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May 20, 2013

Louis B. Jacques, M.D.
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244

Dear Dr. Jacques:

I am writing in follow-up to Public Citizen's March 21, 2013, letter to you urging the Centers for Medicare & Medicaid Services (CMS) to maintain its current National Coverage Decision excluding coverage for β -amyloid positron emission tomography (PET) imaging for the following major reasons:

- (1) There are no data from any completed, well-designed, controlled clinical trials evaluating whether PET imaging of brain β -amyloid changes the health outcomes of patients who display early symptoms or signs of cognitive dysfunction, or in any other patient population.
- (2) There is a lack of correlation in AD patients between the areas of the brain showing a positive signal on β -amyloid PET scans and those areas of the brain having the highest density of β -amyloid deposits at autopsy.
- (3) Interpretation of brain β -amyloid PET scans is subject to significant variability among readers.
- (4) The results of brain β -amyloid PET scans have no clinical utility because the results of such imaging should have no impact on the clinical evaluation of patients with cognitive impairment or early onset dementia.

Enclosed is an authoritative critical review in press in the *Journal of Alzheimer's Disease* (DOI:10.3233/JAD-130485) that further explains the inadequacies of β -amyloid PET scans. Please consider this additional information as CMS deliberates on the National Coverage Decision for such scans.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Enclosure