



May 22, 2020

The Honorable Richard Shelby  
Chairman  
Committee on Appropriations

The Honorable Patrick Leahy  
Vice Chairman  
Committee on Appropriations

The Honorable Roy Blunt  
Chairman  
Subcommittee on Labor, HHS & Education

The Honorable Patty Murray  
Ranking Member  
Subcommittee on Labor, HHS & Education

The Honorable John Hoeven  
Chairman  
Subcommittee on Agriculture & FDA

The Honorable Jeff Merkley  
Ranking Member  
Subcommittee on Agriculture & FDA

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

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

***by electronic delivery***

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

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 2020 (FY20) 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 2021 (FY21) 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 FY21 appropriations bills include at least the following minimum increases:**

- a **\$354 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 FY21**
- 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 billion increase for the NIH, including funds from the 21<sup>st</sup> Century Cures Act for targeted initiatives**
- a **\$120 million increase for the Food and Drug Administration (FDA), in addition to funds included in the 21<sup>st</sup> Century Cures Act for targeted initiatives**
- **fully funding all Older Americans Act programs at the authorized levels for FY21**
- an **\$8.5 million increase for the ACL Alzheimer’s Disease Program**
- a **\$3 million increase for the DoJ Missing Alzheimer’s Disease Alert Program**
- **\$20 million in new funds for the CDC to continue BOLD Act implementation**

**Additionally, in the final section of this letter, we recommend for Appropriations bill report language to translate into action two lessons from the COVID-19 pandemic.**

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.<sup>i</sup> 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.<sup>ii</sup> 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.<sup>iii</sup> Those costs continue to climb and are unsustainable for families, public and private insurers, and our nation’s economy.

Currently, more than 5.8 million Americans are living with dementia, with combined healthcare and long-term care costs of \$305 billion.<sup>iv</sup> Taxpayers foot about two-thirds of that bill -- \$206 billion – directly through the Medicare and Medicaid programs. Individuals with dementia and their families pay out of pocket for another fifth of the cost, \$66 billion. More than 16 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 a nearly \$550 billion loss 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 13.8 million Americans living with dementia. This explosive growth will cause direct costs to increase from an estimated \$305 billion in 2020 to \$1.1 trillion in 2050 (in 2020 dollars) and the hidden costs of uncompensated caregiving to become even more staggering.<sup>v</sup>

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<sup>vi</sup> and — despite a powerful body of evidence for risk-reduction strategies,<sup>vii</sup> which is being expanded with significant NIH investments<sup>viii</sup> — the only one among the top 10 for which there is not yet a proven means of prevention, disease modification or cure.<sup>ix</sup> As the Alzheimer's Association reported in March, one third of older Americans dies with Alzheimer's disease or another form of dementia.<sup>x</sup>

**We support a \$354 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 2021,<sup>xi</sup> and 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. 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.<sup>xii</sup>

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.<sup>xiii</sup> The Food and Drug Administration (FDA) is encouraging new research avenues and clarifying regulatory approval pathways.<sup>xiv</sup> This year, FDA is expected to review new products to address some of the most heart-breaking symptoms of dementia along with what would be the first cerebrospinal fluid diagnostic tests and the first disease modifying therapy.<sup>xv</sup> <sup>xvi</sup> The congressional appropriations committees and NIH have moved mountains to create additional resources, public-private partnerships, and a culture of urgency. Across the 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.<sup>xvii</sup> NIH and its partners are hard at work implementing the *National Strategy*

*for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research*,<sup>xviii</sup> 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 FY21, the National Institute on Aging (NIA) plans to intensify its research focus on better understanding the basic biology of underlying dementia, characterizing novel biomarkers and screening tools such as a blood test, identifying and testing innovative drug targets, supporting clinical trials and infrastructure like the Alzheimer's Clinical Trials Consortium, and improving the diagnosis, care, and support of those living with dementia.<sup>xix</sup>

**We support the recommendation from the Ad Hoc Group on Medical Research to appropriate at least \$44.7 billion in FY21 for the NIH, including funds provided through the 21<sup>st</sup> 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 \$120 million in additional spending on medical products and food safety 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.

**We support the recommendation from the Leadership Council of Aging Organizations (LCAO) fully funding all Older Americans Act programs at the authorized levels for FY 2021.** 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. 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.<sup>xx</sup> 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 in FY20 to protect and support the Lifespan Respite Care program, the ACL Alzheimer's Disease Program Initiative, and Older Americans Act programs like the National Family Caregiver Support Program, in-home supportive services, congregate and home-delivered meals programs, falls prevention programs and much more. We encourage you to provide substantial new funding in

FY21 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.<sup>xxi</sup> These programs provide essential respite, training, and support to help family caregivers meet the needs of persons living with dementia.

**We support an \$8.5 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,<sup>xxii</sup> we applaud the new 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 suffer from considerable stress and depression. Many of the programs are geared towards at-risk dementia populations, such as those who live alone, those with 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.<sup>xxiii</sup>

**We support a \$3 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.

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.

The CDC's Healthy Brain Initiative has launched its 2018-2023 Healthy Brain Aging Road Map to ramp up the nation's public health capacity in addressing dementia; the companion Road Map for Indian Country will launch soon.<sup>xxiv</sup> The Road Map 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.

In addition to needed increases in core funding for the CDC's long-standing and successful Healthy Brain Initiative, **we support a new \$20 million appropriation for CDC to continue implementing the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act (Pub. L. 115 – 406).**<sup>xxv</sup> 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.

### **Lessons from the COVID-19 Pandemic and Recommended Actions**

Only a handful of months into the worst pandemic to strike our county in a century, a number of lessons are emerging both about the present response and about future planning. Hard earned experience has highlighted enormous gaps in our disability rights, health care, home care and long-term care systems, many of which have subjected already marginalized people with dementia and those who give them care to disproportionate and frankly unconscionable risks. In many cases, these same people are acutely vulnerable to the impact both of COVID-19 and the emergency measures taken by governments. We are not interested in casting blame, but we are intent on partnering with all decision-makers and stakeholders to learn, adapt, anticipate and prepare so that preventable shortcomings no longer compromise the wellbeing, safety and lives of more than 20 million Americans who either are living with dementia or give them care. We are grateful to you as appropriators and your colleagues across Congress who already have taken bold steps in the right direction by delivering emergency funding to support the work of social service agencies. We applaud federal agencies that have applied their expertise to provide clear public health education, to work with residential care facilities to recognize family caregivers as essential members of the health team who require access, and to NIH (and its academic and industry research partners) for accelerating the science necessary for improved diagnostics, treatments and manufacturing of medical products. For all that has been done well by innumerable public and private sector decision-makers, we recognize that the gaps, inconsistencies and shortcoming have cost tens of thousands of precious lives and inflicted nearly unfathomable damage to our national economy. **We recommend that the FY21 appropriations bill report language direct HHS to report to Congress within 90 days consensus dementia-specific pandemic preparedness and response action steps to be implemented by federal, state and local governments along with relevant non-governmental organizations.**

Equally important, we all are coming to better understand that chronic diseases and communicable diseases are linked inextricably. Dementia is caused by non-communicable diseases like Alzheimer's or LBD, but people with dementia are among the most susceptible to communicable diseases such as COVID-19 precisely because of their cognitive challenges, physical dependence and social isolation. Simply put, if fewer people had dementia, if its onset could be delayed, or if the progression of dementia were slower, COVID-19's death toll would be considerably lower. As appropriators, you have provided consistently remarkable leadership in providing NIH essential resources to accelerate the scientific pursuit of an effective means to prevent or treat Alzheimer's disease and other forms of dementia. Amid the COVID-19 pandemic, you again have led the way in supporting non-governmental organizations on the front lines of protecting

and serving people with dementia. As you build the FY21 appropriations bills, we ask you to continue making robust investments in the science and services that will reduce dementia prevalence, severity and vulnerability. Doing so is essential for tens of millions of Americans facing dementia now in and in years ahead and equally essential in protecting our entire country against communicable diseases like COVID-19.

Given the dementia public health crisis facing the nation, and what is known today about the promise of non-pharmacological interventions to reduce dementia risk along with the urgent need to modernize the nation's healthcare infrastructure to ensure timely access to forthcoming disease modifying therapies, an intensified focus on early detection, intervention and prevention strategies is needed. **We recommend that the FY21 appropriations bill report language direct HHS to set a national, measurable, time-bound impact goal to reduce dramatically dementia prevalence and deliver an implementation plan to Congress within 180 days, with annual progress updates provided to Congress and the National Alzheimer's Project Act federal advisory committee.** The national goal should include specific measurement for each state's progress and aggressive component goals focused on women, communities of color and other populations that are at elevated risk for dementia. The national goal also should include aggressive component goals for detection, diagnosis and treatment of diseases causing cognitive impairment or dementia. We recommend a commensurate public-private initiative to develop and implement the necessary strategies and accountability measures to ensure the national goal and its component goals are achieved.

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),<sup>xxvi</sup> [ikremer@leadcoalition.org](mailto:ikremer@leadcoalition.org) or (571) 383-9916.

Sincerely,

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

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

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

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

<sup>iv</sup> <https://alz.org/media/Documents/alzheimers-facts-and-figures.pdf>

<sup>v</sup> <https://alz.org/media/Documents/alzheimers-facts-and-figures-2019-r.pdf>

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

<sup>vii</sup> <https://www.thelancet.com/commissions/dementia2017>

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- viii <https://www.nia.nih.gov/news/does-intensive-blood-pressure-control-reduce-dementia>
- ix <http://www.neurology.org/content/early/2014/03/05/WNL.0000000000000240>
- x <https://alz.org/media/Documents/alzheimers-facts-and-figures.pdf>
- xi <https://www.nia.nih.gov/sites/default/files/2019-07/FY21-bypass-budget-report-508.pdf>
- xii <https://aspe.hhs.gov/system/files/pdf/102526/NatIPlan2012%20with%20Note.pdf>
- xiii <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>
- xiv <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM596728.pdf>
- xv <https://ir.acadia-pharm.com/news-releases/news-release-details/acadia-pharmaceuticals-announces-pivotal-phase-3-harmony-trial>
- xvi <http://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease>
- xvii <https://www.nia.nih.gov/sites/default/files/2019-07/FY21-bypass-budget-report-508.pdf>
- xviii <https://www.nia.nih.gov/sites/default/files/2018-10/alzheimers-disease-recruitment-strategy-final.pdf>
- xix <https://www.nia.nih.gov/sites/default/files/2018-07/fy2020-bypass-budget-report-final.pdf>
- xx <https://www.who.int/news-room/fact-sheets/detail/dementia>
- xxi <https://aspe.hhs.gov/system/files/pdf/102526/NatIPlan2012%20with%20Note.pdf>
- xxii <https://www.cdc.gov/aging/healthybrain/Indian-country-roadmap.html>
- xxiii <https://nadrc.acl.gov>
- xxiv <https://www.cdc.gov/aging/healthybrain/roadmap.htm>
- xxv <https://www.congress.gov/bill/115th-congress/senate-bill/2076>
- xxvi <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.