Alzheimer's Association and Alzheimer's Impact Movement Testimony United States Senate Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies National Institutes of Health and Centers for Disease Control and Prevention

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit outside witness testimony on the Fiscal Year (FY) 2022 appropriations for Alzheimer's and other dementia research and public health activities at the U.S. Department of Health and Human Services. Specifically, we respectfully request a \$289 million increase for Alzheimer's research at the National Institutes of Health (NIH) and \$20 million for implementation of the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act (P.L. 115-406) at the Centers for Disease Control and Prevention (CDC).

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 brain disorder that damages and eventually destroys brain cells, leading to a loss of memory, thinking, and other brain functions. Ultimately, Alzheimer's is fatal. We have yet to celebrate the first survivor of this devastating disease.

In addition to the suffering caused by the disease, Alzheimer's is also creating an enormous strain on the health care system, families, and federal and state budgets. The annual cost for all individuals with Alzheimer's or other dementia will total \$355 billion for health care, long-term care, and hospice care in 2021. This does not include the over \$250 billion in unpaid caregiver costs. The U.S. taxpayer-funded federal health care programs Medicare and Medicaid are expected to cover about \$239 billion, or 67 percent, of these costs this year. 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.

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 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.

Addressing Alzheimer's as a Public Health Crisis

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 Act. 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 will help fund additional public health departments and expand the impact of this crucial work into more 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. Finally, as Alzheimer's is one of the most prevalent chronic diseases facing our nation, we look forward to the day that the Subcommittee and CDC elevate Alzheimer's and other dementia to the Division level as with other major chronic diseases.

Conclusion

The Alzheimer's Association and AIM appreciate the steadfast support of the Subcommittee and its priority setting activities. We urge the Subcommittee and Congress to provide an additional \$289 million for Alzheimer's research activities at NIH and \$20 million for full implementation of the BOLD Infrastructure for Alzheimer's Act at CDC in FY 2022.