Written testimony prepared by Jason Karlawish, MD, for the Senate Committee on Finance, Subcommittee on Health Care, at the hearing titled, “Alzheimer’s Awareness: Barriers to Diagnosis, Treatment and Care Coordination,” 20 November 2019. Room 215, Dirsken Senate Office Building.

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Thank you, Senators Toomey and Stabenow, for you and your colleagues’ invitation to talk to the Senate Committee on Finance, Subcommittee on Healthcare, about the state of research and care for persons living with Alzheimer’s disease. I am a physician trained in geriatric medicine and researcher at the University of Pennsylvania. I am the co-director of the Penn Memory Center, a center dedicated to the diagnosis, care and research for persons living with Alzheimer’s disease and their family members.[1]

My overall message is this: America has made remarkable, even spectacular, progress with research to develop better treatments, and to understand the natural history and costs of the disease.

America has not made the same progress with diagnosis, treatment, and care coordination, or, in a word, care.

America has made tremendous progress in research to understand the natural history and costs of Alzheimer’s disease and therefore to improve diagnosis and treatment.

In 1981, the physician and National Book Award-winning essayist Lewis Thomas published “The Problem of Dementia” in the popular science magazine Discover.[2] The esteemed and accomplished former dean of New York University’s and Yale University’s medical schools and, at time of this essay, President of Memorial Sloan-Kettering Cancer Center, pushed Congress to give special consideration and high priority for one particular disease: Alzheimer’s disease. He called it “the disease-of-the-century” and “the worst of all diseases.” He urged Congress to use its budgetary powers to exercise a target and frontal assault on the disease. It took congress some years to listen to his admonition, but you did. Below, I highlight three of your accomplishments:

- In April 1990, at the joint senate-house hearing “Alzheimer’s – the Unmet Challenge for Research and Care” Senator Mark Hatfield, Republican of Oregon, brought room 2322 of the Rayburn House Office Building to a hushed, plaintive silence as he opened the hearing. “My father was a third generation in our family of blacksmithing…” He told his colleagues about a man of extraordinary physical strength who became so forgetful that he lived his last years in a nursing home, “a powerful man reduced to practically nothing

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[1] The services and research performed at the Penn Memory Center are described at www.pennmemorycenter.org

[2] Lewis Thomas. “On The Problem of Dementia.” *Discover*. August 1981, pp 34-36. Reprinted in: “Late Night Thoughts on Listening to Mahler’s Ninth Symphony. The Viking Press, New York: 1983, page 121.

– as almost a vegetable." You listened to your colleague. Senator Hatfield's CARE Act increased funding to NIH by $100 million, a doubling in research funds.

- On January 4, 2011, President Obama signed the National Alzheimer's Project into law. This created and maintains an integrated National Alzheimer's Plan to address the disease.[3] All Federal agencies and departments whose charge affects the lives of persons with Alzheimer's disease participate in providing information and coordinating research and services. Advisory Council members are drawn from across multiple Federal departments and agencies as well as 12 members from outside the Federal government including caregivers, patient representatives, researchers, and "voluntary health association representatives." The plan is accelerating the development of treatment to prevent, halt, or reverse the disease, improve diagnosis, and coordinate care and treatment.

- In December 2014, Congress passed the "Alzheimer's Accountability Act."[4] The Act authorized the director of the National Institutes of Health to prepare an annual budget to meet the benchmarks and goals of the National Alzheimer's Plan. This budget is unique. It bypasses the usual process that begins with Congressional review and revisions, but instead goes directly to the president. Simply put, NIH had been granted the power to ask Congress for exactly how much money is needed to address the Alzheimer's crisis.

These efforts have created and sustained a research infrastructure. Highlights, but by no means exclusive parts, of this infrastructure include Alzheimer's Disease Research Centers, the Alzheimer's Disease Neuroimaging Initiative, the Alzheimer's Disease Cooperative Study (now the Alzheimer's Clinical Trials Consortium), the Resources for Enhancing Alzheimer's Caregiver Health, and the Health and Retirement Study's Aging Dementia and Memory Study.

This infrastructure has revolutionized the ways we understand the costs of Alzheimer's disease and how we treat it. The Health and Retirement Study's Aging Dementia and Memory Study has shown the disease's total yearly costs to the U.S. in 2010 were as much as $215 billion.[5] As much as one-third to one-half of this arresting total is the cost of a family caregiver's time and effort providing care.

Resources for Enhancing Alzheimer's Caregiver Health has shown that caregiver education, problem-solving strategies, care navigation support, support after discharge from a hospital or nursing home, and decision-making support reduce caregiver distress, costs of care and improve patient quality of life.[6] These interventions might also reduce the costs.

This infrastructure has revolutionized the ways we understand what is Alzheimer's disease. When I began my practice in 1997, a person had to have disabling cognitive

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[3] U.S. Code, Title 42. THE PUBLIC HEALTH AND WELFARE. Chapter 118. ALZHEIMER'S DISEASE AND RELATED DEMENTIAS RESEARCH. Subchapter III–A. NATIONAL ALZHEIMER'S PROJECT. Section 11225. The National Alzheimer's Project. 42 U.S. Code § 11225. The National Alzheimer's Project.

[4] https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf.

[5] Hurd MD, Martorell P, Delavande A, Mullen KJ, Langa KM. Monetary Costs of Dementia in the United States. *New England Journal of Medicine*. 2013;368(14):1326-1334. doi:10.1056/NEJMsa1204629

[6] For an overview of the results of the REACH studies, see Richard Schulz, ed. "Handbook on Dementia Caregiving: Evidence-based Interventions for Family Caregiver." Springer Publishing Company, 2000. ISBN-13: 978-0826113122.

impairments to be diagnosed with Alzheimer's disease. In other words, a person had to be diagnosed with dementia in order for me to diagnose whether she had Alzheimer's disease or some other disease that caused her dementia. A definitive diagnosis was only possible after death, when a neuropathologist performed a brain autopsy. In 20 quick years, researchers transformed this.

We made discoveries that allow my colleagues and me at the Penn Memory Center to diagnose the disease when a person has only mild cognitive impairment, commonly called "MCI."[7] We are able to detect biological markers of Alzheimer's pathologies (that is, biomarkers) in the brain of a living person. These markers have led to a revision of the diagnostic criteria for Alzheimer's disease.[8]

The gothic horror story – the need to die to get an accurate diagnosis – is ending.

We are also studying drugs that target the disease. Most provocatively, as part of the NIA-funded Alzheimer's Clinical Trials Consortium, we are testing these drugs in persons who have either biomarkers of the disease or genes that increase the risk of developing dementia, but have no signs and symptoms.[9] At the Penn Memory Center, we have study subjects taking the morning off from work or delaying their departure for a turkey-hunting trip to come in for study visits testing a drug that we hope will delay the time before they have to stop working or hunting because of mild cognitive impairment or dementia.

This research has taught us that Alzheimer's disease is a complex disease. Among the most important recent discoveries is that biomarker patterns in patients with "early onset Alzheimer's disease," meaning before the age of 65, differed from those with "late onset Alzheimer's disease." We have also discovered that dementia in persons over 80 is commonly caused not by the classic Alzheimer's pathologies of amyloid and tau but by those two pathologies and a third and not well understood pathology called "pathologic TDP-43."

These findings are of substantial importance to America. Persons over 80, sometimes called "the oldest old," are the largest proportion of persons with dementia. The aging of the "baby boom" generation assures they're the fastest growing proportion as well.

These findings, therefore, suggest that for persons who are 80-plus, treatment for any one pathology alone, such as amyloid, may not be sufficient to slow the disease. They suggest that a person who started treatment at, say, 70 and lives to 80 may develop a new cause of cognitive impairment.

The unifying word that summarizes these findings is "heterogeneity." Alzheimer's disease is not like polio, a disease caused by a single virus that will be tractable to a single treatment. A reasonable expectation is a cure for some, a chronic disease for many.

Let me close this summary of the progress in our research with an assessment by George Vradenburg, chairman of USAgainstAlzheimer's:

> "I think we're going to be in a world in which we have some successful drugs but the drugs are only going to be partially effective and where we're going to need high-quality care institutions for a very, very long time."[10]

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[7] For an overview of MCI, see Ronald Petersen. Mild Cognitive Impairment, New England Journal of Medicine. 2011; 364:2227-2234. Petersen led the team of Mayo Clinic researchers who discovered the concept.

[8] Jack CR, Knopman DS, Jagust WJ, et al. Tracking pathophysiological processes in Alzheimer's disease: an updated hypothetical model of dynamic biomarkers. *The Lancet Neurology*. 2013;12(2):207-216. doi:10.1016/S1474-4422(12)70291-0

[9] See for example the A4 Study. www.a4study.org

[10] Cynthis Helzel. "Making a Difference." Argentum. 25 August 2017.

Simply put, we’re not going to drug out way out of this complicated problem. We are going to need to care for each other.

Care for persons living with Alzheimer’s disease needs to improve.

On Tuesday, July 15th, 1980, at a few minutes before half past ten in the morning, in room 4232 of the Dirksen Senate Office Building, the people of the United States of America met Alzheimer’s disease for the first time. The occasion was “Impact of Alzheimers disease on the nation’s elderly,” a joint hearing before the Subcommittee on Aging of the U.S. Senate’s Committee on Labor and Human Resources and the Subcommittee on Labor, Health, Education, and Welfare of the House Committee on Appropriations. The host, and the only congress person present at the hearing, was the chair of the subcommittee on aging, Senator Robert Eagleton of Missouri.

The first witness, the first American to speak to her fellow Americans about living with Alzheimer’s disease, was Mrs. Bobbie Glaze, one of the founding members of the organization that would come to be called the Alzheimer’s Association.

Glaze told the story of her husband’s dementia. Life with the disease was “a funeral that never ends.” Her husband was once “a handsome, vital, athletic man, a civic leader, a public speaker, a highly respected businessman.” Now, she explained, he was “a statistic.” It had been four years since he spoke or recognized her. She too felt stripped of identity.

She narrated their years long decline. It was their decline because, as he became more and more disabled, agitated and withdrawn, they became impoverished and she, isolated.

Along the way were unremitting indignities. The neurologist delivered his diagnosis in the waiting room. Ignorance and indifference were the norm. “I was given no explanation of what Alzheimer’s disease is, what to expect, how I might learn to cope, nor was I directed to someone who might be able to direct me in the monumental problems ahead.”

I am confident that had the Glazes been cared for at a memory center such as where I practice, they would not have suffered as they did. I am sad however that there are still too many persons living with dementia and their families who are telling the same stories Bobbie Glaze told some 40 years ago.

The typical new patient visit at the Penn Memory Center begins with a family recounting a despairing narrative of frustrating months, even years, searching for answers and struggling to get care.

To make a diagnosis and care for a person living with Alzheimer’s disease I need about 60 minutes to discover that the person has cognitive impairment and that this impairment causes her to be either less efficient performing day to day tasks, or needs someone else to assist her with tasks. “Day-to-day tasks” means activities of daily living such as managing a check book, using the computer, cooking a dinner, traveling from one place to another. “Less efficient” means the person struggles and takes longer but still can carry on.

A person with cognitive impairment who is less efficient in their day-to-day tasks has what we call “mild cognitive impairment,” or MCI. A person with cognitive impairment who “needs someone else to help” has dementia. The person is disabled.

To gather this information, I interview not one, but two people – the patient with the memory problem and someone else who knows him well, such as a partner or adult child. That person typically becomes the caregiver. I obtain about 25 minutes of cognitive testing and, in most cases, I order tests, most commonly an MRI of the brain.

Later, I see the patient and caregiver for a 30-minute diagnostic follow up visit. At that visit, I explain the diagnosis, stage and care, answer questions and then they meet with a social worker to develop a plan to address the functional inefficiencies and impairments.

This care plan educates the patient and caregiver about the diagnosis, stage and what to expect in the future. It addresses the patient's functional impairments and the sources of caregiver strain. For example, we may recommend the patient undergo a driver's evaluation or the caregiver gain view only access to the patient's bank and credit accounts. This care planning is ongoing. In time, we train the caregiver how to talk to the patient about attending an adult day program and help the caregiver locate and figure out how to pay for the program.

We are able to do this at the Penn Memory Center because we benefit from cross subsidies from research and philanthropy. Our entire social work team is made possible by a generous donation the caregiver of one of our patients.

Some key points.

- We do not have a "test" for dementia or MCI. There is, therefore, no "test for Alzheimer's disease."
- An MRI is very helpful to show neurodegeneration, but it does not explain what caused neurons to die.
- Amyloid and tau tests, such as measured using a PET scan, are very important to show why neurons are dying. When both are present, they show that Alzheimer's disease is the cause of a person's MCI or dementia. Amyloid and tau however are seen in other diseases. These scans are, at present, most valuable when they are negative. A negative result removes Alzheimer's disease as the cause of the person's cognitive impairment. Of course, in the event a drug is discovered that targets tau or amyloid and, as a result, slows the death of neurons, then these tests will be valuable as a means to guide treatment decision making.
- Cognitive testing is a *very important* part of the assessment, but cognitive testing is just one part, and it needs context. This context includes the quality of the person's education and the nature of their occupation. At Penn, we see college graduates who are accomplished executives with nearly normal testing but have MCI or even mild stage dementia caused by Alzheimer's disease. Quality of education is a notable issue for America's older adults, particularly persons of color who were raised and educated in schools that were segregated. Cognitive testing done without context is simply hard to interpret. Context explains why there is not "one test for all." This explains, at least in part, why the Medicare annual wellness visit's requirement for "the detection of the presence of any cognitive impairment" has been difficult to implement.

There are tremendous benefits to this approach to diagnosis and care. Individuals with cognitive decline who sought care from a specialist (that is, a neurologist, psychiatrist or geriatrician) had a shorter time to diagnosis of Alzheimer's disease[11] and had lower Medicare costs in the year after receiving a diagnosis of Alzheimer's dementia than those diagnosed by a non-specialist.[12]

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[11] Kirson, Noam Y et al. "Assessing the economic burden of Alzheimer's disease patients first diagnosed by specialists." *BMC geriatrics* vol. 16 138. 11 Jul. 2016, doi:10.1186/s12877-016-0303-5

[12] Alzheimer's Association. 2019 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2019;15(3):321-87.

Why is what we do at a memory center not routine?

Reason #1: There is a scarcity of physicians skilled in making and disclosing a diagnosis and discussing a treatment plan with a person living with dementia or MCI and their caregiver.

1. There is a shortage of geriatricians.[13]
The American Geriatrics Society estimates 30 percent of the 65-plus patient population will need a geriatrician. One geriatrician can care for ~700 patients. This means "30,000 geriatricians will be needed by 2030 to care for about 21 million older Americans." In 2016, there were 7,293 certified geriatricians in the US or 1 geriatrician for every 1,924 Americans age 65 or older in need of care. The United States has approximately half the number of certified geriatricians that it currently needs.

2. There is a shortage of geriatric psychiatrists.[14, 15]
The American Association of Geriatric Psychiatry has about 2,000 active members. The 2003 President's Commission on Mental Health Subcommittee on Older Adults (2003), concluded that "at the current rate of graduating approximately 80 new geriatric psychiatrists each year and an estimated 3% attrition, there will be approximately 2,640 geriatric psychiatrists by the year 2030 or one per 5,682 older adults with a psychiatric disorder."

3. There is a shortage of neurologists.[16]
A report by the National Center for Health Workforce Analysis estimates that while the supply of US neurologists may have grown by 11% between 2013 and 2025, demand will have grown by 16%.[17] The current national and geographic shortfalls of neurologists are likely to worsen, exacerbating long wait times and reducing access to care for Medicaid beneficiaries.[18] A large number of neurologists do not accept new Medicaid patients and most do not pursue cognitive disorders. Most pursue more lucrative fields such as stroke, MS, epilepsy and neuro-critical care.

4. Primary care physicians struggle to diagnose and treat patients with MCI and dementia.

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[13] Fried, L. P. & Hall, W. J. (2008). Leading on Behalf of an Aging Society. The Journal of the American Geriatrics Society, 56(10), 1791-1795. doi: 10.1111/j.1532-5415.2008.01939, and The American Geriatrics Society. Current Geriatrician Shortfall. Available at: https://www.americangeriatrics.org/sites/default/ files/inline-files/Current-Geriatrician-Shortfall_0.pdf

[14] Membership Directory, American Association for Geriatric Psychiatry. [cited 2019 November 13].

[15] IOM Study on Mental Health Workforce of Older Adults Fact Sheet

[16] Burton, Adrian. "How do we fix the shortage of neurologists?." *The Lancet Neurology* 17.6 (2018): 502-503.

[17] https://bhw.hrsa.gov/sites/default/files/bhw/health-workforce-analysis/research/projections/BHW_FACTSHEET_Neurology.pdf,

[18] Timothy M. Dall, Michael V. Storm, Ritashree Chakrabarti, Oksana Drogan, Christopher M. Keran, Peter D. Donofrio, Victor W. Henderson, Henry J. Kaminski, James C. Stevens, Thomas R. Vidic Neurology Jul 2013, 81 (5) 470-478; DOI: 10.1212/WNL.0b013e318294b1cf

Documented barriers are: time constraints, inadequate knowledge, an inadequate skill set, fear of making an incorrect diagnosis, lack of remuneration, and lack of coordination between physicians and community services.[19]

Reason #2. Physicians who have the skills to detect and work up cognitive impairment lack the resources to practice them. In my research on the Alzheimer's crisis in America, I found only one center that is like the Penn Memory Center and is not affiliated with an academic medical center or a clinical trial center. Memory Care in Asheville, North Carolina, run by Margaret (Peggy) Noel, MD is supported some by Medicare billing but as well depends on donated space, a fee charged to the caregiver for their counselling, and annual fundraising.

What needs to be done?

1. Expand the physician workforce.

- Medicare should consider how its influence over reimbursements to teaching hospitals can incentivize the numbers of persons pursuing residency and fellowship training in geriatrics, geriatric psychiatry and cognitive neurology.

- Persons pursuing geriatrics, geriatric psychiatry and cognitive neurology ought to be able to apply for grants to cover the salary of the trainee.

2. Create a better business model for the diagnosis and care of persons with Alzheimer's disease. The majority of persons with Alzheimer's disease are over 65 and so covered under Medicare. Medicare therefore has a key role in shaping the business model for the care of persons with Alzheimer's disease.

In January 2017 CMS introduced the G0505 Medicare procedure code.[20] Its purpose is to pay clinicians to assess patients with cognitive impairment, including dementia, and the creation of a care plan. One year later, the G0505 code was superseded with CPT code 99483, "Cognitive Assessment and Care Plan Services." These billing codes are tremendous steps forward. Their key innovations are they recognize the complexity of a workup; explicitly include caregivers; require a written, shared care plan.[21]

This is what Bobbie Glaze was looking for.

I applaud the effort of several senators who just one month ago, wrote to Seema Verma at CMS that in 2017 *less than one percent* of seniors eligible to receive this benefit actually accessed it in 2017. The senators were right to urge Administrator Verma to educate clinicians to use the codes and discover the barriers to implementing it.[22]

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[19] Hinton, Ladson, et al. "Practice constraints, behavioral problems, and dementia care: primary care physicians' perspectives." Journal of general internal medicine 22.11 (2007): 1487-1492.

[20] Perry, William et al. "Population Health Solutions for Assessing Cognitive Impairment in Geriatric Patients." *Innovation in aging* vol. 2,2 igy025. 12 Oct. 2018, doi:10.1093/geroni/igy025

[21] "Advisory Council on Alzheimer's Research, Care, and Services." *MEASURING PROGRESS, RECOMMENDATIONS, AND MOONSHOT UPDATES. Washington: Department of Health and Human Services (US)* (2019), https://aspe.hhs.gov/system/files/pdf/261851/Mtg32Sum.pdf

[22] https://www.mcsally.senate.gov/mcsally-bipartisan-group-senators-urge-expanded-access-families-alzheimers

We must study who is using this code and who is not, why and how well it works. We should do this with the same urgency as our studies of Alzheimer's biomarkers.

I close with the results of some preliminary studies to begin to answer these questions.

1. I have learned that some Medicare advantage plans were not paying for it.

2. Primary care physicians need to be instructed on how to spread this work out over several visits.

3. Medicare should study how to integrate this code into its Comprehensive Primary Care Plus initiative.

4. The code should recognize that many of the services for dementia care are effectively and efficiently delivered by nurses, social workers, and community health workers. We at the Penn Memory Center are not using it. Why? The code allows "Any practitioner eligible to report E/M services can provide this service. Eligible providers include physicians (MD and DO), nurse practitioners, clinical nurse specialists, and physician assistants." Social workers perform our care planning.

5. The code does not reimburse for ongoing care management services.[23]
The code ought to cover interventions that can prevent or reduce patient's symptoms and caregiver stress training. These include support to enhance the caregiver's skills, case management and coordination of services and supports among providers and community resources such as an adult day program.

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[23] Boustani, Malaz, et al. "An alternative payment model to support widespread use of collaborative dementia care models." *Health Affairs* 38.1 (2019): 54-59. HTTPS://DOI.ORG/10.1377/HLTHAFF.2018.05154