The Honorable Roger Wicker
United States Senate
425 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Amy Klobuchar
United States Senate
425 Dirksen Senate Office Building
Washington, D.C. 20510

September 5, 2024

Dear Senators Wicker and Klobuchar:

On behalf of the Alzheimer's Association and the Alzheimer's Impact Movement (AIM), including our nationwide networks of advocates, thank you for your continued leadership on issues and legislation important to Americans with Alzheimer's and other dementias and their caregivers. We write to express our support for the bipartisan Better Empowerment Now to Enhance Framework and Improve Treatments (BENEFIT) Act of 2023 (S. 526), which would amend the new drug approval process to require a risk-benefit assessment framework to consider patient experience data submitted by the medical product sponsor or another party as part of the risk assessment framework for new drugs.

Nearly 7 million Americans aged 65 and older lived with Alzheimer's dementia in 2024. Total payments for all individuals with Alzheimer's or other dementias are estimated at $360 billion (not including unpaid caregiving) in 2024. Medicare and Medicaid are expected to cover $231 billion or 64 percent of the total health care and long-term care payments for people with Alzheimer's or other dementias, which are projected to increase to more than $1.1 trillion by 2050. These mounting costs threaten to bankrupt families, businesses, and our health care system. Unfortunately, our work is only growing more urgent.

Alzheimer's is one of the most significant health issues facing Medicare beneficiaries and their families, and now, for the first time, treatments have been approved by the FDA that change the course of the disease. There are two disease modifying therapies currently on the market to treat early Alzheimer's disease, including people living with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease who have confirmation of elevated beta-amyloid in the brain, Lecanemab (marketed as Leqembi) and Donanemab (marketed as Kinsula). This is just the beginning of meaningful treatment advances. History has shown that approvals of the first drugs in a new category invigorate the field, increase investments in new treatments, and encourage greater innovation. The progress we've seen in this class of treatments and the diversification of treatment types and targets over the past few years provide hope to those impacted by this devastating disease, but the work is not done, and by continuing to include the patient experience and voice could help provide a meaningful impact on future drug candidates in the approval pipeline for future generations still struggling with this disease.

Congress has made significant strides in ensuring that patient perspectives are factored into the FDA's evaluation of drug candidates and other medical products. Thanks to updates in the Prescription Drug User Fee Act and the 21st Century Cures Act provisions, the FDA now has various programs and policies to assess potential therapies' benefits and risks and collect and consider patient feedback. Despite these advancements, there are still notable gaps, including the need for a legal mandate requiring the FDA to incorporate patient experience or patient-focused drug development (PFDD) data into its risk-benefit analysis framework.

By establishing a patient experience, patient-focused drug development (PFDD), the BENEFIT Act would amend the Food, Drug, and Cosmetic Act to ensure information from product sponsors or third parties like patient advocacy organizations or academic institutions, which is integral to the risk-benefit assessment process as a risk assessment framework for new drugs. By doing so, the Act will improve transparency and accountability, signaling to all stakeholders that patient experience data will be vital to the FDA's review process. This, in turn, will encourage the continued development and refinement of scientifically rigorous and meaningful tools and data.

The Alzheimer's Association and AIM sincerely appreciate your continued leadership on behalf of all Americans living with Alzheimer's and other dementias. We look forward to continuing to work with you to advance this bill. If you have questions about this or any other legislation, please contact Jennifer Pollack, Director of Access Policy, at jpollack@alz-aim.org or at 202.638.7032.

Sincerely,

Rachel Conant
Executive Director, Alzheimer's Impact Movement
Senior Vice President, Public Policy, Alzheimer's Association