



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

### **United States House Committee on Energy and Commerce, Health Subcommittee Hearing on "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics"**

**February 3, 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 "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics." 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. As the Subcommittee works to reauthorize the user fee agreements, we particularly appreciate the focus on improving diversity in biomedical research. This statement highlights an important bipartisan bill within the Subcommittee's jurisdiction, the Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (H.R. 3085/S. 1548), which would increase the diversity of Alzheimer's clinical trial participants to ensure all populations benefit from the latest scientific advances. This statement also highlights policies that would ensure timely access to safe and effective treatments.

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.

### **Alzheimer's Impact on American Families and the Economy**

Alzheimer's is a progressive and fatal brain disorder that damages and eventually destroys brain cells, leading to a loss of memory, thinking, and other brain functions. There are no survivors.

Alzheimer's is emotionally, physically and financially draining for individuals and families. In addition, Alzheimer's is creating an enormous strain on the health care system, and federal and state budgets. The annual cost for caring for individuals living with Alzheimer's or other dementia will total \$355 billion including health care, long-term care, and hospice care in 2021. The U.S. taxpayer-funded federal health care programs Medicare and Medicaid are expected to cover \$239 billion, or 67 percent, of these costs this year. In addition, American families provide an estimated \$250 billion in unpaid care. While an estimated 6.2 million Americans age 65 and

older are currently living with Alzheimer's, nearly 13 million Americans will have Alzheimer's by 2050 and costs will exceed \$1.1 trillion (in 2021 dollars). Alzheimer's and other dementia threaten to bankrupt families, businesses, and our health care system.

### **Increasing Diversity in Alzheimer's Clinical Trials**

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 include this important bipartisan bill, which already has the support of many Subcommittee and Committee members, in a future legislative package and 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 and Ensuring Timely Access to FDA-Approved Therapies**

The accelerated approval pathway at the Food and Drug Administration (FDA) is critical to providing timely access to new, safe, and effective treatments to people living with serious and life-threatening diseases and conditions for which there are no meaningful alternatives. As Congress intended, this pathway allows for earlier access to drugs for these types of diseases while confirmatory evidence is being generated. As the Subcommittee works to reauthorize the user fee agreements, we ask that you consider a provision that would allow for the use of real-world evidence (RWE) to fulfill or support post-approval study requirements to confirm the predicted clinical benefit of a therapy approved through the accelerated approval pathway. In November 2021, the Alzheimer's Association, American College of Radiology, American Society of Neuroradiology, Department of Biostatistics at Brown University School of Public Health and other clinical research experts announced the formation of the [National Treatment and Diagnostic Alzheimer's Registry](#). This new national registry will be an FDA-approved-agent 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 disease-modifying treatment. 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.

Finally, we ask that you support improved and ongoing communication between the FDA and the Centers for Medicare & Medicaid Services (CMS) with regard to breakthrough therapies, fast track products, and those eligible for accelerated approval.

### **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 on the FDA user fee reauthorizations and urge you to advance the bipartisan ENACT Act (H.R. 3085/S. 1548) to increase the diversity of Alzheimer's clinical trial participants and ensure future approved therapies and diagnostics are safe and effective for the populations most likely to need the treatment.