needs in medical products and food safety programs.[xxii] 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.

Strengthening Quality of Life

Until science delivers effective means to prevent, slow or cure dementia, families and friends along with health care providers rely on 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.

We support the recommendation from the Leadership Council of Aging Organizations (LCAO) to double funding for Older Americans Act (OAA) programs and services. These investments are relatively small but crucial complements to vastly larger Medicaid and Medicare expenditures to protect and promote the wellbeing of people living with dementia and their caregivers along with other older adults. 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. The World Health Organization has noted that dementia is among the leading causes of disability and dependence among older people.[xxiii] Federal programs and initiatives have a vital role in helping people receive a diagnosis so they know what they are facing, can begin disability and care planning processes, maintain independence as long as possible, and – for people with younger onset dementia – seek appropriate workplace accommodations. We commend your work to ensure that OAA programs and services were sustained for older adults during the worst of the coronavirus pandemic. In FY 22, expansion of those same Older Americans Act programs and services would be instrumental to achieving the national plan's goals to enhance care quality, efficiency and expand supports for people living with dementia and their caregivers.[xxiv]

We support a $7.5 million increase for the ACL Alzheimer's Disease Program. The Administration for Community Living (ACL) Alzheimer's Disease Program Initiative (ADPI) supports and promotes the development and expansion of dementia-capable home and community-based service long-term services and support systems in states and communities. As American Indians and Alaska Natives communities experience higher rates of dementia,[xxv] we applaud the recent ADPI grant specific to development of dementia capability in Indian Country. We encourage its funding and continuation in future years. ADPI delivers cutting-edge programs that meet the needs of individuals and caregivers managing dementia. Part of those resources support ACL's National Alzheimer's and Dementia Resource Center (NADRC) based at RTI International. NADRC provides technical assistance to ACL's grantees that build dementia-capable systems to better identify and support people with dementia living in the community and improve training for dementia caregivers who experience considerable stress and depression. Many of the programs are geared towards at-risk dementia populations, such as those who live alone, those with disabilities (including those with intellectual disabilities), and those who reside in rural, poor and minority communities. NADRC also produces dementia- related toolkits and provides technical assistance and webinars on Alzheimer's and other dementias to the public.[xxvi]

We support a $8.263 million increase for the geriatrics education and training programs under Title VII of the Public Health Services (PHS) Act. The Geriatrics Workforce Enhancement Program (GWEP) and the Geriatrics Academic Career Awards (GACAs), administered by the Health Resources and Services Administration (HRSA), are the only federal mechanism for supporting geriatrics health professions education and training. Sustained and enhanced investment will ensure that these two critical resources are maximally deployed to serve older adults nationwide. GWEP awardees educate and engage the broader frontline workforce, including family caregivers, and focus on improving the quality of care delivered to older adults. An important component of the GWEP is developing academic-primary care- community-based partnerships to address gaps in health care for older adults while transforming clinical training environments into integrated geriatrics and primary care sites/systems that become age-friendly health systems and dementia-friendly communities. An essential complement to the GWEP, the GACA program supports professional development for clinician-educators training the future workforce we need and who will become future leaders of GWEPs and other geriatrics programs.

We support a $2 million increase for the Department of Justice (DoJ) Missing Alzheimer's Disease Patient Alert Program, which provides grants for training and technology that help first responders locate people living with Alzheimer's disease or autism who wander and become lost. The program saves lives, strengthens the capacity of search and rescue programs to respond to other community needs, and allows local first responders to conserve both time and money. The program's strong track record, along with rapid growth in the number of people living with dementia and the program's recent expansion to include services for people living with autism, merit and require substantial addition resources to better serve states and communities nationwide.

Promoting Public Health

We support $60 million for the CDC's Alzheimer's Disease and Healthy Aging Program (ADHAP) to continue BOLD Act implementation, expand the CDC Healthy Brain Initiative road map for state and national partnerships, and reduce dementia risk through brain health promotion.

The ADHAP is the only place within the CDC specifically dedicated to promoting the health of older Americans through dementia risk-reduction interventions (e.g. smoking cessation, exercise, education) and across chronic conditions that heighten risk for dementia (e.g. hypertension, hearing loss, depression, traumatic brain injury, diabetes, obesity). The ADHAP also is the central locus for addressing health equity challenges across chronic conditions that share these common risk factors. Yet, last year, total funding of $20.5 million for the ADHAP's vital work represented only approximately 0.25% of the overall CDC budget.

Specifically, the recommended $60 million funding level would support the CDC ADHAP's work to:

- strengthen programs that reduce risk, promote health equity, and support populations with a high burden of Alzheimer's disease and related forms of dementia
- build public health infrastructure through the BOLD Act and Healthy Brain Initiative
- expand capacity in state, tribal and territorial public health departments to promote the health of older adults within an age-friendly public health system

- expand healthy aging work to include coordinating healthy aging efforts across the agency and implementing a public-private initiative to reduce dementia risk
- fund applied research and translation for public health practice
- support public health strategies addressing the social determinants of health that contribute to disparities in healthy aging and brain health.

As part of this overall ADHAP funding, we support a $20 million appropriation for CDC to continue implementing the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act (Pub. L. 115 – 406).[xxvii] Under the law, Congress has directed CDC to strengthen the public health infrastructure nationwide by implementing effective Alzheimer's interventions focused on public health priorities including increasing early detection and diagnosis, reducing modifiable risk, and preventing avoidable hospitalizations. We commend your work to fund CDC's Alzheimer's Disease and Healthy Aging Program and the initial launch of the BOLD Act to support the implementation of the Healthy Brain Aging Road Map. Congress authorized $100 million over five years so that CDC would have the necessary resources to establish Alzheimer's and Related Dementias Public Health Centers of Excellence, provide funding to state, local, and tribal public health departments, and increase data analysis and timely reporting.

Increased funding also would support a significant increase for the CDC's long-standing and successful Healthy Brain Initiative, which is implementing its 2018-2023 Healthy Brain Aging Road Map (and companion Road Map for Indian Country) to ramp up the nation's public health capacity in addressing dementia.[xxviii] The Road Map is advancing strategies to reduce lifestyle risk factors, improve detection and diagnosis, strengthen community supports for people with dementia and their families, and redress health disparities.

We support a $500 million increase for Federally Qualified Health Centers (FQHCs), to bring total funding to $2.2 billion. The FQHCs help address cultural, linguistic, and other barriers to care by delivering coordinated and comprehensive primary and preventive services – helping to reduce health disparities in medically-underserved communities across the nation. Leveraging the capacity of these innovative, high quality, community-based, and trusted providers is an important way to advance health equity while reducing the burden of dementia on the individuals, families, communities, the healthcare system, the federal budget and national economy.

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),[xxix] ikremer@leadcoalition.org or (571) 383-9916.

Sincerely,

Abe's Garden Community

Acadia Pharmaceuticals Inc

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

ACCSES – The Voice of Disability Service Providers

ActivistsAgainstAlzheimer's Network

ADvancing States

African American Network Against Alzheimer's

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Alliance for Aging Research

Alliance for Patient Access

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Drug Discovery Foundation

Alzheimer's Foundation of America

Alzheimer's Los Angeles

Alzheimer's New Jersey

Alzheimer's Orange County

Alzheimer's San Diego

Alzheimer's Tennessee

Alzheimer's Texas

American Academy of Neurology

American Association for Geriatric Psychiatry

American Brain Coalition

American Federation for Aging Research (AFAR)

American Geriatrics Society

American Medical Women's Association

American Society of Consultant Pharmacists (ASCP)

American Society on Aging

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The Balm In Gilead, Inc.

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Caregiver Action Network

Caregiver Voices United

CaringKind, The Heart of Alzheimer's Caregiving

Centene

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ClergyAgainstAlzheimer's Network

Cleveland Clinic Lou Ruvo Center for Brain Health, Nevada

CNS Innovations

Coalition of Wisconsin Aging and Health Groups

The Coelho Center for Disability Law, Policy and Innovation

Cognitive Dynamics Foundation

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Cure Alzheimer’s Fund

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ICAN, International Cancer Advocacy Network

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National Association of Activity Professionals

National Association of Area Agencies on Aging (n4a)

National Association of Chronic Disease Directors

National Association of Counties (NACo)

National Association of Nutrition and Aging Services Programs

National Association of Social Workers (NASW)

National Association of State Long-Term Care Ombudsman Programs (NASOP)

National Caucus and Center on Black Aged, Inc. (NCBA)

National Certification Council for Activity Professionals

National Committee to Preserve Social Security and Medicare

National Consumers League

National Consumer Voice for Quality Long-Term Care

National Council for Behavioral Health

National Down Syndrome Society

National Hispanic Council On Aging (NHCOA)

National Indian Council on Aging (NICOA)

National Prion Disease Pathology Surveillance Center

National Task Group on Intellectual Disabilities and Dementia Practices

NFL Neurological Center

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The Evangelical Lutheran Good Samaritan Society

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WomenAgainstAlzheimer's

Women's Brain Project

World Molecular Imaging Society

Julie M. Zissimopoulos, Ph.D. (University of Southern California*)

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

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[ii] http://www.nejm.org/doi/full/10.1056/NEJMsa1204629

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[xxiv] https://aspe.hhs.gov/system/files/pdf/264206/NatlPlan2020.pdf

[xxv] https://www.cdc.gov/aging/healthybrain/Indian-country-roadmap.html

[xxvi] https://nadrc.acl.gov

[xxvii] https://www.congress.gov/bill/115th-congress/senate-bill/2076
[xxviii] https://www.cdc.gov/aging/healthybrain/roadmap.htm

[xxix] 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.