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

United States Senate Health, Education, Labor, and Pension (HELP) Committee Hearing on "S. 3799, PREVENT Pandemics Act"

March 15, 2022

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit this statement for the record for the Senate HELP Committee's hearing on "S. 3799, PREVENT Pandemics Act." 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 this bipartisan legislation to strengthen the nation's public health and preparedness infrastructure in light of the COVID-19 pandemic, particularly when it comes to protecting the millions of Americans living with Alzheimer's and other dementia.

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.

Improving state and local public health security

The Association and AIM are encouraged to see language included in the bill to improve public health security, and specifically, how Public Health Emergency Preparedness Response (PHEP) Cooperative Grant Recipients are required to provide technical assistance for entities at increased risk for infectious disease outbreak particularly in places such as long-term care facilities. Since the beginning of the COVID-19 pandemic, there has been a clear need for standardized protocols in long-term care facilities regarding testing and care coordination. The Association is pleased to see that cooperative grant recipients will offer detailed descriptions of the types of technical assistance they will offer, which could help state public health entities identify their specific needs to prevent the spread of infectious diseases like COVID-19. The Alzheimer's Association and AIM released *COVID-19 Tips for Caregivers in Long-Term or Community-Based Care Settings* to ensure delivery of person-centered care by helping professionals respond quickly and appropriately to people living with dementia. These guidelines are grounded in the Association's evidence-based Dementia Care Practice Recommendations.

Addressing social determinants of health and improving health outcomes

The Alzheimer's Association and AIM strongly support the provisions to provide resources to help address disparities regarding social determinants of health. Underrepresented populations were disproportionately affected by the environmental, societal, and economic impact of the

COVID-19 pandemic, facing greater risk of losing a job or income and being more likely to be frontline workers with greater risk of exposure to COVID-19. Black and Hispanic Americans also suffered higher incidences of infection and hospitalization from COVID-19.

The bill encourages development of best practices to support improved health outcomes by offering technical assistance, training, and evaluation assistance to health departments, and support to establish and operate regional centers to develop, evaluate, and disseminate effective strategies to address social determinants of health. Racial and ethnic disparities in health and health care, such as those observed during the pandemic, also extend to dementia care. Stigma, cultural differences, awareness and understanding, and the ability to obtain a diagnosis, manage the disease, and access care and support services for dementia vary widely depending on race, ethnicity, geography, and socioeconomic status. Providing more resources to public and nonprofit entities will address an unmet need in helping to improve the gaps between social determinants of health and health outcomes.

Modernizing clinical trials

The Alzheimer's Association and AIM strongly support language requiring the Food and Drug Administration (FDA) to issue three guidances to modernize and improve clinical trials: the inclusion of digital health technologies in clinical trials to help improve recruitment, participation, and data collection; decentralizing clinical trials to improve trial participant engagement; and utilizing flexible and novel clinical trial designs to support the expedited development and review of drugs and biological products.

Reducing participation burden and allowing for the use of digital health technologies for clinical trials are crucial provisions in the AIM priority legislation, the bipartisan Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (S. 1548/H.R. 3085). The ENACT Act increases 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.

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 Black Americans, Hispanic Americans, 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 drug. There is therefore an urgent need for current and future research to include increased numbers of Black Americans, Hispanic Americans, 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%). 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. Community-based participatory research and engagement with community-based organizations (CBOs) are two strategies which can accomplish this goal.

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.

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 these 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 CBOs 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 consider the bipartisan, bicameral ENACT Act in order to modernize and improve clinical trials.

Facilitating the use of real-world evidence

The Alzheimer's Association and AIM support language pertaining to the use of real-world evidence (RWE) in supporting FDA's regulatory decision-making process, and would also include guidance on using RWE in regard to therapies and devices under Emergency Use Authorization.

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.

Improving FDA guidance and communication

The Association and AIM support this provision which requires the FDA to publish reports on best practices for communication with other federal agencies and outside stakeholders, as well as implementation measures for these best practices. We also support similar provisions in the bipartisan 21st Century Cures 2.0 Act, which encourages consistent and ongoing communication between the FDA and the Centers for Medicare & Medicaid Services (CMS) regarding breakthrough therapies, fast-track products, and those eligible for accelerated approval.

Conclusion

The Alzheimer's Association and Alzheimer's Impact Movement (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 people living with Alzheimer's and other dementia, including through the PREVENT Pandemics Act and the bipartisan Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act.