



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 Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases"

July 29, 2021

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 Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases." 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. This statement provides an overview of policies to increase the diversity of Alzheimer's clinical trial participants, speed the discovery of Alzheimer's treatments and strengthen a nationwide public health infrastructure to ensure cutting edge research can be effectively and efficiently disseminated into local communities.

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 twice as likely to develop Alzheimer's and Hispanic Americans are 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 31 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 hold a markup on this important bipartisan bill, which already has the support of many Committee members, and look forward to working with the Chair and Ranking Member as it moves through the legislative process.

Investing in Alzheimer's Treatments

The Food and Drug Administration (FDA) recently approved the first treatment for Alzheimer's disease since 2003 and the first to address the underlying biology of Alzheimer's disease. The FDA determined there is substantial evidence that aducanumab (marketed as Aduhelm) reduces amyloid plaques in the brain and that the reduction in these plaques is reasonably likely to predict important benefits to patients.

This approval represents an important step forward in Alzheimer's research. This new treatment is pivotal, while not a cure. This is the first of a number of new treatments to come. We recognize the drug may work differently for everyone who takes it, and may not work for some individuals. Importantly, aducanumab was studied in and appropriate for people living with early Alzheimer's dementia and mild cognitive impairment (MCI) due to Alzheimer's who showed evidence of a buildup of amyloid plaques in the brain. The therapy has not yet been tested on people with more advanced cases of dementia or Alzheimer's disease.

The recent years of increased investment provided by Congress to the National Institutes of Health (NIH) have been integral to this and other promising therapeutic approaches to treating Alzheimer's disease. For example, NIH supported basic science investigations behind the discovery of immunotherapies like aducanumab, as well as translational research for next-generation immunotherapies. Additionally, the selection of participants for aducanumab clinical trials hinged on amyloid PET imaging, a technology that would not exist today without the publicly-funded research supported by NIH. The federal commitment, combined with unprecedented philanthropic support, provides the foundation for an optimistic view of the future, which is needed because there is much work to be done.

This is just the beginning of meaningful treatment advances. History has shown us that approvals of the first drug in a new category invigorates the field, increases investments in new treatments, and encourages greater innovation. We are hopeful that this drug is just the beginning for better treatments to come. Looking at the big picture of science, there is a crucial need for effective treatment options for diverse populations living in all stages of Alzheimer's. Alzheimer's must be addressed through multiple different pathways — more than just amyloid — with an eye toward effective combination therapies, pharmacological and nonpharmacological, that work at different stages of the disease.

While recent NIH funding increases have laid the foundation for breakthroughs in diagnosis, treatment, and prevention, and enabled significant advances in understanding the complexities of Alzheimer's, there is still much left to be done. We cannot leave any stone unturned. Investment in Alzheimer's research is only a fraction of what's been applied over time, with great success, to address other major diseases. Between 2000 and 2017, the number of people dying from Alzheimer's increased by 145 percent while deaths from other major diseases have decreased significantly or remained approximately the same. It is vitally important that NIH continues to build upon promising research advances. **An increase of \$289 million in Alzheimer's research at NIH in FY2022** would enable scientists to conduct more inclusive, efficient, and practical clinical

trials; increase knowledge of risk and protective factors in individuals and across diverse populations; discover better biomarkers to detect disease and monitor treatment response; pursue a precision medicine approach to detect the disease earlier and tailor treatment plans to an individual's unique symptoms and risk profile; and leverage emerging digital technologies and big data to speed discoveries. We need to continue to increase investment in Alzheimer's and dementia research to maximize every opportunity for success.

Strengthening Alzheimer's Public Health Response

As scientists continue to search for ways to cure, treat, or slow the progression of Alzheimer's through medical research, public health plays a critical role in promoting cognitive function and reducing the risk of cognitive decline. Now more than ever it is apparent how crucial it is to have an established infrastructure in place to respond to public health threats.

In 2018, Congress acted decisively to address Alzheimer's as an urgent and growing public health threat through the passage of the bipartisan BOLD Infrastructure for Alzheimer's Act (P.L. 115-406). This law authorizes \$100 million over five years for CDC to build a robust Alzheimer's public health infrastructure across the country focused on public health actions that can allow individuals with Alzheimer's to live in their homes longer and delay costly long-term nursing home care. Congress appropriated \$10 million for the first year of BOLD's implementation in FY20, which allowed CDC to award funding to three Public Health Centers of Excellence (PHCOE), focused on risk reduction, caregiving, and early detection, and 16 public health departments across the country. These state, local, and tribal public health department recipients are creating statewide dementia coalitions, hiring dementia coordinators, and developing or updating Alzheimer's and other dementia strategic plans. The \$15 million Congress appropriated for the second year of BOLD's implementation in FY21 funded seven additional public health departments to expand the impact of this crucial work in communities across the country.

The Alzheimer's Association is grateful to be leading the Dementia Risk Reduction PHCOE, focusing on community-level actions to reduce the risk of developing Alzheimer's and other dementia. Researchers are increasingly studying the impact that lifestyle behaviors may have on the risk of developing Alzheimer's and other dementia. The future of reducing Alzheimer's could be in treating the whole person with a combination of drugs and modifiable risk factor interventions, as we do now with heart disease. The Center will work with public health agencies on addressing social determinants of health with respect to dementia risk; capacity building to enable smaller public health agencies to engage in dementia risk reduction activities; and partnering with health systems in their communities to advance risk reduction.

Over 65 percent of American adults have at least one risk factor for dementia. Although risk factors like age, genetics, and family history cannot be changed, other risk factors can be modified to reduce the risk of cognitive decline and dementia. Examples of modifiable risk factors are physical activity, smoking, education, staying socially and mentally active, blood pressure, and diet. In fact, the 2020 recommendations of The Lancet Commission on dementia prevention,

intervention, and care suggest that addressing modifiable risk factors might prevent or delay up to 40 percent of dementia cases.

The Alzheimer's Association is leading a five-year clinical trial to evaluate a two-year intervention to see whether lifestyle interventions that simultaneously target multiple risk factors can protect cognitive function in older adults at increased risk for cognitive decline. The U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk (U.S. POINTER) will evaluate the effects of lifestyle interventions, like physical exercise, a healthier diet, cognitive and social stimulation, and self-management of heart and vascular health, on changes in cognitive function. It is crucial that forthcoming findings from studies like U.S. POINTER are translated into public health interventions across the country. Investing now in a robust public health infrastructure ensures cutting edge research can be effectively and efficiently disseminated into local communities.

While these BOLD implementation efforts are important steps forward, and we are grateful to this Subcommittee and Congress for the initial funding, CDC must receive the full \$20 million authorized in the law for FY2022 to ensure the meaningful impact that Congress intended. **The Alzheimer's Association and AIM urge Congress to include the full \$20 million for the third year of BOLD's implementation at CDC in FY2022.** Activities supported by the requested \$20 million in FY22 would enable CDC to award additional PHCOEs, focused on important priorities such as Tribal Health and avoiding preventable hospitalizations, and expand the number of state, local, and tribal public health departments across the country that receive funding for Alzheimer's public health activities.

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 and other members of Congress in a bipartisan way to help advance treatments and cures for neurodegenerative diseases, like Alzheimer's, through policies that increase the diversity of Alzheimer's clinical trial participants, speed the discovery of Alzheimer's treatments and strengthen a nationwide public health infrastructure to ensure cutting edge research can be effectively and efficiently disseminated into local communities.