Congress of the United States
Washington, DC 20510

March 31, 2022

The Honorable Xavier Becerra
Secretary Health and Human Services
200 Independence Avenue, SE
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure,

We write to express our strong concern regarding the Centers for Medicare and Medicaid Services's (CMS) proposed non-coverage determination for monoclonal antibodies for the treatment of Alzheimer's Disease (AD) issued on January 11, 2022. We urge you to re-propose or revise the proposed decision and issue a final decision that would provide coverage for treatments as indicated by the Food and Drug Administration (FDA) label, while continuing to carefully assess the effects of drugs in real-world populations. Further, we request that CMS ensure that its final coverage decision will not reinforce barriers to equitable access for communities historically excluded from clinical research.

We understand CMS's expressed desire to gather evidence on new Alzheimer's treatments, but this proposed Coverage with Evidence Development (CED) framework effectively denies access to an entire – and currently the only—known class of drugs that is reasonably likely to affect the course of the disease. We are very concerned about the impact that this proposed rule would have on Alzheimer's patients – including patients of color and patients with a higher risk of Alzheimer's such as people with Down Syndrome– and their families who have waited far too long for a new Alzheimer's therapeutic. As thousands of patients per day progress to later stages of the disease and become ineligible for these therapeutics, Americans cannot wait while CMS further delays access.

Latinos are 1.5 times as likely and African Americans are two times as likely to develop Alzheimer's when compared to non-Hispanic White Americans.[1] More than 60 percent of people living with Alzheimer's are women and more than 60 percent of dementia caregivers are women. When seeking Alzheimer's care, 34% of Asian Americans experienced some form of discrimination compared to 9% of white Americans.2 Additionally, it is estimated that greater than 90 percent of people with Down Syndrome over the age of 60 develop AD. Despite this higher risk, these communities face major gaps in access to Alzheimer's diagnostics, treatments, and research. As drafted, the proposed NCD will severely limit access to current and future FDA approved treatments for these communities.

1 https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf
2 https://www.medicalnewstoday.com/articles/dementia-in-the-asian-community#prevalence

CMS's decision to restrict access to participants enrolled in qualifying randomized controlled trials (RCT) in a hospital outpatient setting will limit coverage only to individuals with access to traditional clinical trial sites.[3] On average, these trial sites have posed significant challenges for people of color and lower income families in Alzheimer's research studies from both a design and recruitment standpoint. The trials themselves and the requirement that the drugs be administered in a hospital outpatient setting – thereby ruling out many alternative sites of care frequented by disadvantaged communities – may inadvertently exclude people of color, people who are low income, people who have a disability, and people who live in rural areas.

A progressive disease such as Alzheimer's by its nature requires the earliest possible intervention, which is the direction science is moving. The class of drugs covered by the decision is aimed at delaying the progression of disease for persons in the early stages of Alzheimer's disease. By attacking the disease early, though, evidence of direct clinical benefit is very hard to discern. Waiting for the slope of the disease to grow steeper when clinical benefit is easier to detect is almost certainly too late to help the patient. This is the essence of the FDA's accelerated approval pathway and why scientists are dependent on surrogate endpoints (such as beta amyloid) for evidence of efficacy.

We believe that as more evidence is gathered, patients and their families should be given the choice as whether, when faced with a disease that is a death sentence, to access approved AD treatments in consultation with their doctors. This is commonly accepted practice for cancer patients, and we believe Alzheimer's patients should be given similar deference.

Like you, we, and millions of other American families, have personally experienced the tragic consequences of AD. While there may be legitimate, appropriate needs to gather data about treatments in the Medicare population, drugs that have been found to be safe and effective, or reasonably likely to be so, by the FDA should be available to the Medicare population in consultation with their doctors. We are concerned that these additional CMS requirements to confirm the safety and effectiveness of the AD treatments for Medicare patients duplicates the existing FDA approval process which has already been completed by one AD treatment. Furthermore, we are deeply concerned with the unprecedented requirement of randomized controlled trials for an entire class of drugs, including an FDA-approved product and multiple drugs at various stages in the development pipeline, that will preemptively restrict access to an entire class of drugs and discourage ongoing and future research and development in AD treatments or cures.

In summary, we believe there is a way to gather additional evidence where needed while not denying access to patients in desperate circumstances in the meantime. These mechanisms include the data that will be collected through the Phase IV Aduhelm trials, the Phase III results for multiple other monoclonal antibodies for treating Alzheimer's disease, as well as the current FDA adverse reaction reporting mechanisms which are well respected and effective.

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3 https://www.cms.gov/newsroom/press-releases/cms-proposes-medicare-coverage-policy-monoclonal-antibodies-directed-against-amyloid-treatment

Thank you for all you and the department are doing to fight Alzheimer's disease. We urge you to ensure that CMS makes the significant changes needed as outlined above. We cannot have another generation of Alzheimer's patients left without access to therapeutics.

Sincerely,

Nanette Diaz Barragán
Member of Congress

Barbara Lee
Member of Congress

Brett Guthrie
Member of Congress

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Member of Congress

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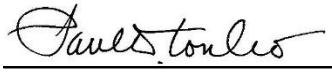

Paul D. Tonko
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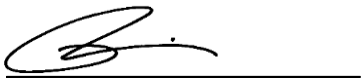

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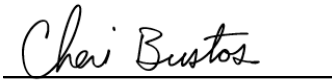

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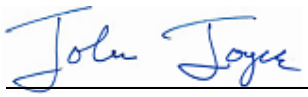

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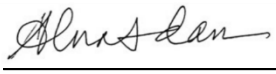

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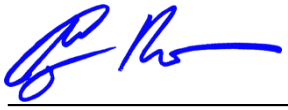

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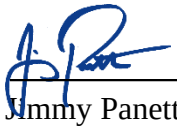

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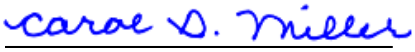

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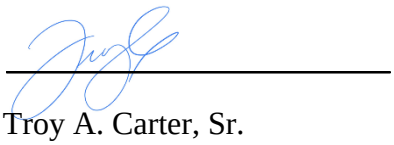

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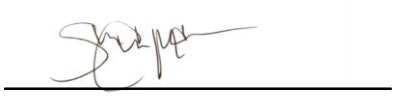

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