



The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, D.C. 20515

July 31, 2024

Dear Representatives DeGette and Bucshon:

On behalf of the Alzheimer's Association and the Alzheimer's Impact Movement (AIM), including our nationwide network of advocates, thank you for your continued leadership on issues and legislation important to Americans living with Alzheimer's and other dementia, and their caregivers. We appreciate the opportunity to provide additional input on the bipartisan 21st Century Cures 2.0 text as well as the implementation of the 21st Century Cures Act (P.L. 114-255), which aims to further improve the way our nation delivers new life-saving treatments to the people that need them. Our comments on the text and implementation are below.

Section 203: Increasing Diversity in Clinical Trials

The Alzheimer's Association and AIM strongly support the inclusion of this section in the bill, which, among other priorities, requires the Department of Health and Human Services (HHS) to conduct a clinical trial public awareness campaign, particularly in underrepresented communities, and establish a task force to make Clinicaltrials.gov more user- and patient-friendly.

Alzheimer's and other dementia disproportionately affect older Black and Hispanic Americans compared to older Whites. Black Americans are about twice as likely to develop Alzheimer's and Hispanic Americans are about one and a half times more likely to develop the disease. However, much of the Alzheimer's research to date has not included sufficient numbers of Blacks, Hispanics, Asian Americans/Pacific Islanders, and Native Americans to be representative of the U.S. population. The underrepresentation of these populations not only hinders the ability of researchers to understand these health disparities, but it also restricts their knowledge of how an approved therapy or diagnostic may affect the population most likely to need the treatment. There is, therefore, an urgent need for current and future research to include increased numbers of Blacks, Hispanics, Asian Americans/Pacific Islanders, and Native Americans in clinical trials to ensure everyone benefits from advances in Alzheimer's science.

According to the [Alzheimer's Association 2021 Alzheimer's Disease Facts and Figures special report](#), nearly two-thirds of Black Americans (62%) believe medical research is biased against



people of color — a view shared by substantial numbers of Asian Americans (45%), Native Americans (40%), and Hispanic Americans (36%) as well. In fact, only half of Black Americans (53%) trust a future cure for Alzheimer's will be shared equally, regardless of race, color, or ethnicity. This underscores the need to build and restore trust in underrepresented communities. Strong community relationships can serve to address misconceptions and mistrust about research because the community has a sense of ownership in the research initiative.

The National Institute on Aging (NIA) has established a good foundation of centers across the country that offer local resources, support, and opportunities to participate in Alzheimer's and other dementia research. The NIA currently funds over 35 Alzheimer's Disease Research Centers (ADRCs) at major medical institutions across the United States and two Exploratory ADRCs that are designed to expand and diversify research and education opportunities to new areas of the country, new populations, and new areas of science and approaches to research. There are also eight Alzheimer's disease-focused Resource Centers for Minority Aging Research (RCMARs) which focus on enhancing the diversity of the aging research workforce by mentoring promising scientists from underrepresented groups for sustained careers in aging research. These ADRCs and RCMARs are well-positioned to increase education and outreach activities to underrepresented populations within their communities.

To ensure future treatments and means of prevention are effective in all populations, Alzheimer's and other dementia research must be reflective of all Americans. To address this issue, AIM worked with bipartisan congressional champions to develop the Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (H.R. 3085/S. 1548). Since the introduction of Cures 2.0, key provisions of the bipartisan ENACT Act were included in the Fiscal Year 2023 budget in December 2022. These provisions aim to increase the participation of underrepresented populations in Alzheimer's and other dementia clinical trials by expanding education and outreach to these populations, encouraging the diversity of clinical trial staff, and reducing participation burden in clinical trials, among other priorities.

The Alzheimer's Association and AIM also appreciate the bill's inclusion of a provision to establish a task force to make Clinicaltrials.gov more user- and patient-friendly. The Alzheimer's Association has learned many lessons through [TrialMatch](#), a free, easy-to-use clinical studies matching service that connects individuals living with Alzheimer's disease, caregivers, and healthy volunteers with current research studies. The continuously updated database of Alzheimer's and dementia clinical studies includes hundreds of pharmacological and non-pharmacological studies being conducted at sites across the country.

Section 201: Educational Programs and Training for Caregivers



The Alzheimer's Association and AIM strongly support the inclusion of this section in the bill, which would authorize \$25 million per year for three years to provide grants for educational programs and training for caregivers. We are encouraged to see the text include an expanded list of educational and training programs that would be accessible to caregivers, including caregiver psychosocial support - like cognitive-behavioral, supportive, and bereavement counseling - and caregiver health self-management.

Alzheimer's takes a devastating toll on caregivers. Eighty-three percent of the help provided to older adults in the United States comes from family members, friends, or other unpaid caregivers. Nearly half of all caregivers who provide help to older adults do so for someone living with Alzheimer's or another dementia. Compared with caregivers of people without dementia, twice as many caregivers of those with dementia indicate substantial emotional, financial, and physical difficulties. Of the total lifetime cost of caring for someone with dementia, 70% is borne by families — either through out-of-pocket health and long-term care expenses or from the value of unpaid care. In 2023, over 11 million unpaid caregivers provided 18.4 billion hours of care valued at nearly \$350 billion. Alzheimer's caregivers also report higher levels of stress, depression, and worse health outcomes when compared to others who are providing care to individuals without dementia.

In the 117th Congress, the Alzheimer's Association and AIM supported the bipartisan Alzheimer's Caregiver Support Act (H.R. 1474/S. 56) which would provide caregivers and their families much needed support by providing grants to public and non-profit organizations to expand and improve training and support services. These services can empower caregivers to provide quality care for their loved ones while giving them tools to manage and improve their own health.

Section 204: Patient Experience Data

The Association and AIM appreciate the inclusion of this section, which would require the transparent and uniform collection and consideration of patient experience data as part of clinical trials. Patient experience data provides meaningful information that sponsors can use to improve upon the patient experience and incorporate that feedback into the trial benefits, providing value to participants. We recommend that the patient experience data is collected in a thoughtful, uniform way at consistent intervals, which does not unnecessarily add to the patient burden.

Section 304 Increasing the use of Real World Evidence

The Association and AIM appreciate increasing the use of real-world evidence (RWE) to inform clinical practice and enhance innovative research. The collection of RWE is



integral to the discovery, evaluation, and evolution of novel avenues for the diagnosis, prevention, treatment, and care of Alzheimer's and other dementia. This includes understanding the long-term effects of any new treatment approach. To this end, in November 2021 the Association, along with the American College of Radiology (ACR), the American Society of Neuroradiology, the Department of Biostatistics at Brown University School of Public Health, and other clinical research experts, launched the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET).

ALZ-NET collects real-world clinical and imaging data about patients being evaluated for memory concerns or receiving treatment with new FDA-approved Alzheimer's therapies, including new drugs/medications and devices. This collection of real world evidence allows ALZ-NET to serve as a resource for evidence gathering, information sharing, and education across clinical and research communities, while also encouraging innovative, inclusive research and supporting opportunities to improve care. We appreciate the continued support for increasing the use of RWE.

Section 305: Improving FDA-CMS Communication Regarding Transformative New Therapies

The Alzheimer's Association and AIM support improved and ongoing communication between the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) with regard to breakthrough therapies, fast track products, and those eligible for accelerated approval.

Section 309: Post-Approval Study Requirements for Accelerated Approval

The Alzheimer's Association and AIM appreciate the expansion of acceptable RWE that can be used to fulfill post-approval study requirements to confirm the predicted clinical benefit of a therapy approved through the accelerated approval pathway. Specifically, the updated text includes evidence based on analyses of data in clinical care data repositories, patient registries, or other sources of RWE.

ALZ-NET continues to be an agnostic approach to gathering routine clinical practice data and outcomes from providers caring for patients diagnosed with Alzheimer's disease who are taking an FDA-approved treatment or therapeutic. Using data like this as RWE in post-approval study requirements could help facilitate the completion of more timely phase IV studies, and could yield greater insight to the therapy's impact on underrepresented populations and those with comorbid conditions - populations which may be harder to enroll in placebo-controlled trials.

Section 403: Extending Medicare Telehealth Flexibilities



The Alzheimer's Association and AIM appreciate the inclusion of this section, which would permanently remove Medicare's geographic and originating site restrictions and allow HHS to permanently expand the types of health care providers that can offer telehealth services and the types of services that can be reimbursed under Medicare. Flexibilities such as these allow for greater access to telehealth technology, which is especially important to the delivery of home health for people living with Alzheimer's and other dementia. Thirty-two percent of individuals using home health services have Alzheimer's or other dementia. The ability to receive care in the home decreases visits to unfamiliar places that may cause agitation in people with dementia and can ease some burden on caregivers. This increased flexibility can reduce interruptions in access to this kind of quality care.

Conclusion

Again, we thank you for your work on this important bipartisan legislation, which would benefit all Americans, including those living with Alzheimer's and other dementia, and their caregivers. We look forward to working with you as the 21st Century Cures 2.0 effort moves through the legislative process. If you have any questions about this or any other legislation, please contact Rachel Conant, Senior Vice President of Public Policy, at rconant@alz-aim.org or at 202.638.7121.

Sincerely,

Robert Egge
Chief Public Policy Officer, Alzheimer's Association
President, Alzheimer's Impact Movement