



The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health, Education, Labor and Pensions
Washington D.C. 20510

April 3, 2024

Dear Senator Cassidy:

The Alzheimer's Association and the Alzheimer's Impact Movement (AIM) appreciate the opportunity to provide comments on the request for information on laboratory developed tests (LDTs) and clinical diagnostics.

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support, and research. The Alzheimer's Impact Movement (AIM), the advocacy arm of the Alzheimer's Association, is a nonpartisan, nonprofit organization and works in strategic partnership with the Alzheimer's Association to make Alzheimer's a national priority. Today, there are nearly 7 million Americans living with Alzheimer's. As the size and proportion of the United States population age 65 and older continue to increase, the number of Americans with Alzheimer's and other dementias will grow: 13 million people 65 and older may have the disease by 2050. With new much-needed therapies and diagnostics coming to market, we believe increased oversight of LDTs to ensure their scientific rigor is appropriate.

In this new era of treatments that change the progression of the disease and new innovation around testing for Alzheimer's and related dementia, scientific rigor and confidence in the science is particularly important. Early and accurate diagnoses have always been a top priority for the Alzheimer's Association and the Alzheimer's Impact Movement, and individuals need a variety of diagnostic options including blood based biomarkers, as some people may not be able to access imaging centers for amyloid PET scans or may not be eligible for cerebrospinal fluid tests, for example.

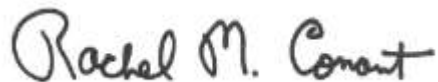
We previously responded to the FDA's proposal on LDTs. We believe it is important to drive good science in the development of new LDTs and provide a more rigorous review of them which will, in turn, inspire confidence in patients and clinicians. Tests may also be critical for disease staging and progression, treatment decisions, treatment or safety monitoring, and, in the future, a valuable indicator of susceptibility or risk for Alzheimer's or another dementia, once again requiring scientific rigor and integrity.

We encouraged the FDA in the public comment period to consider potentially detrimental impacts to other stakeholders that rely on LDTs. For instance, therapeutic products currently in development that rely on existing laboratory developed tests for screening eligible participants or monitoring or evaluating their

disease progression may be halted until the agency can review and approve the LDTs, delaying progress in the development of the investigational therapy and ultimately access for patients. We also encouraged the FDA to consider any chilling effect the proposal may have on future test development, particularly for areas with unmet medical needs, and take steps to work with industry to encourage rapid innovation. Finally, we strongly urged the agency to share with the public how it intends to ensure adequate staffing and resources to implement this oversight without disrupting or delaying its other crucial functions.

Thank you for the opportunity to comment. The Alzheimer's Association and AIM would be glad to serve as a resource for the Committee as it considers these important issues and how they relate to individuals living with Alzheimer's and related dementias. Please contact Jennifer Pollack, Director, Access Policy, at 202-638-7032 or jpollack@alz-aim.org if you have questions or if we can be of additional assistance.

Sincerely,

A handwritten signature in black ink that reads "Rachel M. Conant". The signature is written in a cursive, flowing style.

Rachel Conant
Vice President, Federal Affairs, Alzheimer's Association
Executive Director, Alzheimer's Impact Movement