



## **Alzheimer's Association and Alzheimer's Impact Movement Statement for the Record**

### **United States House Committee on Energy and Commerce, Health Subcommittee Hearing on "The Future of Medicine: Legislation to Encourage Innovation & Improve Oversight"**

**March 17, 2022**

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit this statement for the record for the House Committee on Energy and Commerce, Health Subcommittee hearing on "The Future of Medicine: Legislation to Encourage Innovation & Improve Oversight." The Association and AIM thank the Subcommittee for its continued leadership on issues important to the millions of people living with Alzheimer's and other dementia and their caregivers. Among other issues, this statement highlights the importance of the bipartisan Equity In Neuroscience and Alzheimer's Clinical Trials (ENACT) Act, which would increase the diversity of Alzheimer's clinical trial participants to ensure all populations benefit from the latest scientific advances and inclusion in Alzheimer's clinical trials.

The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support, and research. It is the nonprofit with the highest impact in Alzheimer's research worldwide and is committed to accelerating research toward methods of treatment, prevention, and, ultimately, a cure. AIM is the advocacy affiliate of the Alzheimer's Association, working in strategic partnership to make Alzheimer's a national priority. Together, the Alzheimer's Association and AIM advocate for policies to fight Alzheimer's disease, including increased investment in research, improved care and support, and development of approaches to reduce the risk of developing dementia.

#### **Equity In Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (H.R. 3085/S. 1548)**

A significant hurdle in developing therapeutics and care models for Alzheimer's disease that work for people of all ethnic and racial backgrounds is the recruitment and retention of traditionally underrepresented groups in clinical trials. 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, 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. NIA currently funds over 30 Alzheimer's Disease Research Centers (ADRCs) at major medical institutions across the United States and four 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.

The bipartisan **Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (H.R. 3085/S. 1548)** would 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, among other priorities.

Specifically, the ENACT Act would provide funding for NIA to expand the number of ADRCs in areas with higher concentrations of underrepresented populations, such as through entities like Historically Black Colleges and Universities (HBCUs), Hispanic-Serving Institutions, Tribal Colleges and Universities (TCUs), or centers of excellence for other underrepresented populations. The ENACT Act would provide funding for ADRCs and RCMARs to increase education and outreach to underrepresented communities and primary care physicians to let them know about current trial opportunities, the importance of participation, and the disparate impact of the disease on their populations. Importantly, ADRCs and RCMARs would use community-based engagement strategies in their outreach to underrepresented populations.

The ENACT Act would direct the NIA to enhance the diversity of principal investigators and study staff conducting Alzheimer's and other dementia clinical trials, so they are more representative of the populations they're trying to enroll. The bill directs the NIA to provide training to principal investigators from underrepresented populations on topics like clinical protocols and how to apply

for grants, so they have the necessary expertise. NIA would also ensure senior researchers from underrepresented populations are included when making awards for leadership and excellence in Alzheimer's research.

The ENACT Act would reduce participation burden to make it easier for underrepresented populations to participate in Alzheimer's and other dementia clinical trials by providing incentives for locating Alzheimer's clinical trial sites in areas with high concentrations of underrepresented populations, as identified by data from the U.S. Census and Medicare claims data. The bill would direct NIA to ensure grantees use community-based engagement strategies in their outreach to underrepresented populations. The bill also encourages the use of remote health technology in communities, such as remote patient monitoring, to ease the burden of participation. Importantly, the bill would direct NIA to ensure grantees appropriately budget for outreach activities to underrepresented populations and include a description of outreach plans. NIA would also encourage grantees to engage with community-based organizations in efforts to increase clinical trial participation of underrepresented populations.

Finally, the ENACT Act would ensure inclusion and exclusion criteria are not unnecessarily restrictive so that older adults and individuals with a mild form of comorbid conditions are included, unless there is a strong clinical or scientific justification to exclude them. The bill also encourages the use of adaptive clinical trial design which could expand to include broader populations as the trial progresses through Phases I, II, and III. This is important because Black and Hispanic Americans with Alzheimer's have higher rates of comorbid conditions, such as cardiovascular disease and diabetes, and these conditions should not unnecessarily disqualify these populations from participating in clinical trials. This is consistent with FDA's November 2020 guidance, "Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry."

We urge the Subcommittee to move this important bipartisan bill, which already has strong bipartisan support of many members of the Committee, and we look forward to working with the Chair and Ranking Member as it moves through the legislative process. There is also growing support for the ENACT Act off the Hill: in addition to the Alzheimer's Association and AIM, groups that support this bipartisan bill include the AME International Health Commission, American Academy of Neurology, Black Nurses Rock, National Asian Pacific Center on Aging, National Caucus and Center on Black Aging, Inc., National Hispanic Council on Aging, National Hispanic Medical Association, National Indian Council on Aging, SAGE (Services & Advocacy for LGBT Elders), and UsAgainstAlzheimer's.

### **Accelerated Approval Pathway**

As we indicated in our letter dated March 16, the Alzheimer's Association and AIM strongly support FDA's Accelerated Approval pathway and urge the Committee to preserve and strengthen this critical tool for bringing therapies to patients currently living with unmet medical need. At each turn when Congress has legislated on accelerated approval, the pathway has been reaffirmed

and the Agency has been encouraged to fully harness the promise of the pathway on behalf of patients. Lives have been saved, extended and improved.

Millions of American families are grateful for these past actions by Congress and fully expect this Congress to continue to support and encourage the use of accelerated approval for all of the patients who today live with unmet medical needs. These patients are Americans living with rare diseases, 95% of which currently have no approved treatments. They are Americans living with Alzheimer's where treatments are just beginning to emerge but the unmet need remains vast.

As you begin consideration of the FDA User Fee reauthorization, the Alzheimer's Association and AIM strongly support preserving the accelerated approval pathway and ensuring that all patients living with unmet need, regardless of their specific condition, can continue to have confidence in the FDA's utilization of the pathway.

We stand ready to support any effort you may undertake to reaffirm Congress' ongoing support for accelerated approval. There are diseases that went from a death sentence to chronic because of accelerated approval including many cancers that have been beaten back. It is only reasonable to continue to offer that same hope and deliver on the same results for the millions of patients still living with unmet need including people living with Alzheimer's and other dementia.

### **Advanced Research Projects Agency for Health**

The Alzheimer's Association and AIM support Congressional efforts to establish the Advanced Research Projects Agency for Health (ARPA-H). We were pleased to see Alzheimer's listed as one of the disease areas of focus. However, we urge Congress to ensure ARPA-H does not duplicate or supplant current Alzheimer's research efforts at the National Institutes of Health (NIH). There are still many important unfunded targets that NIH can and should fund, as outlined in the NIH Professional Judgment Budget for Alzheimer's Disease and Related Dementias for Fiscal Year 2023. One example of this great work is the Accelerating Medicines Partnership Alzheimer's Disease (AMP AD). The AMP AD program is a precompetitive partnership among government, industry, and nonprofit organizations that focuses on discovering novel, clinically relevant therapeutic targets and on developing biomarkers to help validate existing therapeutic targets. AMP AD 2.0 launched in February 2021, with the goal of enabling a precision medicine approach to the discovery of novel targets and biomarkers.

ARPA-H can fill an important role in supplementing the current work at NIH by driving transformational innovation in research and speeding the application and implementation of cutting edge breakthroughs. Examples of Alzheimer's-related projects ARPA-H could undertake are accelerating the discovery of brain imaging, eye imaging and blood or fluid biomarkers capable of measuring synaptic loss, neuronal death, and glial inflammatory pathways, as a means of tracking responses to potential Alzheimer's disease therapies. There are also opportunities to explore the use of digital technologies for diagnosis, assessment, and disease monitoring, such as novel ways to measure and evaluate cognition and function of an individual, develop tools focused on voice recognition and other passive ways to measure changes that may be reflective

of brain diseases, such as Alzheimer's. In addition, opportunities that will enable the complex modeling of contributions to risk are additional areas ripe for investment; such opportunities may help develop risk assessments based on the individual - including genetic, biologic, and clinical measures. We also urge ARPA-H to focus on activities that include providing a validated algorithm for disease risk using all available data, like biomarker, digital and emerging technology, to support a translatable resource for clinicians and drug discovery experts.

We caution that ARPA-H should not operate in silos or in isolation. Transparency surrounding the activities at ARPA-H will be key, as will data sharing and the open resources development of data and information.

### **Diverse Trials Act (H.R. 5030/S. 2706)**

The Alzheimer's Association and AIM support the bipartisan DIVERSE Trials Act (H.R.5030/S. 2706) which would enable the Department of Health and Human Services (HHS) to enter into contracts and grants with entities supporting education, outreach, and recruitment for clinical trials for therapies which have a disproportionate impact on underrepresented populations, as well as requiring HHS to issue guidance on how to lower barriers to participation in diverse communities by using digital health technologies. Efforts to expand diversity for clinical trials, both with Alzheimer's research and generally, must be accelerated using innovative means, such as the DIVERSE Act's use of free digital technologies. This provision would better enable individuals to participate in decentralized clinical trials by reducing participation burden associated with time, travel, and costs. The bill also enhances data collection methods first employed under Coronavirus Aid, Relief, and Economic Security Act (CARES) Act in order to better address social determinants of health - which is key for addressing health equity in underrepresented populations.

### **Cures 2.0 Act (H.R. 6000)**

We thank the Committee 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 legislation moves through the Committee process.

Among the numerous provisions we support in the bill, the Alzheimer's Association and AIM strongly support the inclusion of the educational programs and training for caregivers 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.

The burden of living with Alzheimer's and other dementias extends to millions of Americans caring for those with the disease. In 2021, more than 11 million unpaid caregivers provided

more than 16 billion hours of care valued at nearly \$272 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. The physical and emotional impact of dementia caregiving is estimated to have resulted in \$11.8 billion in health care costs in the United States in 2018. The more caregivers understand Alzheimer's disease or other dementia, the better they can care for their loved ones and themselves.

## **Conclusion**

The Alzheimer's Association and AIM appreciate the steadfast support of the Subcommittee and its continued commitment to advancing legislation important to the millions of families affected by Alzheimer's and other dementia. We look forward to working with the Subcommittee in a bipartisan way to address the challenges facing the dementia community including passing the ENACT Act.