



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

### **United States Senate Health, Education, Labor, and Pensions Committee Hearing on "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, FDA Center Directors"**

**April 26, 2022**

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit this statement for the record for the Senate Health, Education, Labor, and Pension Committee hearing on "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, FDA Center Directors." The Association and AIM thank the Committee for its continued leadership on issues important to the millions of people living with Alzheimer's and other dementia and their caregivers. This statement highlights the importance of the Accelerated Approval Pathway and 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.

#### **Accelerated Approval Pathway**

As we indicated in our letter dated March 16, 2022, 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.

### **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 Committee 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.

## **Conclusion**

The Alzheimer's Association and AIM appreciate the steadfast support of the Committee 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 Committee in a bipartisan way to address the challenges facing the dementia community including strengthening the Accelerated Approval Pathway and passing the ENACT Act.