

March 29, 2012

To Whom It May Concern:

The Society of Nuclear Medicine (SNM), headquartered in Reston, Va., is a nonprofit scientific and professional organization that promotes the science, technology and practical application of nuclear medicine and molecular imaging. SNM strives to be a leader in unifying, advancing and optimizing molecular imaging, with the ultimate goal of improving human health. With 17,000 members worldwide, SNM represents nuclear and molecular imaging professionals, all of whom are committed to the advancement of the field. For more than 50 years, SNM members have developed—and continue to explore—innovations in medical imaging to allow for noninvasive diagnosis, management and treatment of diseases, benefiting countless patients. Members include physicians, technologists, physicists, pharmacists, scientists, and laboratory professionals.

Since the conception of cross-sectional imaging of the human brain in the 1960's, SNM has been a leading international organization to advance imaging methods to better investigate dementing illness and educate physicians about clinical applications. We have witnessed significant advances in brain perfusion imaging, brain metabolism imaging, and now dopamine and amyloid imaging. Molecular imaging is able to improve the diagnosis and management of neurodegenerative brain disorders, including Alzheimer's, Parkinson's and other dementias and movement disorders.

Significant advances in imaging have made it possible to detect the onset of Alzheimer's disease, track its progression, and monitor the effects of treatment. These advances are being leveraged by the National Institute of Aging and the public-private Alzheimer's Disease Neuroimaging Initiative (ADNI) which will help identify and monitor disease progression, even in the early stages before individuals show symptoms of the disease. Empowered with the knowledge of brain pathology, clinicians will be more likely to begin and maintain appropriate treatment.

Despite these great technical achievements, there have been limited advances in treatment and no improvement in mortality related to Alzheimer's disease. Far too many people with Alzheimer's disease are not diagnosed until their symptoms have become severe. The standard clinical diagnostic approach, which is used to infer underlying Alzheimer's disease pathology, has less than optimal specificity and sensitivity, even in expert hands. By the time dementia is obvious, deficits often are so pervasive that the typical phenotype may be difficult to recognize.

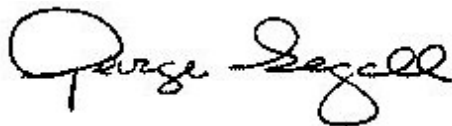
Therefore, SNM strongly supports the decision of the President and the Secretary of Health of Human Services to enhance dementia care through the establishment of a National Plan to Address Alzheimer's Disease. We would encourage the President and HHS Secretary to include a greater emphasis on molecular imaging in the plan. Molecular imaging is one of only a few methods that can unveil pathophysiological and pathogenic changes in living human patients. To make future breakthroughs, further investments are critical, including the investigational use of molecular imaging and the effective implementation of imaging technologies in the clinic.

In addition, we suggest that DHHS to consider not only supporting dementia imaging research through NIH NIA/ADNI initiative, but also more broadly investing in basic and translational research to develop new diagnostic tools and advance them to human applications through multiple NIH Institutes (e.g., NINDS, NIBIB), FDA for accelerated review, and CMS for clinical implementation.

Specific comments are:

- Action 1.B.5: The plan should recognize the importance of molecular imaging as a means to facilitate and accelerate pharmacological clinical trials. Molecular imaging can greatly assist in the development of new therapeutic agents at several different stages. Molecular imaging can be used to better select patients with Alzheimer's disease for clinical trials, to exclude patients with other diseases who might not benefit from the therapy, and to demonstrate the presence of the therapeutic target for anti-amyloid therapies. Properly applied in early clinical testing, imaging data can assist in making a go/no-go decision about the effectiveness of potential new therapies. Utilized in later clinical development, molecular imaging can serve as a biomarker of response, substituting for a clinical endpoint.
- Action 1.C.1 could be strengthened by expanding the organizations supported beyond ADNI. In order to see significant breakthroughs with regard to pathophysiology and develop new molecular imaging agents that image a range of biological pathways, research investments are needed at a range of academic, private, and public entities, including other NIH Institutes such as NINDS and NIBIB.
- Strategy 2B would be strengthened by including utilization of existing neuroimaging tools and investment in new tools. Molecular imaging methods can show abnormal patterns in Alzheimer's disease and can help in the differential diagnosis of dementing disorders. Their use would help achieve the goals of facilitating appropriate assessment and giving healthcare providers tools to make accurate and timely diagnoses. Therefore, patients would benefit more rapidly from the increased access to healthcare resources for Alzheimer's disease care that the Affordable Care Act will provide.

Sincerely,



George Segall, MD  
President, Society of Nuclear Medicine