

# ASNR/ASFNR Statement on CMS Coverage of Amyloid PET Imaging

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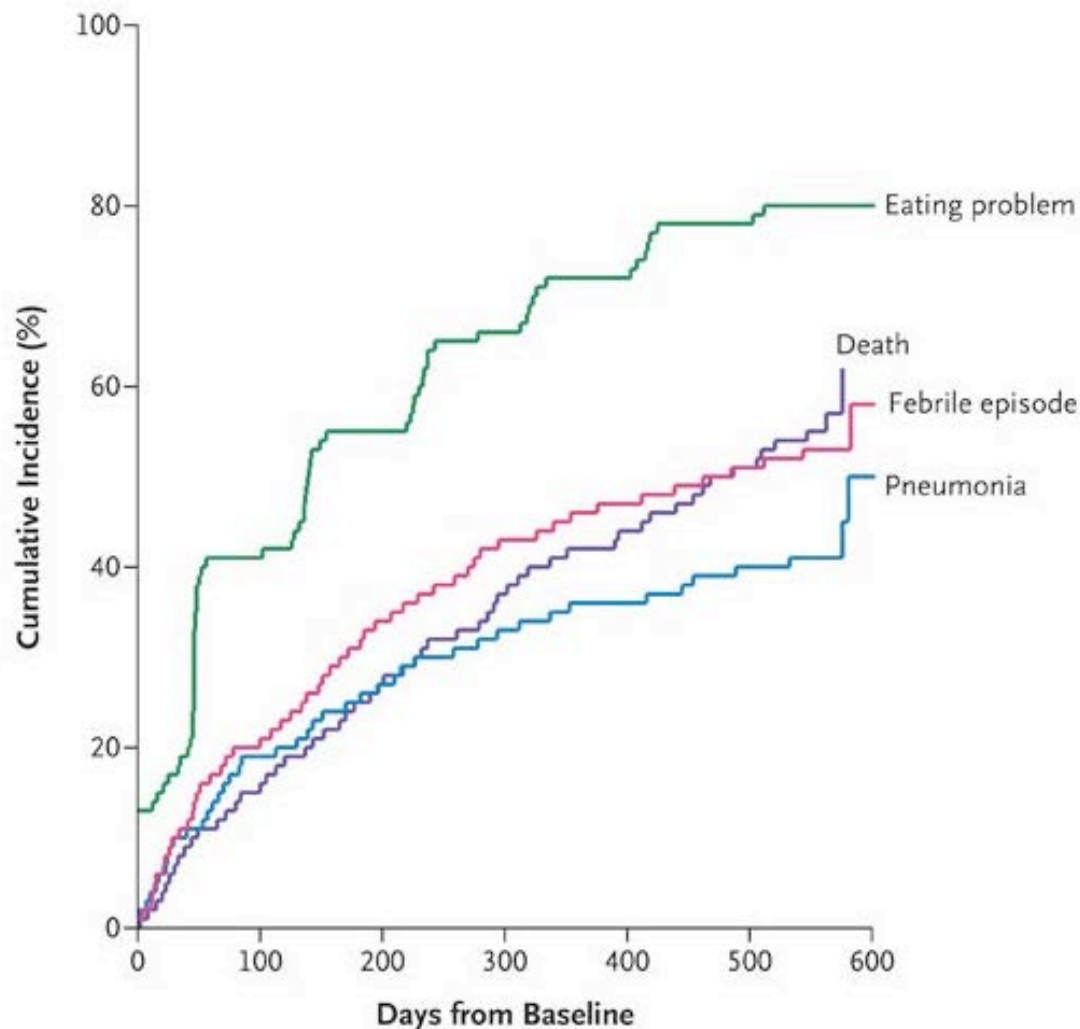


# Disclosure

1. No personal financial or intellectual conflicts of interest. Specifically, no personal financial interests including consulting, research support or advisory board membership.
2. Mykol Larvie has participated in clinical trials involving the following entities, with no financial support:  

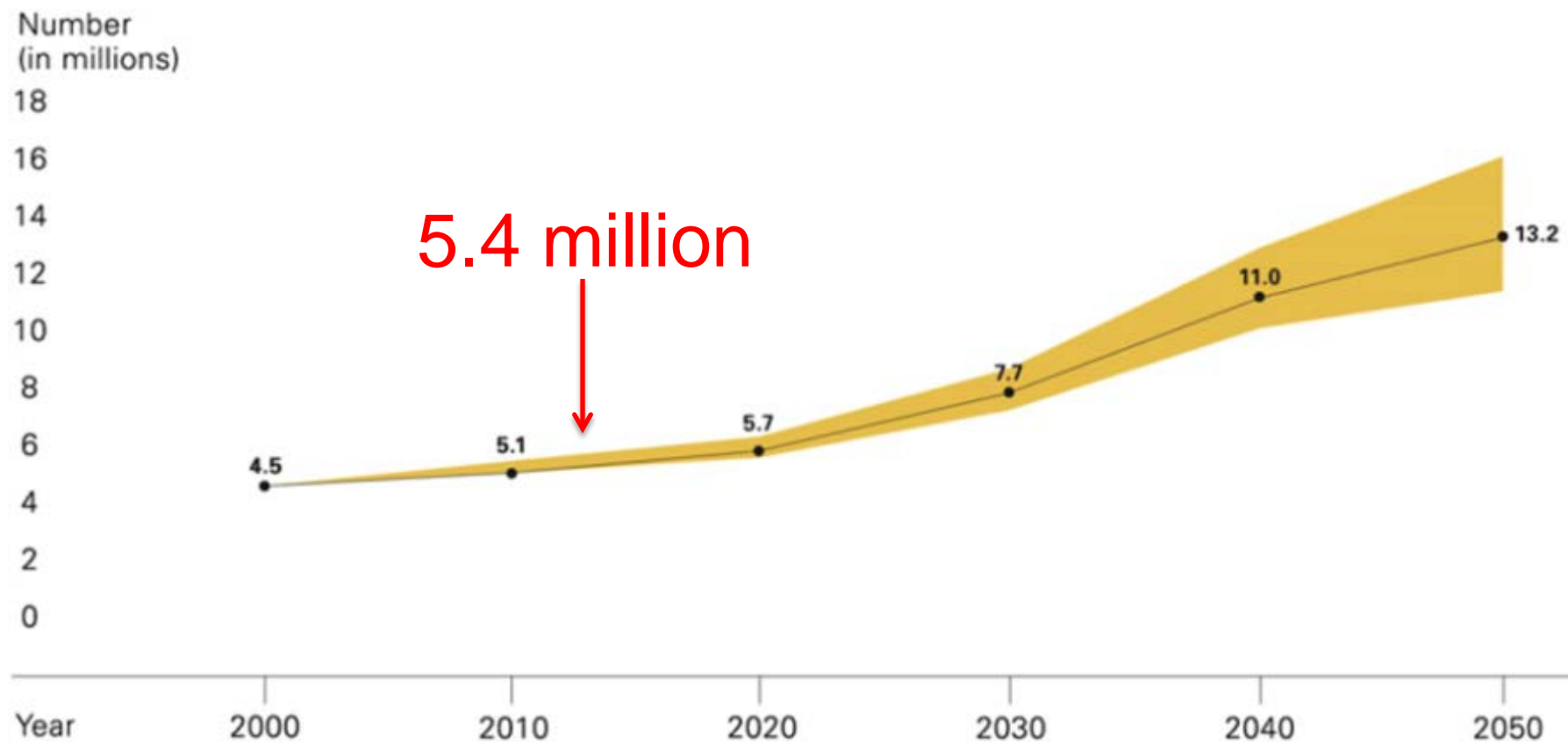
Janssen-Pfizer	Lilly-Avid
Navidea	WorldCare
3. Transportation and related expenses for attending today's meeting paid by the ASNR. No other conflicts for ASNR or ASFNR.

# Dementia is a Terminal Disease



N Engl J Med. 2009 Oct 15;361(16):1529-38. The clinical course of advanced dementia. Mitchell SL, Teno JM, Kiely DK, Shaffer ML, Jones RN, Prigerson HG, Volicer L, Givens JL, Hamel MB.

# Increasing Prevalence of Alzheimer's Disease



Alzheimer's Association (2012). 2012 Alzheimer's disease facts and figures. *Alzheimers Dement* 8, 131–168.

# Imaging in the Evaluation of Neurocognitive Deficits

## Identify irreversible disease

- Infarction
- Traumatic brain injury
- Amyloid angiopathy

## Identify treatable conditions

- Hydrocephalus
- Hematoma
- Metabolic disease
- Tumor

## Identify neurodegenerative disease

- Alzheimer's disease
- Lewy body disease
- Frontotemporal lobar degeneration

# Diagnosis of Neurocognitive Deficits

## Clinical examination

- Neuropsychological testing

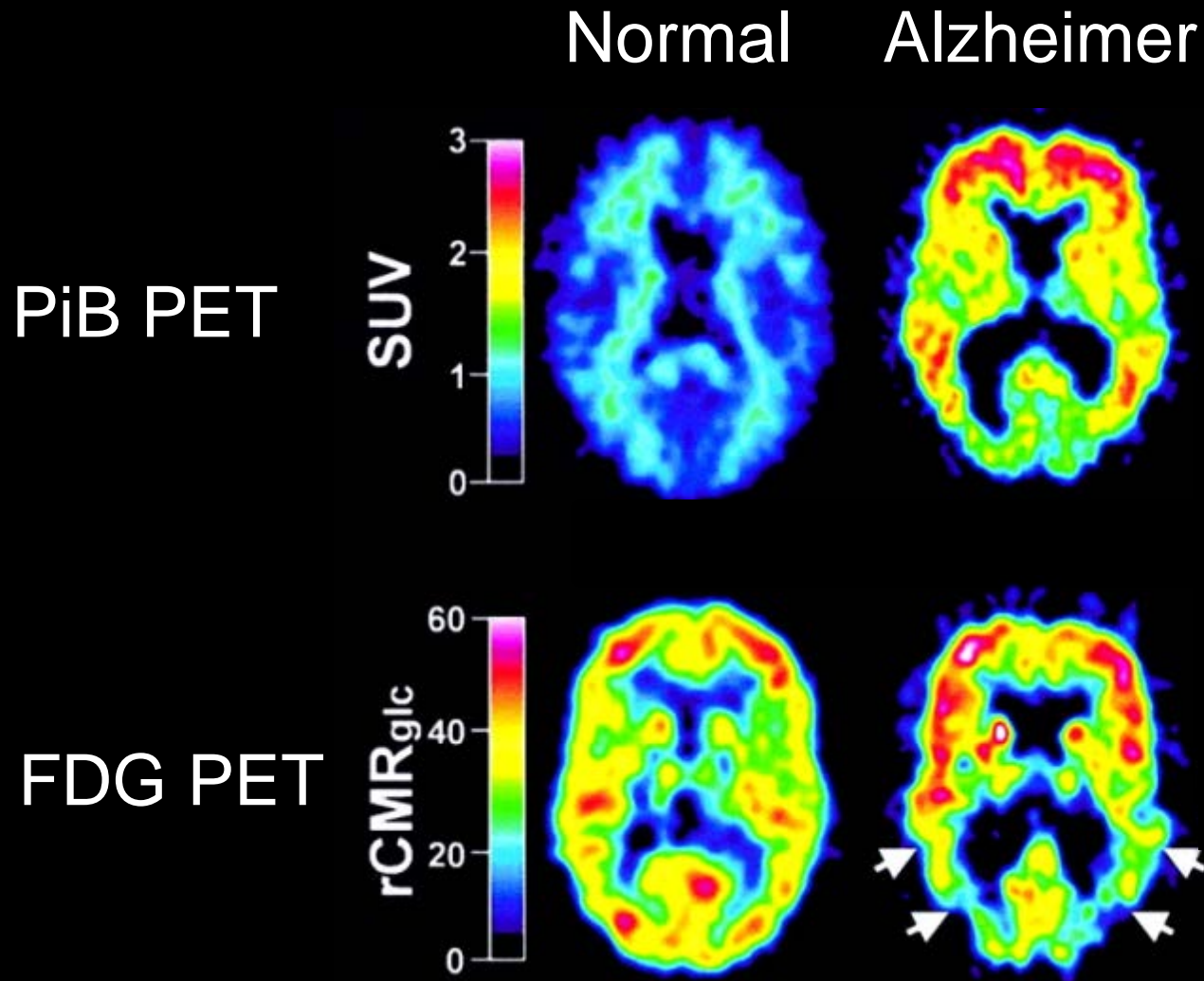
## Laboratory studies

- CSF analysis

## Imaging

- CT
- MRI
- FDG PET
- Amyloid PET

# PET Imaging: FDG & PiB



Klunk WE, Engler H, Nordberg A, *et al.* (2004) Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B. *Ann Neurol* **55**: 306–319.

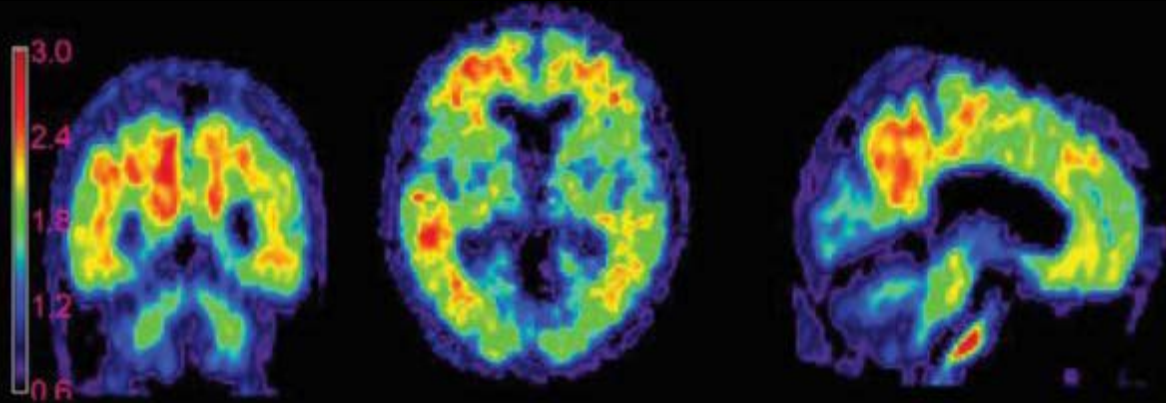
# BENEFITS of Diagnosis in Neurodegenerative Disease

- Appropriate utilization of medical therapies
- Identify appropriate caregiving strategies
- Diagnosis decreases depression and anxiety in patients and their caregivers
- Life planning

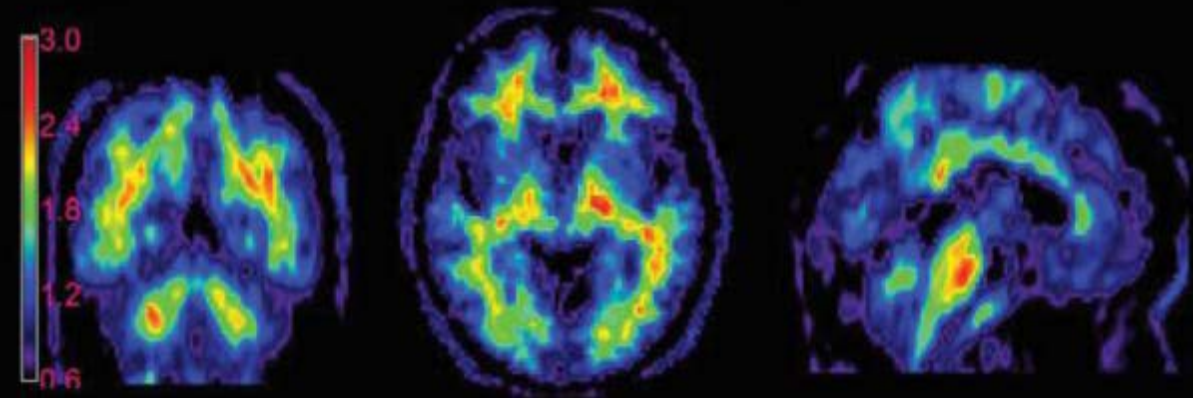


# Amyloid Imaging: Florbetapir PET

77 year old female  
Mild AD  
MMSE 24



82 year old male  
Cognitively healthy  
MMSE 30



Wong et al. In Vivo Imaging of Amyloid Deposition in Alzheimer Disease Using the Radioligand  $^{18}\text{F}$ -AV-45. *Journal of Nuclear Medicine* (2010).

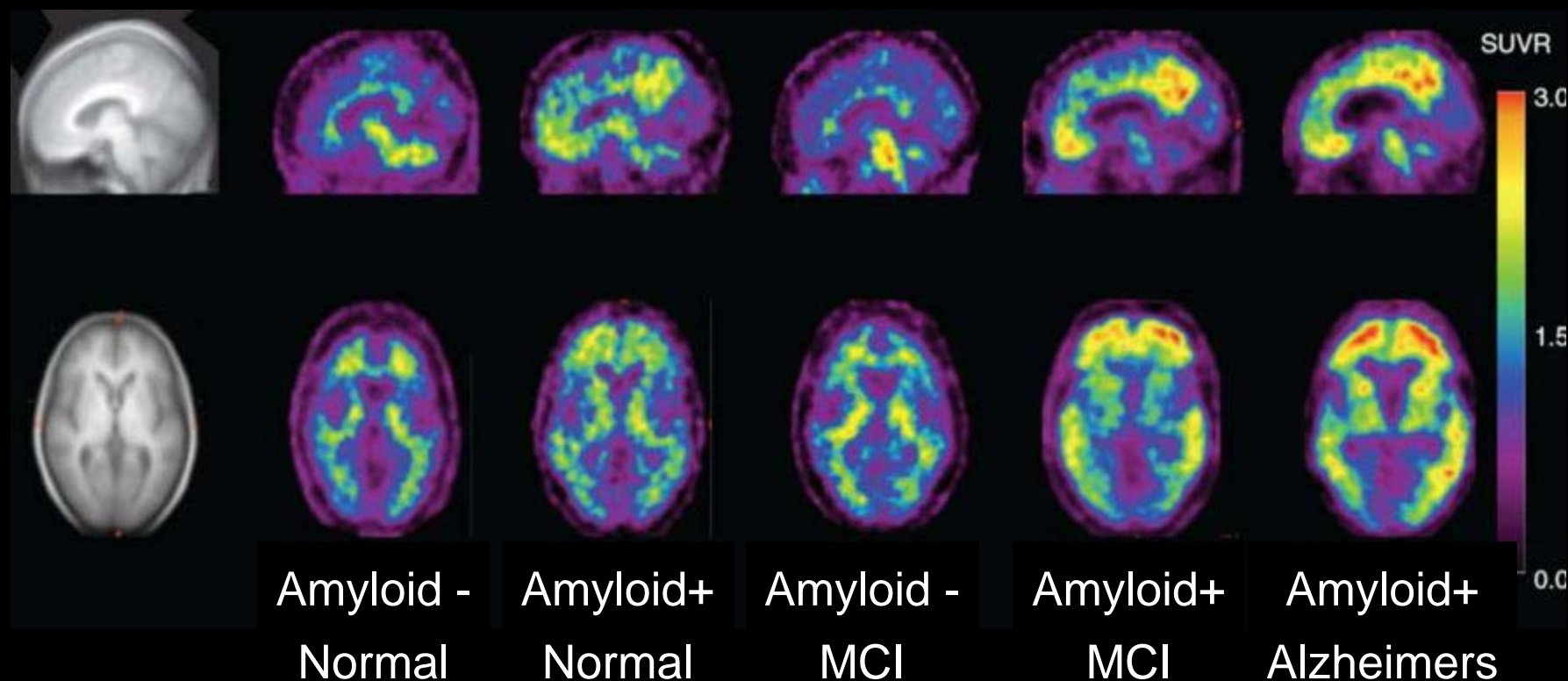
# RISKS of Diagnosis in Neurodegenerative Disease

- Inaccurate diagnosis
  - False negative
  - False positive
- Stigma
- Increased distress to patient and caregivers
- Absence of disease modifying therapy
- Elderly patients are vulnerable to exploitation
- Amyloidosis in the absence of cognitive deficits is an ambiguous condition

# Asymptomatic Amyloidosis

- May represent pre-clinical Alzheimer's disease
- May NOT progress to AD
- There are currently no clear criteria to identify asymptomatic amyloid (+) patients who are likely to progress to AD and those who are not
- Such patients are at risk of inappropriate therapy, which may come at great cost

# Variability of Brain Amyloid



Modified from Rodrigue et al. Beta-amyloid deposition and the aging brain. Neuropsychol Rev (2009) vol. 19 (4) pp. 436-50

# Goals of Diagnosis in Neurodegenerative Disease

- Improved patient outcomes
  - Quality of life
  - Survival
- Decrease caregiver stress & anxiety
- Decrease family stress & anxiety
- Lower costs of care

# Utility of Amyloid PET Imaging

- **Amyloid PET imaging improves diagnostic confidence:** Schipke et al. Impact of beta-amyloid-specific florbetaben PET imaging on confidence in early diagnosis of Alzheimer's disease. Dement Geriatr Cogn Disord 2012; 33:416-422.
- **Amyloid PET imaging may contribute to clinical management:** Grundman et al. Potential Impact of Amyloid Imaging on Diagnosis and Intended Management in Patients With Progressive Cognitive Decline. Alzheimer Disease and Associated Disorders 2012.

# Coverage Options

## Coverage for approved indications

- E.g., SNM/AA guidelines for appropriate and inappropriate uses

## Coverage with Evidence Determination (CED)

- Refine framework for evaluation of diagnostic accuracy
- Assess outcomes
- Cost analysis

# ASNR Recommendations - 1

- CMS coverage of amyloid PET imaging is in the best interests of patient care
- Improved patient outcomes are a primary objective
- Cost-effective care remains a critical consideration
- Balance of these objectives requires research to define best practices



# ASNR Recommendations - 2

- Amyloid PET imaging and interpretation should be standardized and high quality.
- Patients should be appropriately selected for amyloid PET imaging.
- Amyloid PET imaging should not be performed as a screening test outside of IRB-approved research.
- Utilization guidelines should be established for the benefit and protection of patients.

# ASNR Recommendations - 3

- Elderly patients represent a vulnerable population

Systematic protections warranted to prevent unnecessary or inappropriate examination and treatment

- Potential for inappropriate utilization

Prospects of unproven disease modifying therapy may drive unnecessary testing and treatment

# Service of ASNR in Evaluation of Amyloid PET Imaging

- Physicians committed to objective patient advocacy
- Imaging QA/QC
  - Accreditation of imaging facilities (with ACR)
- Education: Imaging and Interpretation
- Research:
  - Interpretation performance
  - Diagnostic utility: accuracy, clinical management
  - Utilization
- Collaboration with American College of Radiology, Society for Nuclear Medicine and American Society of Functional Neuroradiology and pharmaceutical and imaging equipment manufacturers

# Questions?



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