May 19, 2022

The Honorable Rosa DeLauro  
Chair  
Committee on Appropriations

The Honorable Kay Granger  
Ranking Member  
Committee on Appropriations

The Honorable Rosa DeLauro  
Chair  
Subcommittee on Labor, HHS & Education

The Honorable Tom Cole  
Ranking Member  
Subcommittee on Labor, HHS & Education

The Honorable Sanford Bishop, Jr.  
Chair  
Subcommittee on Agriculture & FDA

The Honorable Andy Harris  
Acting Ranking Member  
Subcommittee on Agriculture & FDA

The Honorable Matt Cartwright  
Chair  
Subcommittee on Commerce, Justice, Science, and Related Agencies

The Honorable Robert B. Aderholt  
Ranking Member  
Subcommittee on Commerce, Justice, Science, and Related Agencies

by electronic delivery

Dear Chair DeLauro, Ranking Member Granger, Ranking Member Cole, Chair Bishop and Ranking Member Fortenberry, Chair Cartwright and Ranking Member Aderholt:

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 2022 (FY22) 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, sustained, and robust action during the pandemic to address the needs of older adults who are among the most vulnerable both to COVID-19 and to the unintended consequences of public health necessities that exacerbate already precarious living conditions.

As you work to construct Fiscal Year 2023 (FY23) 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 FY23 appropriations bills include at least the following minimum levels:
• a $226 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 FY23

• a $3.8 billion increase (to $49 billion) for the NIH’s base program level, and an increase of $4 billion for the Advanced Research Projects Agency for Health (ARPA-H) to supplement, rather than supplant, this core investment in NIH.

• A $60 million increase for the BRAIN Initiative

• A $336 million increase for the FDA, in addition to funds included in the 21st Century Cures Act for targeted initiatives

• $25 million to establish a Neuroscience Center of Excellence at the FDA using the inter-center institute model authorized by the 21st Century Cures Act

• double funding for Older Americans Act programs and services

• a $7.5 million increase for the ACL Alzheimer’s Disease Program

• a $36.8 million increase for the HRSA geriatrics workforce programs

• a $5 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)

We also support appropriations report language to advance accomplishing goals of the National Alzheimer’s Plan.

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

Currently, more than 6 million Americans are living with dementia, with combined healthcare and long-term care costs of $321 billion. 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 25% of the cost, $81 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 nearing $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 $321 billion in 2022 to approximately $1 trillion in 2050 (in 2022 dollars) and the hidden costs of uncompensated caregiving to become even more staggering.\textsuperscript{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\textsuperscript{vi} and — despite a powerful body of evidence for risk-reduction strategies\textsuperscript{vii} which is being expanded with significant NIH investments\textsuperscript{viii} — the only one among the top 10 for which there is not yet a proven means of prevention, disease modification or cure.\textsuperscript{ix} One third of older Americans dies with Alzheimer’s disease or another form of dementia.\textsuperscript{x}

**Advancing Science**

We support a $226 million increase for National Institutes of Health (NIH) research on Alzheimer’s disease and other forms of dementia to accelerate progress as proposed in the NIH FY23 Bypass Budget.\textsuperscript{xii} The choice before our nation is not whether to pay for dementia -- we are paying dearly. The question is whether we will emulate the sustained investment strategies that have led to remarkable progress in fighting other leading causes of death 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.\textsuperscript{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.\textsuperscript{xiii} The Food and Drug Administration (FDA) is encouraging new research avenues, clarifying regulatory approval pathways,\textsuperscript{xiv} and reviewing products to modify disease pathology, clinical progression, and the most heart-breaking symptoms of dementia. 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, communities of color, 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.\textsuperscript{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.\textsuperscript{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,\textsuperscript{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 FY23, 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 $49 billion for the NIH’s base program level, and an appropriation of $5 billion for the Advanced Research Projects Agency for Health (ARPA-H) to supplement, rather than supplant, this core investment in NIH. This core NIH investment of $49 billion 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 also support $5 billion for the Advanced Research Projects Agency for Health (ARPA-H) above the core NIH appropriation; funding for ARPA-H must not come at the expense of the steady and predictable annual increases Congress has been providing to NIH. Modeled on the Defense Advanced Research Projects Agency (DARPA), ARPA-H will 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. Robust growth in the foundational research that NIH supports in labs nationwide is essential to achieving ARPA-H’s objective of leveraging this research to push the boundaries of translational research and development for diseases such as Alzheimer’s and other forms of dementia. For example, the swift delivery of safe and effective COVID-19 vaccines was made possible by over a decade of basic and clinical research discovery supported by NIH funding. To replicate this success, Congress must ensure that it continues to expand the NIH’s capacity to support fundamental science that is the essential foundation for ARPA-H translation.

We support the recommendation from the American Brain Coalition for a $60 million increase 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 $2.4 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 the roll out of three large transformative projects that will build a comprehensive atlas of cell types in the human brain, develop and scale up the tools necessary to complete a micro-connectivity map of an entire mammalian brain, and provide tools for precision access to the identified
cell types to allow interrogation and modulation of neural circuits. Together, these tools will enable the eventual development of novel interventions—including molecular and gene-editing therapies—for human circuit disorders.\textsuperscript{xxi}

\textbf{We support the recommendation from the Alliance for a Stronger FDA for a $336 million increase for the FDA to meet the most pressing needs in medical products and food safety programs.}\textsuperscript{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.

\textbf{We support the recommendation from the American Brain Coalition and the Neuroscience Working Table to appropriate $25 million to establish a Neuroscience Center of Excellence at the FDA. We also ask that the following report language be included:}

\begin{quote}
\textit{Neuroscience Center of Excellence. – The Committee provides $25 million to establish a Neuroscience Center of Excellence at the FDA using the inter-center institute model authorized by the 21\textsuperscript{st} Century Cures Act. Brain- and central nervous system-related diseases, conditions, and injuries impact millions of Americans and impose enormous personal and financial costs on American families and caregivers and the federal and state governments. In addition, they affect millions of people worldwide. The Committee is concerned by the slow pace of therapeutic development for such conditions. The Committee understands that a greater than 50\% decline in such drug discovery and development by major pharmaceutical companies in the past decade has left many patients without sufficient treatment options. A Neuroscience Center of Excellence at FDA will create a transparent process to engage all relevant stakeholders on diseases, conditions, and injuries impacting the brain and central nervous system to help ensure safe and effective treatments and devices for patients.}
\end{quote}

\textbf{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.

\textbf{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.\textsuperscript{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 23, 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). 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 form of dementia to the public.xxvi

We support a $36.8 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 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 is designed to build a pipeline of individuals with academic and research expertise who can become leaders in their fields and to enhance the educational or research capacity at the grantee’s institution. Increased appropriations would enable 60 GACAs at $100,000 per award (currently there are 26 GACAs funded at $75,000) and 80 GWEPs at $950,000 per program (currently, there are 48 GWEPs funded at $750,000). The proposed increases would enable every state to have a GWEP program and ensure that more rural and underserved areas of the country can have access to geriatrics training and expertise to expand the capacity of the existing health care delivery and caregiving workforce. The increases for GACAs would ensure a larger and geographically more diverse pipeline of geriatrics research and training expertise with needed incentives and resources to grow the field.
We support a $5 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 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 roadmap 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 adults 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 for the ADHAP’s vital work represented only approximately 0.25% of the overall CDC budget.

Specifically, the $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 $30 million for CDC to continue implementing the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer’s Act (Pub. L. 115 – 406). Under the law, Congress 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 ADHAP its BOLD Act work to support 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. 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). 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.

Appropriations Report Language

We also support appropriations report language to advance accomplishing goals of the National Alzheimer’s Plan and request that the following be included:

- **National Strategy for Recruitment and Participation in Alzheimer’s and Related Dementias Clinical research**

  The Committee applauds the National Institute on Aging’s (NIA) efforts to initiate, identify, and develop a “National Strategy for Recruitment and Participation in Alzheimer’s and Related Dementias Clinical research.” An effective way of determining whether those recommended strategies are being well-implemented and having the desired impact is through data collection and reporting. The Committee urges the NIA to provide an assessment of the data and metrics it collects related to the planning, recruitment, and retention of clinical trial participants from underrepresented communities and how those data have been or plan to be used in grantmaking decisions. The assessment should also address how NIA plans to provide more timely data to Congress and greater access to the public about the planning, engagement, and recruitment efforts of its extramural grantees, including a focus on addressing barriers to inclusive and representative enrollment such as eligibility criteria, language accessibility, and adequate planning for diverse enrollment among grantees. The Committee respectfully requests that the NIA provide this assessment to Congress within 180 days of the enactment of this legislation.

- **Centers for Disease Control and Prevention, Alzheimer’s Disease and Healthy Aging Program (ADHAP)**

  The Committee is encouraged by research demonstrating the positive impact of risk reduction on dementia prevalence and commends the Secretary for updating the National Alzheimer’s Plan to reflect the latest science. To ensure high burden populations are reached, the Committee directs CDC to increase capacity to support populations with a high burden of Alzheimer’s and other dementias through public health promotion and workforce development by increasing Healthy Brain Initiative grants from $5.5 million to $10 million. We urge CDC to ensure appropriate capacity
support to implement NAPA’s Goal 6 and we encourage ADHAP to collaborate with CMS, HRSA and the VA to identify ways to translate what we know about risk reduction into opportunities within current agency authority to improve risk reduction and early intervention for ADRD in clinical and community practice.

- **National Alzheimer’s Disease Prevention Strategy**

The Committee commends the Secretary for updating the National Plan to include a sixth goal focused on reducing the risk of dementia and promoting healthy aging. To ensure this goal is realized, the Committee directs the Secretary to include specific, measurable, timebound milestones and commensurate strategies to achieve this goal in the annual plan update and to align these milestones with budget requests. Milestones should be developed in collaboration with a broad group of non-governmental stakeholders including payers, technology platforms, consumer wellness and lifestyle innovators, health equity advocates, experts in the social determinates of health, and voluntary health organizations focused on each of the risk factors for ADRD.

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), 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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Second Wind Dreams, Inc./ Virtual Dementia Tour
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The Evangelical Lutheran Good Samaritan Society
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University of Rochester Alzheimer's Disease Care, Research and Education Program (AD-CARE)
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USAGening
USC Edward R. Roybal Institute on Aging

USF Health Byrd Alzheimer's Institute
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iii http://annals.org/article.aspx?articleid=2466364#
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.