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Editorial

Impact of Aduhelm Approval on Care and Policy

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The more than 6 million Americans living with Alzheimer's disease face a future filled with progressive loss of their cognitive abilities ending with certain death (1). They will eventually require help in all aspects of daily living, and that help is provided by over 11 million unpaid caregivers (2). At this time, Alzheimer's remains a clinical diagnosis and unfortunately, many individuals who would meet the diagnostic criteria are not diagnosed (3). The Food and Drug Administration's (FDA) accelerated approval of aducanumab (Aduhelm™) as a treatment for Alzheimer's makes early detection, accurate diagnosis and quality care even more critical, to ensure individuals receive the most benefit at the earliest point possible. Furthermore, the approval of this treatment opens up a new landscape in Alzheimer's care that comes with many implications for effective public policy to enhance access to quality care.

This drug is a complement to comprehensive care, not a substitute for care. All individuals living with Alzheimer's, at every stage of the disease, should have access to high quality comprehensive care, including care planning, management, and coordination. However, access to quality dementia care is limited for many older adults, due to a shortage of specialty physicians (4). Primary care providers have limited capacity and expertise to assist in all the areas of need associated with dementia (5), and especially traditionally non-medical activities such as counseling, education, and referrals to community-based organizations (6). Meeting the growing demand for dementia care requires increasing the specialty workforce and improving capacity in primary care, including the expansion of successful collaborative and coordinated care models/programs that use primary care providers. Pilot programs for individuals with dementia have reduced hospital and emergency room visits and nursing home placement (7). A change in payment structure to value-based payment is also necessary to enable effective dementia care management. The Comprehensive Care for Alzheimer's Act (S. 1125/H.R. 2517) would ask the Center for Medicare & Medicaid Innovation (CMMI) to implement a dementia care management model to test the effectiveness of comprehensive care management services. This dementia care management model would provide comprehensive care services including caregiver education and support, ensure patients have access to providers with dementia care expertise, and reimburse providers through payment based on performance.

Black and Hispanic Americans are at increased risk for Alzheimer's and related dementia yet have been underrepresented in the Aduhelm clinical trials and most other clinical trials for dementia treatments in the United States. Stigma, cultural differences, awareness and understanding, 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 (8). The Alzheimer's Association supports the bipartisan Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act (S. 1548/H.R. 3085), which 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.

The accelerated approval of Aduhelm is an important step in addressing the underlying biology of Alzheimer's disease, as the first FDA-approved treatment to reduce one of the defining brain changes of Alzheimer's, known as amyloid plaques. However, it is not a cure, and more research is needed to determine if removing amyloid plaques will be effective to slow clinical decline. It is also very clear that more research is necessary to advance other therapeutic approaches that include the acceleration of anti tau approaches and so many others, for the ultimate goal of treating this complex disease with combination therapies and to treat populations that respond differently. That is why it is imperative that Congress continue its commitment to increased investments in Alzheimer's research at the National Institutes of Health (NIH). 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, but there is still much left to be done. Investment in Alzheimer's research is only a fraction of what's been applied over time, with great success, to address other major diseases. An increase of $289 million in Alzheimer's research at the NIH in Fiscal Year 2022 would enable scientists to maximize every opportunity for success.

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Until disease modifying treatments are developed and widely available and accessible, a public health approach to Alzheimer's disease plays a critical role in promoting prevention, early detection, accurate diagnosis, comprehensive care management, and support for caregivers. Through their mandated responsibility to protect the public's health, governmental public health agencies can advance proven strategies to support and maintain the health, well-being, and productivity of caregivers. 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. This law authorizes $100 million over five years for the Centers for Disease Control and Prevention (CDC) to build a robust Alzheimer's public health infrastructure across the country focused on public health actions. Congressional appropriations have allowed CDC to award funding to three Public Health Centers of Excellence focused on risk reduction, caregiving, and early detection, and 16 public health departments across the country. While these BOLD implementation efforts are important steps forward, CDC must receive the full $20 million authorized in the law for FY2022 to ensure the meaningful impact that Congress intended.

Early detection, an accurate diagnosis and access to dementia care are now more important than ever. The possibility for some individuals living with dementia to benefit from a new type of treatment presents new opportunities and new challenges for public and private leadership, to increase clinical capabilities and institute policies for access to quality care. The Alzheimer's Association will do everything in its power to ensure access to any treatment, diagnostic tests needed during the treatment process, and other associated costs for all who could benefit. Ensuring access is part of our commitment to ensuring quality, person-centered care for all who are affected by this devastating disease. The Alzheimer's Association likewise calls on leaders in health care and health policy to improve access to dementia detection, diagnosis and care, and the Association is here to work with others to this end.

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References

1. Rajan KB, Weuve J, Barnes LL, McAninch EA, Wilson RS, Evans DA. Population estimate of people with clinical AD and mild cognitive impairment in the United States (2020-2060). Alzheimers Dement 2021;17. In press.
2. Alzheimer's Association. 2021 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2021;17(3).
3. Alzheimer's Association. 2021 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2021;17(3).
4. Alzheimer's Association. 2020 Alzheimer's disease facts and figures. Alzheimer's Dement., 16: 433.
5. Bernstein et al. 2019
6. Reuben et al., 2003; Reuben et al., 2010
7. Alzheimer's Association. 2020 Alzheimer's disease facts and figures. Alzheimer's Dement., 16: 439.
8. Alzheimer's Association. 2021 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2021;17(3).

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