

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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April 16, 2024

Dr. Joanne Pike, Dr. P.H.
President and CEO
Alzheimer's Association
225 North Michigan Avenue, Floor 17
Chicago, IL 60601

Dear Dr. Pike:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 14, 2024, to testify at the hearing entitled "Legislative Proposals to Support Patients and Caregivers."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, May 1, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Brett Guthrie

Chair

Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Gus Bilirakis

1. Can you provide specific examples of how the National Alzheimer's Project has helped advance Alzheimer's research and care and why this National Plan model has worked well to coordinate at the federal level?

As you know, the National Alzheimer's Project Act (NAPA) (P.L. 111-375), unanimously approved by Congress in 2010 and signed into law in 2011, required the Department of Health and Human Services (HHS) to create a national strategic plan to address the Alzheimer's crisis and to update it annually. Prior to 2011, there was no cohesive national plan in the United States to address one of the country's most deadly diseases: Alzheimer's. The first National Plan to Address Alzheimer's Disease ("the National Plan") was released in 2012 and continues to be a vital, comprehensive framework for addressing this disease on a national level.

The National Plan focuses on goals to promote rapid research on Alzheimer's disease and other dementia and improve the delivery of clinical care and services for individuals and their families. It is updated annually to reflect advances and developments in the field of Alzheimer's and other dementia. The most recent update to the Plan was in December 2023, focusing on successes in care and support, treatment, and research we have seen over the past year.

The National Plan originally contained five goals: prevent and effectively treat Alzheimer's disease by 2025; optimize care quality and efficiency; expand support for people with Alzheimer's disease and their families; enhance public awareness and engagement; and track progress and drive improvement. In 2021, the Advisory Council added a sixth goal: accelerate action to promote healthy aging and reduce risk factors for Alzheimer's disease and related dementias.

The National Plan has led to great advancements in Alzheimer's research. For example, the National Institutes of Health (NIH) has held annual dementia research summits since 2012 to help identify research priorities. The most recent summit, which focused on care and support research, was held in March 2023. Since the Plan has been in place, the investment of funds by the Administration and additional funds provided by Congress has led to a 650 percent increase in NIH research funding for Alzheimer's disease in a decade. Further, the Plan calls for coordinating research efforts with international public and private entities - the G8 nations held a dementia summit in 2013 and the World Health Organization approved a global action plan on dementia in 2017.

The Health Resources and Services Administration (HRSA) developed a uniform curriculum on Alzheimer's to ensure the workforce has the necessary skills to provide high-quality dementia care. Finally, recent updates to the Plan include action items on better understanding health disparities and expanding access to care planning tools.

2. To what extent does untreated hearing loss contribute to the development or progression of Alzheimer's Disease and related dementias?

Hearing loss has also been strongly associated with increased rates of cognitive decline and dementia risk. Older adults with severe hearing impairment often have widespread cognitive impairments. A recent meta-analysis found that age-related hearing loss may be a modifiable risk factor for cognitive decline, cognitive impairment, and dementia.¹

There is currently insufficient evidence to determine whether preventing disease or injury to the sensory organs can improve cognitive trajectories or prevent/delay dementia. The mechanisms that link sensory impairment to cognitive decline are likely complex. Some processes, such as vascular disease, may concurrently damage both the brain and sensory organs. Additionally, aging may contribute to a bidirectional relationship between peripheral sensory function and central cognitive function: age-related changes in sensory function may worsen cognition, while age-related changes in brain function may alter how sensory input is perceived. Finally, sensory impairments may lead to cognitive and physiological outcomes, such as excess cognitive load (when your working memory receives more information than it can handle), impairments in brain structure and function, social isolation, depression, and reduced activity - all of which in turn can result in cognitive decline.

3. Does the Alzheimer’s Association have any data it could share with this committee on the impact of improved access to audiology services on cognitive function and dementia risk in older adults?

In July, at the Alzheimer’s Association International Conference® (AAIC®) 2023, in Amsterdam, Netherlands, results from the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, the largest randomized, controlled clinical trial of hearing aids for reducing long-term cognitive decline in older adults, were reported for the first time². While the results were negative in the total study population, the hearing intervention slowed cognitive decline in older adults with mild to moderate hearing loss by 48% in a pre-specified segment of the study population consisting of 238 people participating in an ongoing observational study of heart health. The findings from the ACHIEVE study were simultaneously published in *The Lancet*³.

Findings from the ACHIEVE study suggest that older adults at increased risk for cognitive decline and dementia who also have hearing loss may benefit the most from this hearing intervention within three years. According to the ACHIEVE researchers, the hearing intervention may slow down the decline in thinking and memory by making listening easier for the brain, or by helping people remain more socially and physically active. More research is needed to investigate how hearing aids and counseling provide cognitive benefits and to understand the longer-term benefits of hearing intervention.

4. In your experience, what are some of the challenges faced by individuals with Alzheimer's Disease or related dementias who also have untreated hearing loss?

a. How do these challenges impact their quality of life and ability to communicate?

Individuals with Alzheimer’s disease and untreated hearing loss face additional challenges with communication, participation in conversations and social engagements, and impact on overall

¹ <https://www.alz.org/media/Documents/sensory-impairment-ph.pdf>.

² https://aaic.alz.org/releases_2023/hearing-aids-slow-cognitive-decline.asp

³ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(23\)01406-X/abstract](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01406-X/abstract)

quality of life. It may also impact some of the assessments used to adjudicate the extent of cognitive decline.

As part of the normal course of disease progression, the ability to communicate will become more difficult for the person living with Alzheimer's. Untreated hearing loss will make communication more difficult and may result in the person exhibiting dementia-related behavior as a form of communication.

5. From a policy perspective, what measures do you believe could be implemented to improve access to audiology services for older adults, particularly those at risk of or living with Alzheimer's disease or related dementias?

Currently, I serve as a member of the Advisory Council on Alzheimer's Research, Care, and Services. In the 2023 update of the National Plan under Goal 6, Accelerate Action to Promote Health Aging and Reduce Risk Factors for Alzheimer's Disease and Related Dementias, strategy 6.B focused on facilitating the translation of risk reduction research findings into clinical practice. The Food and Drug Administration (FDA) was responsible for action 6.B.2. to increase access to hearing aids for individuals with hearing loss. Hearing loss has been identified as a risk factor for AD/ADRD, and recent research has demonstrated that hearing aid use is associated with reduced dementia risk. Hearing aids are often expensive, making them inaccessible to many individuals who could benefit. In October 2022, the FDA established a new regulatory category for over-the-counter (OTC) hearing aids and made related amendments to update the regulatory framework for hearing aids. Among other things, the final rule provides for reasonable assurance of the safety and effectiveness of OTC hearing aids and aims to foster innovation in hearing aid technology. It also is expected to improve access to hearing aids, as OTC options are easier to obtain and less expensive.

I do not have specific measures that could be implemented to improve access to audiology services for older adults; however, I recognize the importance of access to audiology services for older adults, especially those at risk of or living with Alzheimer's disease or other dementia. I look forward to keeping your office updated as research on this important issue progresses.

6. Are there any ongoing initiatives or programs led by the Alzheimer's Association aimed at addressing the intersection of hearing loss and dementia?

a. If so, could you provide some insight into these initiatives and their potential impact?

The Alzheimer's Association's BOLD Public Health Center of Excellence on Dementia Risk Reduction works to translate the science of dementia risk reduction into public health action. The Center has published briefs reviewing the science of dementia risk factors, including sensory impairments, and the public health implications, and has released state fact sheets and county-level heat maps on the prevalence of certain risk factors. The Center hosted a workshop in 2022 on social determinants of health-related to dementia risk and a two-day Dementia Risk Reduction Summit in 2023 that highlighted ways for public health to promote brain health.

The New York University Grossman School of Medicine has been awarded funding from the Centers for Disease Control and Prevention (CDC), establishing it as a BOLD Public Health Center of Excellence (PHCOE) dedicated to improving the early detection of dementia. One of

three such PHCOEs funded under the CDC's Alzheimer's Disease and Related Dementias initiative, the Center of Excellence is a national resource supporting the implementation of evidence-based and evidence-informed public health strategies that increase capacity for early detection of dementia and has added addressing sensory health, including hearing loss, to their recommendations.

As scientists continue to search for a way to prevent, cure, or slow the progression of Alzheimer's through medical research, public health plays an important role in promoting cognitive function and reducing the risk of cognitive decline. The BOLD Infrastructure for Alzheimer's Act (P.L. 115-406) has led to great progress in building and strengthening the Alzheimer's public health infrastructure nationwide through the Public Health Centers of Excellence. However, this important program is set to expire this year. It is vital that Congress swiftly passes the bipartisan BOLD Reauthorization Act of 2024 (H.R. 7218/S. 3775) to extend this important law and continue to invest in a nationwide Alzheimer's public health response that will help further population-level improvements, achieve a higher quality of life for those living with the disease while furthering research on risk factors such as sensory impairment. I am grateful for your support of this important bill and look forward to working with you during the legislative process.

7. In your opinion, how important is it for healthcare providers, caregivers, and policymakers to recognize and address the link between hearing loss and Alzheimer's Disease or related dementias?

a. What steps can be taken to raise awareness about this issue and promote early intervention?

Maximizing our brain's health will also extend to addressing sensory health, including hearing loss, and is incredibly important for healthcare providers, caregivers, and policymakers alike when considering treating this vulnerable population.

The Alzheimer's Association's BOLD Public Health Center of Excellence on Dementia Risk Reduction translates the latest science on dementia risk reduction into actionable tools, materials, and messaging that public health agencies can use to reduce dementia risk for all people — including those in diverse, underserved, and higher-risk communities. The Alzheimer's Association is working with public health agencies to promote risk reduction strategies in communities across the country. The Center of Excellence helps implement strategies from [*The Healthy Brain Initiative: State and Local Road Map for Public Health*](#) and [*Healthy Brain Initiative Road Map for Indian Country*](#), which provide frameworks for public health agencies to lead with urgency and act for impact in their communities to improve brain health across the life course and support caregivers.

As scientists continue to search for a way to prevent, cure, or slow the progression of Alzheimer's through medical research, public health plays an important role in promoting cognitive function and reducing the risk of cognitive decline. The BOLD Infrastructure for Alzheimer's Act (P.L. 115-406) has led to great progress in building and strengthening the Alzheimer's public health infrastructure nationwide through the Public Health Centers of Excellence. However, this important program is set to expire this year. It is vital that Congress swiftly passes the bipartisan BOLD Reauthorization Act of 2024 (H.R. 7218/S. 3775) to extend

this important law and continue to invest in a nationwide Alzheimer's public health response that will help further population-level improvements, including raising awareness on sensory health and promoting early intervention. I am grateful for your support of this important bill and look forward to working with you during the legislative process.

8. How can collaboration between organizations like the Alzheimer's Association and other stakeholders, such as government agencies, healthcare providers, and advocacy groups, help address the multifaceted challenges associated with hearing loss and dementia?

By fostering collaboration among various stakeholders, including advocacy groups, government agencies, healthcare providers, and research institutions, we can better address the complex challenges associated with hearing loss and dementia. For example, in the 2023 update of the [National Plan to Address Alzheimer's Disease](#), under Goal 6, Accelerate Action to Promote Health Aging and Reduce Risk Factors for Alzheimer's Disease and Related Dementias, action 6.A.7 focused on continuing clinical trials on the most promising health promotion interventions, which included research funded by the National Institute on Aging on the impact of hearing loss and dementia risk in older adults. Through the Aging and Cognition Health Evaluation in Elders Study, investigators recently found that a hearing intervention may reduce cognitive change over three years in older adults at increased risk for cognitive decline but had no effect in those at decreased risk for cognitive decline. These findings suggest that older adults at increased risk for cognitive decline who also have hearing loss may benefit the most from hearing interventions.

The Honorable Neal Dunn, M.D.

1. Genetic counselors play an essential role when there are genetic aspects to disease and conditions. They ensure patients and family members who would benefit from genetic testing gain access to appropriate testing and ensure physicians and their patients understand test results well. Genetic counselors also help navigate follow-up care and identify clinical trials that may be of benefit. Today, Medicare does not reimburse genetic counselor services. Should this policy change?

In the new era of treatment for Alzheimer's disease, genetic testing for APOE-e4 will become more standard practice as the treatments advance. There are two categories of genes that influence whether a person develops a disease: (1) risk genes and (2) deterministic genes. Researchers have identified hereditary Alzheimer's genes in both categories. Risk genes increase the likelihood of developing a disease but do not guarantee it will happen. Researchers have found several genes that increase the risk of Alzheimer's. APOE-e4 is the first risk gene identified and remains the gene with the strongest impact on risk. Researchers estimate that between 40-65% of people diagnosed with Alzheimer's have the APOE-e4 gene. Those who inherit one copy of APOE-e4 from their mother or father have an increased risk of developing Alzheimer's. Those who inherit two copies from their mother and father have an even higher risk, but not a certainty. In addition to raising risk, APOE-e4 may tend to make symptoms appear at a younger age than usual. An estimated 20-30 percent of individuals in the United States have one or two copies of APOE-e4; approximately two percent of the U.S. population has two copies of APOE-e4.

Genetic tests are available for both APOE-e4 and the rare genes that directly cause Alzheimer's. However, health care professionals do not currently recommend routine genetic testing for Alzheimer's disease. Testing for APOE-e4 is sometimes included as a part of research studies.

Although the hereditary genes that cause "familial Alzheimer's" are rare, their discovery has provided important clues that help our understanding of Alzheimer's. All of these genes affect the processing or production of beta-amyloid, the protein fragment that is the main component of plaques. Beta-amyloid is a prime suspect in the decline and death of brain cells. Two treatments, aducanumab (Aduhelm®) and lecanemab (Leqembi®) have demonstrated that removing amyloid from the brain is reasonably likely to reduce the cognitive and functional decline in people living with early Alzheimer's. Several other amyloid-targeting therapies are also in development.

Two international investigations are underway to gain further insight into Alzheimer's disease by studying individuals with deterministic Alzheimer's genes: (1) The Dominantly Inherited Alzheimer Network (DIAN), funded by the NIA, includes 10 flagship research centers in the United States, the United Kingdom, and Australia. (2) The Alzheimer's Prevention Initiative (API) focuses on an extended family in Antioquia, Colombia, in South America. At 5,000 members, this is the world's largest family in which a gene that causes Alzheimer's has been identified. API collaborators include DIAN.

Genetic tests are available for both APOE-e4 and the rare genes that directly cause Alzheimer's. The Alzheimer's Association cautions against routine genetic testing for Alzheimer's disease risk until an individual has received proper counseling and understands the information necessary to make an informed decision, including the social and economic factors that could be impacted by having this genetic information. However, there may be specific instances when an individual living with Alzheimer's should discuss genetic testing with their physician, as the results could impact a treatment decision. For example, people who are eligible to take anti-amyloid treatments such as lecanemab may be at an increased risk for a serious side effect if they carry the APOE-e4 gene. Individuals should seek the services of a genetic counselor before and after deciding to undergo testing.