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Douglas K. Owens, M.D., M.S.
Chairperson, U.S. Preventive Services Task Force
USPSTF Program Office
5600 Fishers Lane, Mail Stop 06E53A
Rockville, MD 20857

LEAD
Leaders Engaged on Alzheimer's Disease

RE: Draft Recommendation Statement and Draft Evidence Review: Screening for Cognitive Impairment in Older Adults

Dear Chairman Owens:

We thank the U.S. Preventive Services Task Force (USPSTF) for the opportunity to provide comment on its Draft Recommendation Statement and Draft Evidence Review: Screening for Cognitive Impairment in Older Adults (USPSTF Draft). We write on behalf of millions of Americans and their families facing Alzheimer's disease and other forms of dementia, including many who overcame enormous obstacles to receive their diagnosis and at least half of whom remain undiagnosed, along with tens of millions of people whose cognitive health may be at risk.

The USPTF Draft concludes that current evidence is insufficient to assess the balance of benefits and harms of screening for cognitive impairment in older adults. **Respectfully, we disagree and urge USPSTF to revise its recommendation to Grade B, encouraging providers to screen persons 65 and older for cognitive impairment, and to further specify that:**

- **Screening should be conducted in health care settings by staff who are appropriately trained to use the screening test(s) and with procedures in place for follow-up**
- **Screening should be followed by an evaluation to diagnose the cause of any detected cognitive impairment, treatments to reduce modifiable causes, and ongoing efforts to reduce the impact of diagnosed dementia and support people with dementia and their caregivers.**

There is an ethical imperative for persons affected by cognitive impairment or dementia to be able to obtain accurate and timely diagnosis. Public surveys confirm that people would want their doctors to be honest with them if they were exhibiting signs of memory loss or confusion. While conceptually screening is distinct from early detection, from a practical perspective, the USPSTF Draft risks reinforcing both the widespread tendency among many Americans to wrongly dismiss valid cognitive concerns as "normal aging" and many healthcare providers' ambivalence about raising the topic of cognitive impairment, or following up on patients' expressed concerns regarding cognitive status, and delivering a dementia diagnosis after a comprehensive evaluation.

The USPSTF Draft conclusions might be reasonable when taking a disease-centric perspective on brain function focused on cure, but is not reasonable when adopting a health perspective. It appears USPSTF failed to consider: 1) if screening has the potential to improve overall health outcomes; and 2) if interventions for asymptomatic older adults and those with mild cognitive impairment (MCI) could delay or slow progression to Alzheimer's disease and other forms of dementia, or 3) that dementia is a significant health disparity requiring an approach that considers how cognitive screening can impact those at greatest risk. (Solomon et al., 2005; Knopman et al., 2000)

The USPSTF draft risks reinforcing the discredited notion that physicians and other advanced practice providers (APPs) only need to or ought to diagnose that which they are able to cure or treat with a pill or a surgical intervention. Think of the catastrophic damage done for decades in oncology and again during the early years of the HIV/AIDS epidemic – before effective biomedical treatments – from anti-detection biases which impeded efforts to account for the full scope of the public health burden, raise awareness and reduce stigma, generate data for bench and social science researchers and provide services and supports to improve quality of life for those with the condition. The "I" recommendation inadvertently equates to, and reinforces, "indifference" toward the many non-cure benefits from early identification of cognitive impairment.

Cognitive health screening for MCI and dementia in older adults is merited for several important reasons:

- Validated screening instruments currently are widely available. (Draft Evidence Review, 2019)
- Waiting for subjective cognitive complaints alone can result in both over- and underdiagnosis of MCI. Use of a brief, validated cognitive assessment instrument is needed. (Foster et al., 2019)
- Cognitive impairment is a dominant comorbidity influencing what care is recommended for that condition and how care for all co-existing health conditions should be provided. Consequently, knowing the cognitive health status of high-risk patients, especially older patients, has inherent clinical relevance. (Foster et al., 2019)
- There is strong evidence that promoting cognitive health by addressing key risk factors (hypertension, sedentarism, social isolation, smoking, hearing loss, depression, diabetes, and obesity) may slow or prevent the progression of cognitive decline. Screening for cognitive impairment offers an opportunity to employ counseling interventions for the lifestyle interventions recommended by the World Health Organization, the Lancet Commission, and others to address these key risk-factors as supported by USPSTF's own recommendations. (Livingston et al., 2017) (Ngandu et al., 2015; World Health Organization 2019)
- Screening can pick-up on early onset dementia, when cognitive decline and impairment appears out of norm for the persons age or is appears early in at-risk groups such as adults with Down syndrome and other cognitive disabilities (World Health Organization, 2012).
- Screening can identify cognitive impairment that is caused by treatable conditions (including nutritional deficiencies, subdural hematoma, normal pressure hydrocephalus, and medication side effects) that are not dementia but may result in dementia-like symptoms. (Chari et al., 2015)
- Screening can prompt health care professionals and others to counsel people with cognitive impairment or dementia and their families about important safety risks including falls, motor vehicle or firearm accidents, and vulnerability to financial exploitation. (Hsieh et al., 2015; Levy-Storms et al., 2017; O'Connor et al., 2019)
- Cognitive impairment screening is a measure of brain health. If healthcare providers make screening more routine and systematic, changes in cognitive status can be detected earlier. This is important because indications of treatable cognitive decline begin well before the symptoms of full-blown dementia occur. (Tarawneh and Holtzman, 2012)
- Cognitive impairment screening can improve access to and utilization of available therapies along with effective services and supports for people with cognitive impairment or dementia and their families and other caregivers.

Conclusions embedded within the USPSTF Draft are inconsistent with and contrary to existing federal government policies and programs – and emerging efforts by state and local government agencies and private sector organizations – thereby slowing progress toward earlier diagnosis of dementia, improved care and services, and better outcomes for people with dementia and their families. Recognizing the importance of detection of cognitive impairment, earlier diagnosis of dementia, and improved care and services for people with dementia and their caregivers, the federal government has taken decisive steps to advance detection, diagnosis, medical care, residential and home and community-based services, family caregiver support, and research participation. Recent steps by U.S. Department of Health and Human Services agencies include:

- Healthy People 2020 and proposed 2030 Public Health Objectives to increase provider-patient discussions of SMI (specifically Objectives DIA-2030-01, DIA-2030-02, and DIA-2030-03) (HHS, ODPHP, 2019)
- CMS' updates to the Medicare Physician Fee Schedule that encourage dementia diagnosis and care planning (ref. HCPCS 99483)
- CMS' new Medicare Advantage (MA) rules that increase benefits for Alzheimer's and dementia care, along with risk score adjustments for MA Plans caring for people with dementia (Pyenson, B.S. and Steffens, 2019)
- CDC's 2018-2023 Brain Health Roadmap and implementation planning for the 2018 BOLD Infrastructure for Alzheimer's Act (Alzheimer's Association, 2018)
- The 2017 NIH National Research Summit on Care, Services, Supports for Persons with Dementia and Their Caregivers, which now will be conducted in 3-year cycle with NIH's Alzheimer's Disease Summit and its Alzheimer's Disease-Related Dementias Summit (ASPE, 2018)

- CMS' Behavioral Health Payment and Care Delivery Innovation Summit (CMS, 2017)
- The Administration on Community Living (ACL) Alzheimer's Disease Programs Initiative (ADPI) that provides grants to support **and** promote the development **and** expansion of **dementia**-capable home **and** community-based service (HCBS) systems in both states **and** communities (ACL, 2018)
- HRSA's GWEP program and online training materials for physicians, APPs and other health care professionals (HRSA, 2019)
- The 2018 "NIH National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research" (NIA, 2018) (which has a special emphasis on health disparities)
- The FDA's 2018 updated "Early Alzheimer's Disease: Developing Drugs for Treatment, Guidance for Industry." (FDA, 2018)

Leading NGOs representing healthcare providers and patients have called for increased screening, most recently the American Academy of Neurology (AAN) (Foster et al., 2019), the American Diabetes Association (ADA, 2018), the Endocrine Society (LeRoith et al., 2019), Alzheimer's Disease International, the American Heart Association (Gorelick et al., 2018), the UsAgainstAlzheimer's Brain Health Partnership (Tumlinson, 2019), the National Academy of Neuropsychology (Perry et al., 2018), the Alzheimer's Foundation of America (Borson et al., 2013), the Heart Failure Society of America (Lindenfield et al., 2010), and the Alzheimer's Drug Discovery Foundation.

The AAN recently updated its practice guidelines on cognitive impairment stating that:

> In the United States, the Medicare Annual Wellness Visit requires an assessment to detect cognitive impairment. Subjective cognitive complaints alone can result in both over- and underdiagnosis of MCI and thus are insufficient to screen for MCI. Clinicians assessing for cognitive impairment should use a brief, validated cognitive assessment instrument in addition to eliciting patient and informant history regarding cognitive concerns. (Petersen et al., 2018)

The USPSTF draft recommendation on detection of cognitive impairment is inconsistent with patient and healthcare provider preferences. In 2018, surveys of 1,000 primary care physicians and almost 2,000 people age 65 and older were conducted for the Alzheimer's Association (Alzheimer's Association, Special Report, 2019). Survey findings show that "although nearly all PCPs and four of five seniors think brief cognitive assessments are beneficial, only half of seniors are being assessed and just one in seven is getting regular brief cognitive assessments." About one third of the older adults surveyed were aware that the Annual Wellness Visit includes detection of cognitive impairment, and only 32% recalled a healthcare provider asking them about memory or thinking problems during an Annual Wellness Visit. Support for better cognitive assessments extends to caregivers themselves who strongly recommend providers receive adequate training on the prognosis and disease course of different types of dementia, effective pharmacological and non-pharmacological interventions and caregiving resources. (Griffin et al., 2019) Despite this strong support, estimates based on national surveys and clinical studies continue to indicate that only about half of older people who have dementia have had a diagnostic evaluation (Lang et al., 2017). If USPSTF fails to change its recommendation, those numbers are unlikely to improve, and a rapidly increasing number of older adults will have undiagnosed cognitive impairment along with the attendant risks to management of comorbid conditions and quality of life – resulting in increases in the costs of long-term care.

We urge USPSTF to broaden its consideration to include benefits of cognitive impairment screening to address:

1. **identification of modifiable causes of cognitive impairment**
2. **risk-reduction and progression of MCI**
3. **care for co-occurring chronic conditions**
4. **access and utilization of available therapies and support services**
5. **identification of safety risks and available information and programs to address the risks**
6. **development of a baseline for improved care and better research**
7. **value of currently available screening tools**

1. Addressing modifiable causes of cognitive impairment

Cognitive impairment in older adults takes many different forms and can lead to a variety of health problems, worsen health outcomes and significantly increase otherwise unnecessary utilization of the health care system. The USPSTF Draft, which states "[O]ne potential harm [of screening] is labeling a person with an illness that is typically progressive and for which treatment appears to have limited effectiveness," relies on the false premise that the only cause of cognitive impairment is a progressive neurodegenerative disease. This false premise threatens to undermine important opportunities to improve Americans' health.

Screening tests generally are intended to identify previously unidentified problems. When a screening test indicates a previously unidentified problem, it is expected that the test will be followed by an evaluation to diagnose the cause of the problem, decisions about the best approaches to treat and either cure, reduce, or manage the problem, and implementation of the selected approaches. In older people, cognitive impairment can be caused by many factors or conditions that are not dementia but may result in dementia-like symptoms, including some that can be treated and cured or reduced and managed. Such treatable conditions (Mayo Foundation, 2019) include:

- Infections and immune disorders. Fever or other side effects of the body's attempt to fight off an infection can cause cognitive impairment. Multiple sclerosis and other conditions in which the body's immune system attacks nerve cells also can cause cognitive impairment.
- Metabolic problems and endocrine abnormalities. Thyroid problems, low blood sugar, too little or too much sodium or calcium, or problems absorbing vitamin B-12 can cause cognitive impairment.
- Nutritional deficiencies**.** Dehydration along with deficiencies in vitamin B-1, B-6 and B-12, copper and vitamin E can cause cognitive impairment.
- Medication side effects. Side effects of medications, a reaction to a medication, polypharmacy can cause cognitive impairment.
- Subdural hematomas**.** Bleeding between the surface of the brain and the covering over the brain, which is common in older adults after a fall, can cause symptoms similar to those of dementia.
- Poisoning. Exposure to heavy metals such as lead, and other poisons such as pesticides, as well as recreational drug or excessive alcohol use can lead to cognitive impairment.
- Anoxia. Severe sleep apneas, asthma, heart attack, or carbon monoxide poisoning cause organ tissue not to receive adequate oxygen, resulting in cognitive impairment symptoms.
- Normal-pressure hydrocephalus. This condition is caused by enlarged ventricles in the brain.
- Psychiatric conditions. Affective disorders, such a depression, can lead to memory problems and disorientation, and may be misdiagnosed as MCI or dementia.

Although these treatable conditions may be identified by other screening and medical tests, a low cognitive screening test score is one avenue by which healthcare professionals may become aware of these conditions and begin treatment.

2. Addressing risk-reduction and progression of MCI

Recent research findings about the impact of programs to reduce potentially modifiable risk factors for dementia suggest that, for as much as one-third of the population, it may be possible to prevent dementia and perhaps also slow the progression of mild cognitive impairment (MCI) to dementia. Results from the comprehensive FINGER study – excluded by USPSTF from its consideration – indicate that lifestyle modifications, including dietary guidance, physical activity, cognitive training, social activities, and monitoring and management of metabolic vascular risk factors, can improve or maintain cognitive function in older adults.

The SPRINT MIND study found that people with hypertension who received intensive treatment to lower systolic blood pressure were less likely (than their peers receiving standard blood pressure treatment) to develop memory problems that often progress to dementia. The SPRINT MIND findings demonstrated that keeping tight control of blood pressure can reduce by 19% the risk of developing MCI. According to the Lancet Commission, that more than a third of dementia cases potentially are preventable by addressing nine factors accounting for 35% of the

population dementia risk including, for those over 65, treatment of hypertension, exercise, social engagement, smoking, and hearing loss, depression, diabetes, and obesity.

Brief, inexpensive cognitive training methods have been shown to increase functional independence, maintain accident-free driving, improve mood and enhance cognitive functions for as long as 10 years post training and may significantly reduce dementia risk after 10 years. Systematic reviews confirm the effectiveness of cognitive training on everyday function and dementia risk in older adults.

The USPSTF previously made recommendations related to several of these risk factors for cognitive impairment, including pharmacotherapy and counseling for tobacco cessation; screening and counseling to reduce unhealthy alcohol use; counseling to promote healthy diet and physical activity; statins to reduce cardiovascular disease risk; and screening for hypertension; abnormal blood glucose, and depression, therefore providing primary care providers with ample guidance around preventive interventions indicated for pre-clinical MCI or dementia.

In fact, leading government agencies and advisory groups are aligned in the position that promoting brain health can strengthen the brain's resistance to brain conditions later in life and reduce the risk of dementia:

- The World Health Organization's 2019 Guidelines state "the existence of potentially modifiable risk factors means that prevention of dementia is possible through a public health approach, including the implementation of key interventions that delay or slow cognitive decline or dementia."
- The 2015 Institute of Medicine report on cognitive aging recommends that health and payer systems "promote cognitive health in regular medical and wellness visits among people of all ages."
- The Lancet Commission urged that the "prevention or delay of dementia onset is a public health priority with potential to reduce not only the disability of individuals but also the associated societal and economic burden."
- The American Academy of Neurology, in its September 2019 recommendation calling for annual cognitive assessments, recognized that "early diagnosis can help identify forms of mild cognitive impairment that may be reversible, including those caused by sleep problems, depression or medications, and lead to treatments that can improve a person's quality of life such as correcting hearing loss and avoiding social isolation."
- The American Heart Association noted in its 2017 Presidential Advisory that "advances in our understanding of the role of cardiovascular risks have shown them to be closely associated with cognitive impairment and dementia. Because many cardiovascular risks are modifiable, it may be possible to maintain brain health and prevent dementia in later life."
- The CDC's Healthy Brain Initiative leads with "While a person with mild cognitive impairment is at greater risk of developing dementia, this is not inevitable. There is growing scientific evidence that healthy behaviors, which have been shown to prevent cancer, diabetes, and cardiovascular disease, also may reduce risk for cognitive decline and possibly dementia."

The USPSTF, by restricting the evidence assessment to adults who have been screen-detected with cognitive impairment and those with mild to moderate dementia or MCI, dangerously underestimates the impact of risk reduction not only for dementia but also for related risk factors such as hypertension, diabetes, and depression. A brain health perspective eschews such binary diagnostic classifications and instead assesses a range of cognitive strengths and weaknesses with a view to recommending appropriate strategies for building brain health. This approach has much in common with a primary care provider's regular assessment of vital signs which might by the catalyst to recommending lifestyle changes such as losing weight, increasing physical activity, engaging in relaxation exercises or improving sleep hygiene.

By excluding from its evidence review those primary prevention trials in which treatment was aimed at preventing or delaying the onset of cognitive impairment in older adults without known cognitive impairment, the USPSTF undermines the central purpose of its own recommendations: to evaluate the evidence of preventive interventions for people with no signs or symptoms of the specific disease or condition. When healthcare providers detect the earliest manifestations of mild cognitive impairment or decline, they can prioritize managing interconnected health conditions and direct patients to interventions that may prevent or slow progression of those interconnected health

conditions. Depending on underlying disease, healthcare providers may be able to help patients reverse mild cognitive impairment or prevent or delay progression to dementia.

3. Addressing care for co-occurring chronic conditions

The AAN recently released a cognitive impairment quality measure stating that: "Cognitive impairment is a dominant comorbidity influencing not only what care is recommended for that problem, but also how care for all other illnesses should be provided. Consequently, knowing the cognitive health status of high-risk patients, especially older patients has inherent clinical relevance." (Foster et al., 2019)

The majority of people with cognitive impairment are living with one or more co-existing chronic conditions. (Nelis et al., 2019) While 26% of Medicare beneficiaries with Alzheimer's or other forms of dementia have five or more chronic conditions, only four percent of Medicare beneficiaries without dementia have five or more chronic conditions. (Alzheimer's Association, 2019)

A systematic review of studies about dementia and co-existing medical conditions found that people with multiple chronic conditions plus dementia had more functional impairments (ADLs/IADLs) than people with multiple chronic conditions and no dementia (Snowden et al., 2018). An analysis for 15 co-existing medical conditions in people with and without dementia – including congestive heart failure, chronic renal failure, chronic obstructive pulmonary disease (COPD), diabetes, heart attack and stroke – found that prevalence and costs were higher for each condition in people with dementia than in people without dementia (Salber et al., 2018). Another review of studies about care for people with various co-existing medical conditions and cognitive impairment or dementia also found high prevalence of co-existing conditions and evidence of reduced access to and quality of treatment for those co-existing conditions (Bunn et al., 2014).

People with cognitive impairment or dementia often have difficulty recognizing and reporting symptoms and/or side effects, adhering to medication, and complying with treatment and follow-up recommendations because of deficits in memory, language, judgment, and reasoning ability (McGuire **et al.**, 2006; Boustani **et al.**, 2007; Arlt **et al.**, 2008; Punthakee **et al.**, 2012**).** These deficits can have negative effects on treatment of co-existing medical conditions. For example:

- A study of older adults with heart failure found that those who had cognitive impairment had poorer medication adherence than those without cognitive impairment (Dolansky et al., 2016)
- A systematic review of the impact of cognitive impairment on self-care by people with heart failure concluded that cognitive impairment screening is essential for effective heart failure management (Cameron et al., 2017)
- A study of older people with COPD found that those with cognitive impairment or dementia had reduced COPD treatment adherence and effective self-management, including inability to use an inhaler effectively (Baird et al., 2017)
- A systematic literature review found older patients with dementia have a low level of medication adherence. Medication adherence ranged from 17-42 percent. Nonadherence was associated with an increased risk of hospitalization or death, while increasing age, choice of medication, use of concomitant medications, and medicines' costs were reported to decrease medication adherence. (El-Saifi, et al., 2018)

By contrast, policies and procedures that improve detection of cognitive impairment may encourage timely diagnosis and treatment that can reduce the negative effects of cognitive impairment and dementia on treatment for co-existing medical conditions. (Snowden et al.,2018)

4. Addressing access and utilization of available therapies and support services

Recognition of impairment can benefit the individual with impairment, caregivers, family and society (deVugt et al., 2006). For the affected individual, identification of early stage dementia allows early aggressive use of most available treatments. The person can be offered support groups and other services to diminish the disorder's psychological impact. Most individuals, regardless of degree of impairment, tend to experience a sense of relief after receiving the diagnosis (Carpenter et al., 2008) Moreover, the total medical care for a cognitively impaired individual can be adjusted to meet his or her needs. Patient education, self-medication, compliance and hospital

care can be addressed to meet the needs of a person with mild dementia who is at risk for common complications such as delirium and depression. The early identification of dementia supports individual patient rights and self-determination. Most mildly impaired individuals are capable of charting the future course of their care and making substantial decisions on issues such as end-of-life care, resuscitation and disposition of wealth. It has long been established that informing individuals about abnormal screening results does not produce hardship or harm to the individual or family caregiver (Lantz et al., 2004; Turnbull et al., 2003; Post and Whitehouse, 1995; Johnson et al., 2000; Maguire et al., 1996).

Although no treatments are currently available to cure dementia, widely available FDA-approved medications can reduce symptoms, and information and non-drug approaches are available to help people with dementia, families, and other caregivers reduce safety risks, manage symptoms, maintain independent functioning for as long as possible, and reduce the negative effects of dementia for the person and the family. It is clear, however, that if cognitive impairment is not detected, older people are unlikely to be offered a diagnostic evaluation and, without a dementia diagnosis, those who have dementia and their families are unlikely to be offered information and non-drug approaches that could help them manage the symptoms and improve quality of life.

Screening and early identification may benefit society by protecting individuals and reducing healthcare costs. Unrecognized dementia can increase likelihood of avoidable complications such as delirium, adverse drug reactions and noncompliance. These complications can reduce the autonomy of the individual with dementia. Enhancing compliance and protecting those with dementia have obvious financial benefits to the healthcare system. Adverse outcomes from screening programs have been rare when reported in published peer-reviewed literature or experienced by community providers.

The practical reality is that the progressive cognitive decline intrinsic to Alzheimer's disease and related forms of dementia places an absolute premium on making advance care planning decisions as early in the disease course as possible. Once decision-making skills diminish and competency is lost, the individual cannot participate in determining their own care. That is an unfair, unreasonable and – with the benefit of screening to aid in early detection and diagnosis – unnecessary burden on the individual and family, friends or court-appointed guardians.

Use of approaches to detection of cognitive impairment that are allowed in the Annual Wellness Visit regulations (observations of the person by a primary are provider and concerns raised to the provider by the person, family, friends, or other caregivers) can result in detection of cognitive impairment. Over many years, government agencies, professional associations, and advocacy organizations have developed and delivered training programs and materials to help primary care and other providers detect cognitive impairment in their older patients. These organizations also have developed public information programs and materials to encourage older people and their families to express cognitive concerns to their health care provider. Available evidence indicates these efforts and resources work. But more needs to be done and the USPSTF's 2003 and 2014 recommendations have been a consistent and harmful obstacle to greater utilization of the Annual Wellness Visit's cognitive assessment benefit.

5. Addressing identification of safety risks and available information and programs to address the risks

Use of cognitive screening tests can prompt healthcare professionals and others to counsel people with the cognitive impairment or dementia and their families about important safety risks including falls, motor vehicle accidents, firearm accidents, and vulnerability to financial exploitation. Effective resources to identify and address safety risks for people with cognitive impairment or dementia and their caregivers have been developed (Hsieh et al., 2015; Levy-Storms et al., 2017; O'Connor et al., 2019), but are unlikely to be recommended or used if cognitive impairment has not been detected.

- Falls in older people are a significant public health concern, and awareness of the association between fall risk and cognitive impairment and dementia is growing. (Muir, et al. 2012, Montero-Odasso, et al 2017). Early recognition of cognitive impairment can allow for home modifications, exercise programs and other care interventions that may reduce fall risk (Booth V, et al. 2016).

- Cognitive impairment is associated with driving difficulties and increased risk of motor vehicle accidents in older people with cognitive impairment (Fraade-Blanar, et al., 2018., Huisingh et al., 2018; Oh and Rabins, 2019).
- People with dementia may experience delusions, hallucinations, and aggressive behaviors. Approximately 17% of people with dementia have access to a firearm, and nearly half of those people also experienced delusions and behavioral disturbances (49% and 44% respectively) (Hsieh et al., 2015)
- People with cognitive impairment are at risk of poor financial decision making, including susceptibility to scams and other financial exploitation (Han et al., 2015.) One study found older people may experience poor financial decision making even before their cognitive impairment is diagnosable (Boyle et al., 2012)

6. Addressing development of a baseline for improved care and better research

Cognitive impairment screening is a measure of brain health. If healthcare providers make screening more routine and systematic, healthcare systems can detect more quickly cognitive changes and introduce lifestyle and other risk-reduction strategies. Research shows that indications of treatable cognitive decline begin well before the symptoms of dementia occur. The pathology of Alzheimer's disease may begin as many as 20 years before dementia symptoms surface. (Perl, 2010; Bateman et al., 2012) For this reason, since 2013, the Alzheimer's Association has recommended that older adults receive "initial cognitive evaluation and regular follow-up assessment in a medical setting to establish a baseline and track change over time."

The Agency for Healthcare Research and Quality's own commissioned evidence review recognized that the baseline status of study participants needs to be better measured and documented. Medicare, which already provides and recommends a cognitive assessment as part of its Annual Wellness Visit, has the opportunity to create such a baseline for improved study using formal guidelines such as those from the National Institute on Aging and the Alzheimer's Association, yet the USPSTF Draft recommends against using them citing lack of said baseline.

The AAN recently released a mild cognitive impairment quality measurement set that includes an annual cognitive health assessment for patients 65 years and older quality measure (Foster et al., 2019). The quality measure highlights the value for physician and treatment teams to monitor how frequently they are screening individuals 65 years and older for cognitive impairments. The measure had patient, care partner, and physician support prior to finalization given the known gap in care and ability to complete screening using brief, validated tools.

Disturbingly, the USPSTF Draft omits the fact that dementia is a significant health disparity and ignores important context for considering how cognitive screening can benefit those at greatest risk for dementia (e.g., Latinx, African-Americans). Specifically, Latinx, African Americans, Native Americans/Native Alaskans, and other racial/ethnic minority populations are at significantly increased risk for Alzheimer's disease and other forms of dementias compared with non-Hispanic white adults. (Chin et al., 2011) Although the causes of these disparities are multifactorial, delayed detection and late diagnosis may be a prime culprit, contributing to poorer health outcomes. It is important to note that a potential barrier to early detection and diagnosis is the shortage of culturally and linguistically trained cognitive screeners; additionally, effective screening instruments are limited for special populations, particularly those with intellectual disabilities such as Down syndrome.

Harms associated with misinterpretation of screening results (false positives and negatives) noted in USPSTF's evidence review could be mitigated by appropriate healthcare provider training and routine practices in place to follow up with further evaluation of people whose screening test indicate a problem – as we expect for medical tests more generally. Failure of healthcare systems to implement routine practices for diagnosing and managing patients with screen-detected cognitive impairment or dementia should not be attributed to screening as such.

Five studies of screening for cognitive impairment in older adults conducted in the United States show some encouraging results. Four of the studies show an increase in diagnosis of MCI or dementia and increased prescriptions for cognition enhancing medications in older adults with screening-detected cognitive impairment (Boise et al., 2010; Borson et al., 2006; McCarten et al., 2012; Rosenbloom et al., 2015). It is important to note, however, that the 4 studies also show that many of the older adults with screening-detected cognitive impairment did not receive a follow-up evaluation for MCI or dementia or a desirable change in medications. One additional

study conducted in a large community hospital (Boustani et al., 2012) found no significant changes in physician follow-up of patients with screening-detected cognitive impairment. Researchers who conducted these studies noted that "additional efforts are needed to help primary care physicians follow up appropriately on information suggesting cognitive impairment in older patients." (Borson et al., 2006) Researchers also recommended that "At a minimum, a recommendation similar to that delivered by USPSTF for depression screening – that screening is warranted provided systems are in place to follow up with suitable diagnosis and treatment – is warranted with respect to dementia. (Borson)

Failure in follow-up for screen-detected cognitive impairment cannot be entirely attributed to physician or other health provider practices. Several studies have shown that many older adults with screen-detected cognitive impairment who received a physician recommendation to come back for a diagnostic evaluation to determine the cause of the person's cognitive impairment did not return for the evaluation (Boustani et al., 2005; Fowler et al., 2015; Harris et al., 2011; McCarten et al., 2012. Thus, additional efforts are also needed to help people with screen-detected cognitive impairment and their families understand that the cognitive screening test results are not sufficient for a diagnosis of MCI or dementia and that additional evaluation is critical to identify modifiable causes of cognitive impairment that may eliminate or reduce the impairment.

Unfortunately, there are serious deficiencies in the healthcare system's ability to recognize dementia (Boustani et al., 2003). Recent studies showed that among patients aged 70 years or older, seen in primary care settings, cognitive impairment goes unrecognized in more than 50% of cases. (Kotagal, et al., 2015) Among older Latinx adults, approximately 40% have undiagnosed cognitive symptoms for 3 years or more. (Novak et al., 2004) Failure to recognize cognitive impairment delays diagnosis, appropriate treatment, and information to improve quality of life for patients and caregivers. (Espino, 2001)

The USPSTF Draft also appears unaware of or insensitive to the voluminous real-world experience of millions of Americans whose opportunity to participate fully in their own advance care planning and to accrue consequent non-medical benefits have been lost due to late detection and diagnosis that could have been avoided through earlier screening for cognitive impairment in older adults. The NIA recognized in its 2008 report entitled "Alzheimer's Disease: Unraveling the Mystery" that "it is best to find out sooner rather than later," because there are important medical and practical benefits to early detection. As NIA noted: "The drugs now available to treat AD can help some people maintain their mental abilities for months to years;" and "the sooner the person with AD and the family have a firm diagnosis, the more time they have to make future living arrangements, handle financial matters, establish a durable power of attorney and advance directives, deal with other legal issues, create a support network, and even consider joining a clinical trial or other research study." (National Institute on Aging, 2008)

The value of knowing includes supporting the individual's right to information to make the best available health care, support and quality of life choices in as timely a manner as possible. In 2016, the Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) study was initiated in response to the National Coverage Decision for amyloid PET imaging made by CMS. More than 18,000 patients participated in this practice based study, and the results published to date on over 10,000 individuals showed that measuring beta amyloid plaque, a neuropathological indicator of Alzheimer's disease, using amyloid PET imaging resulted in a change in management for more than 60% of patients, in many cases changing the diagnosis of whether Alzheimer's disease existed or not (Rabinovici, et al., 2019). We understand that amyloid PET imaging is not a screening tool, but the results from this study indicate that the imaging test results were successful in changing physician management of cognitive impairment. Moreover, the imaging test results helped to distinguish the underlying cause of cognitive impairment in those with mild cognitive impairment and dementia of uncertain etiology. The differential diagnosis of Alzheimer's disease from other types of dementia can be challenging given the overlap of clinical symptoms, hence there is frequent misdiagnosis. Early detection and an accurate diagnosis can affect treatment decisions and quality of life issues, with potential substantial savings for medical costs. Fundamentally, people need to know as early as possible both whether they have dementia and which underlying cause is responsible in order to make the most self-directed and effective decisions about the medical and non-medical care and quality of life.

7. Addressing value of currently available screening tools

Multiple screening instruments are available to assess individuals for cognitive decline with acceptable levels of sensitivity and specificity as well as interrater or rate-rerate reliability. Several screens have adequate sensitivity and specificity to serve as routine, cost-worthy evaluations, similar to other established screening tests, such as a mammography and Pap smear. However, the effectiveness of available screening instruments is limited for special populations, particularly those with intellectual disabilities, such as Down syndrome. The consequences of delayed detection have been raised repeatedly by the National Task Group on Intellectual Disabilities and Dementia Practice (NTG, 2012) and should be noted in the USPSTF Draft. Naturally, there is value in continuing to develop improved screening tools. The USPSTF Draft has the potential unintended consequence of diminishing the perceived and actual return on investment for research focused on developing new screening tools that could provide improved sensitivity, specificity and overall efficacy.

Beyond ensuring that those with the earliest signs of cognitive impairment receive appropriate interventions, early assessment also plays an important role in improving recruitment for Alzheimer's clinical research. The majority of interventional studies seek participants with prodromal or early Alzheimer's – overall, at least 70,000 volunteers are needed to participate in more than 150 active clinical trials and studies designed to better understand, diagnose, treat, and prevent Alzheimer's disease. Participation in a clinical trial is a highly personal and individualized decision that can empower patients facing any life-threatening or life-limiting disease at any stage of life. Without meaningful cognitive impairment screening and detection to enable early diagnosis, individuals with cognitive impairment all too frequently are denied the opportunity to consider clinical trial participation when it might benefit them and others the most. Failing to encourage – and effectively discouraging – screening for cognitive impairment risks similar damage and threatens to have a chilling effect on development of improved screening and diagnostic tools, delay diagnosis of people with MCI and undermine efforts to recruit clinical trial participants for research aimed at earlier and more effective interventions to improve functional and clinical outcomes.

At a time when we have within our grasp opportunities for profound advances in public attitudes and scientific research regarding cognitive impairment and dementia, it is vitally important that USPSTF include in its final Recommendation Statement a Grade B. Such a decision would be evidence-based, in clear alignment with federal agencies and established national policy. It also would be an ethical step forward in solidarity with people searching for answers about undetected and unexplained emergent cognitive decline.

Thank you for considering our views and for your commitment to overcoming all forms of dementia. For any questions or additional information, please contact Ian Kremer, Executive Director of Leaders Engaged on Alzheimer's Disease (the LEAD Coalition),[i] ikremer@leadcoalition.org or (571) 383-9916.

Sincerely,

Abe's Garden Alzheimer's Center of Excellence
Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) Coalition
ActivistsAgainstAlzheimer's Network
ADVancing States
African American Network Against Alzheimer's
AgeneBio
Neelum T. Aggarwal, MD (Rush University Medical Center*)
Aging and Memory Disorder Programs, Howard University
Aging Life Care Association®
Paul S. Aisen, MD (Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute*)
Alliance for Aging Research
Alliance for Patient Access
Alzheimer's & Dementia Alliance of Wisconsin
Alzheimer's Drug Discovery Foundation
Alzheimer's Foundation of America
Alzheimer's Los Angeles
Alzheimer's Mississippi
Alzheimer's New Jersey
Alzheimer's Orange County
Alzheimer's San Diego
Alzheimer's Tennessee
Alzheimer's Texas
American Academy of Neurology
American Association for Geriatric Psychiatry
American Medical Women's Association
American Society of Consultant Pharmacists (ASCP)
Laura D. Baker, PhD (Wake Forest University Health Sciences*)
Banner Alzheimer's Institute

David M. Bass, PhD (Benjamin Rose Institute on Aging*)
Beating Alzheimer's by Embracing Science
Andrew R. Bender, Ph.D. (Michigan State University)
Benjamin Rose Institute on Aging
Biogen
Deborah Blacker, MD, ScD (Harvard Medical School and Harvard School of Public Health*)
Boehringer Ingelheim Pharmaceuticals, Inc.
Soo Borson MD (Minnesota Brain Aging Research Collaborative*)
James Brewer, M.D., Ph.D. (UC San Diego and Alzheimer's Disease Cooperative Study*)
Bridge Builder Strategies
BrightFocus Foundation
Christopher M. Callahan, MD (Indiana University Center for Aging Research*)
Caregiver Action Network
Caregiver Voices United
CaringKind, The Heart of Alzheimer's Caregiving
Center for Alzheimer Research and Treatment, Harvard Medical School
Center for BrainHealth at The University of Texas at Dallas
Center for Memory Health at Hebrew SeniorLife
Center to Advance Palliative Care
Sandra Bond Chapman, PhD (Center for BrainHealth at The University of Texas at Dallas*)
Joshua Chodosh, MD, MSHS, FACP (New York University*)
ClergyAgainstAlzheimer's Network
Cleveland Clinic Foundation
Coalition of Wisconsin Aging and Health Groups
Cognition Therapeutics
Cognitive Dynamics Foundation
Suzanne Craft, PhD (Wake Forest School of Medicine*)
Jeffrey Cummings, MD, ScD (Cleveland Clinic Lou Ruvo Center for Brain Health*)
Cure Alzheimer's Fund
Walter Dawson, Dphil (Portland State University*)
Dementia Alliance International
Department of Neurology, Washington University School of Medicine
Drexel University College of Nursing and Health Professions
Drexel University Memory and Cognitive Disorder Center
Duke Dementia Family Support Program
Eisai Co., Ltd.
Gary Epstein-Lubow, MD (Alpert Medical School of Brown University*)
Faith United Against Alzheimer's Coalition
Michela Gallagher, PhD (Johns Hopkins University School of Medicine*)
Sam Gandy, MD, PhD (Icahn School of Medicine at Mount Sinai*)
Daniel R. George, Ph.D, M.Sc (Penn State College of Medicine*)
Georgetown University Medical Center Memory Disorders Program
Gerontological Advanced Practice Nurses Association
Gerontological Society of America
Laura N. Gitlin, PhD (Drexel University, College of Nursing and Health Professions*)
G. Peter Gliebus, MD (Drexel University, College of Medicine*)
Global Alzheimer's Platform Foundation
Global Coalition on Aging
Lisa P. Gwyther, MSW, LCSW (Duke University Medical Center*)
Hilarity for Charity
Nancy A. Hodgson, RN, PhD, FAAN (University of Pennsylvania School of Nursing*)
David P Hoffman DPS CCE (Maria College*)
David M. Holtzman, MD (Washington University School of Medicine, Department of Neurology*)
Home Instead Senior Care
International Association for Indigenous Aging
Iona Senior Services
Janssen R&D
Kathy Jedrziewski, PhD (University of Pennsylvania*)
Johns Hopkins Memory and Alzheimer's Treatment Center
Katherine S. Judge, PhD (Cleveland State University*)
Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute
Keep Memory Alive
Theresa Rohr-Kirchgraber, MD, FACP, FAMWA (Indiana University National Center of Excellence of Women's Health*)
Latino Alzheimer's and Memory Disorders Alliance
LatinosAgainstAlzheimer's
Lewy Body Dementia Association
Life Molecular Imaging
Linked Senior, Inc
Livpact Inc.
Lou Ruvo Center for Brain Health
LuMind IDSC Foundation
Lundbeck
Kostas Lyketsos, M.D., M.H.S. (Johns Hopkins Memory and Alzheimer's Treatment Center*)

Julie Brody Magid, Psy.D (Harvard Medical School, Department of Psychiatry*)
Tabassum Majid, PhD (The Erickson School of Aging, University of Maryland Baltimore County*)
Yannick Marchalant, Ph.D. (Central Michigan University*)
David X. Marquez, PhD (Department of Kinesiology and Nutrition, University of Illinois at Chicago*)
Medical Imaging & Technology Alliance (MITA)
Michigan State University Alzheimer's Alliance
Milken Institute Center for the Future of Aging
Minnesota Brain Aging Research Collaborative
Mary Mittelman, DrPH (New York University Medical Center*)
David G. Morgan, PhD (Michigan State University*)
Darby Morhardt, PhD, LCSW (Northwestern University Feinberg School of Medicine*)
Mount Sinai Center for Cognitive Health
National Alliance for Caregiving
National Asian Pacific Center on Aging
National Association of Activity Professionals
National Association of Area Agencies on Aging (n4a)
National Association of Chronic Disease Directors
National Association of Nutrition and Aging Services Programs
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National Certification Council for Activity Professionals
National Council for Behavioral Health
National Down Syndrome Society
National Task Group on Intellectual Disabilities and Dementia Practices
NFL Neurological Center
Noah Homes
NYU Langone Alzheimer's Disease Center
NYU Langone Center on Cognitive Neurology
Thomas O. Obisesan, MD, MPH (Howard University Hospital*)
The Ohio Council for Cognitive Health
Otsuka Pharmaceutical Development and Commercialization
Monica W. Parker, MD (Goizueta Alzheimer's Disease Research Center, Emory University*)
Planetree International, Inc.
Daniel C. Potts, MD, FAAN (University of Alabama College of Community Health Sciences*)
Prevent Alzheimer's Disease 2020
Peter Reed, PhD (Sanford Center for Aging, University of Nevada Reno*)
Eric Reiman, MD (Banner Alzheimer's Institute*)
ResearchersAgainstAlzheimer's
Quincy Miles Samus, PhD, MS (Johns Hopkins School of Medicine*)
Second Wind Dreams, Inc./ Virtual Dementia Tour
Amanda G. Smith, M.D. (USF Health Byrd Alzheimer's Institute*)
Reisa A. Sperling, MD, MMSc (Center for Alzheimer Research and Treatment, Harvard Medical School*)
Erin Stevens, DO (Harvard Medical School*)
Rudolph Tanzi, PhD (Department of Neurology, MGH/Harvard Medical School*)
The Association for Frontotemporal Degeneration
The Youth Movement Against Alzheimer's
Geoffrey Tremont, Ph.D., ABPP-CN (Alpert Medical School of Brown University*)
John Q. Trojanowski M.D., Ph.D. (Perelman School of Medicine at the University of Pennsylvania*)
R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)
University of Pennsylvania Alzheimer's Disease Core Center
University of Pennsylvania Center for Neurodegenerative Disease Research
University of Pennsylvania Center on Alpha-synuclein Strains in Alzheimer Disease & Related Dementias
UsAgainstAlzheimer's, LEAD Coalition co-convener
USF Health Byrd Alzheimer's Institute, University of South Florida
VeteransAgainstAlzheimer's
Anand Viswanathan, MD, PhD (Massachusetts General Hospital and Alzheimer's Disease Research Center*)
Stella L. Volpe, PhD (Drexel University, Department of Nutrition Sciences*)
Volunteers of America, LEAD Coalition co-convener
Victoria Walker, MD CMD (Sanford School of Medicine, University of South Dakota*)
Carol J. Whitlatch, PhD (Benjamin Rose Institute on Aging*)
Jennifer Wolff, PhD (Johns Hopkins Bloomberg School of Public Health*)
WomenAgainstAlzheimer's
Women's Brain Project

** Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of affiliated institutions.*

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[i] http://www.leadcoalition.org Leaders Engaged on Alzheimer's Disease (the LEAD Coalition) is a diverse national coalition of member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and home and residential care providers, large health systems, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation's strategic attention on dementia in all its causes – including Alzheimer's disease, vascular disease, Lewy body dementia, and frontotemporal degeneration – and to accelerate transformational progress in detection and diagnosis, care and support, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.