



# SNM Annual Meeting Educational Activities

The Washington, DC, location of the 2007 SNM Annual Meeting (June 2–6) provides an excellent opportunity for the molecular imaging and therapy community to get together with policymakers and regulators to discuss issues of shared concern. Continuing education sessions provided by the Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) have been among the most highly successful educational offerings of past SNM Annual Meetings. SNM hopes to expand upon this success in 2007 with an increase in the number of FDA and CMS reimbursement offerings, an additional session on radiation safety regulation moderated by the Nuclear Regulatory Commission (NRC), and specialty workshops from the National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bio-Engineering (NIBIB) and National Cancer Institute (NCI). Last, but certainly not least, SNM will offer an educational session on health policy and communication with legislators featuring meetings on Capitol Hill.

Below is a preliminary look at the SNM 2007 Annual Meeting educational program related to health policy and regulatory affairs (subject to change). More information on each of these sessions is available via the online meeting planner at [www.snm.org/am](http://www.snm.org/am).

## Congress

**Capitol Hill Day: Molecular Imaging and the Public Policy Agenda** (preregistration and confirmation required): Tuesday, June 5, 11:00 AM–3:00 PM

## FDA

**FDA Session I: Research with Radiolabeled Drugs:** Monday, June 4, 4:30–6:00 PM

**FDA Session II: Final PET Drug CGMP** (or other FDA CDER issues if the final rule is not ready by June): Wednesday, June 6, 8:00–9:30 AM

## CMS

**Reimbursement & Coding Part I: Approaches to P4P and CMS Quality Initiatives:** Monday, June 4, 12:30–2:00 PM

**Reimbursement & Coding Part II: Coding and Policy Changes: What You Need to Know:** Monday, June 4, 2:30–4:00 PM

## NRC

**NRC: Running an NRC Compliant Radiation Safety Program:** Tuesday, June 5, 9:45–11:15 AM

## NIH

**NIH-NCI Workshop: Use of PET CT in the Clinic and Clinical Trials: Quantitation for Change Analysis:** Saturday, June 2, 10:00 AM–5:00 PM

**NIH-NIBIB Workshop: Molecular Biology for Imagers:** Saturday, June 2, 10:00 AM–5:00 PM



**Hugh Cannon**  
Director of Health Policy and Regulatory Affairs, SNM

## 2007 Nuclear Medicine Reimbursement Roadshow Book and CD

The educational materials from the highly successful 2007 Nuclear Medicine Reimbursement Roadshow seminars are now available for purchase on the SNM Web site at <http://interactive.snm.org/index.cfm?PageID=6025>.

The seminars addressed appropriate coding of nuclear medicine procedures and radiopharmaceuticals, such as how to use current CPT manuals, identify nuclear medicine procedures that are covered (or not covered) by Medicare and third-party payers, and many other topics.

Distinguished nuclear medicine coding experts Gary L. Dillehay, MD; Kenneth A. McKusick, MD; and Denise A. Merlino, CNMT, MBA, moderated the seminars, which took place in Nashville, TN, San Francisco, CA, and Boston, MA.

## NRC

At this writing, the NRC staff is in the process of compiling a preliminary agenda for the June public meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The NRC staff is considering providing up to a full day of open discussion on 10 CFR Part 35 training and experience (T&E) requirements. Relevant certification boards and professional organizations will be invited to provide input for the consideration of the NRC staff and ACMUI.

## OSHA

On March 16 the Occupational Safety and Health Administration (OSHA) hosted the first of 4 stakeholder meetings on “Occupational Exposure to Ionizing Radiation.” The first meeting was dedicated to issues specifically pertaining to health care professionals. Future meetings will be dedicated to various nonmedical professionals.

SNM was represented at the meeting by Robert W. Atcher, PhD, vice president-elect. More than 20 various professional and trade organizations were also represented, including the American College of Radiology, American Association of Physicists in Medicine, and Council on Radionuclides and Radiopharmaceuticals.

The primary objective of the meeting was to generate discussion and ideas from stakeholders. At this exploratory stage, OSHA staff did not disclose or verify any specific plans to modify their existing ionizing radiation regulations (29 CFR 1910.1096).

### CARE Legislation

The American Society of Radiologic Technologists (ASRT) held their annual "RT in DC" event on March 18–20 in Washington, DC, to support the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and

Radiation Therapy bill (CARE bill). The event featured an educational workshop on CARE and appropriate communication with legislators, followed by a full day of legislative visits for approximately 140 technologist attendees.

Senators Michael B. Enzi (R-WY) and Edward M. Kennedy (D-MA) introduced the Senate version of the CARE bill (S 1042) on March 29. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions.

The House of Representatives' version of the CARE bill (HR 583) was introduced in the 110th Congress on January 19. At this writing there are approximately 49 cosponsors of this bill.

*Hugh Cannon*

*Director of Health Policy and Regulatory Affairs, SNM*

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nuclear, MR, CT, ultrasound, and optical methods and described approaches that employ in vitro models, small and large animal imaging, and studies in humans. MI has a role to play in all stages of drug development. MI studies of the interaction of a proposed new drug with its target tissue can help test the underlying biological hypothesis about how the drug acts, select the range of drug doses to use in human studies, and provide early information to terminate development of a drug before carrying out more costly steps. Using MI in the later phases of drug development can result in smaller, speedier clinical trials, making them both less expensive and safer.

Christopher Rowe, MD, of the Department of Nuclear Medicine and Centre for PET at the Austin Hospital (Melbourne, Australia) presented the third lecture, on "A $\beta$  Imaging with  $^{11}\text{C}$ -PIB PET: A Biomarker for Early Detection of Alzheimer's Disease."  $^{11}\text{C}$ -PIB is a radiopharmaceutical developed by scientists at the University of Pittsburgh specifically to image the A $\beta$  plaques that accumulate in AD. Potential roles for  $^{11}\text{C}$ -PIB include accurate diagnosis of early AD, early intervention when patients are minimally impaired, selection of patients for clinical trials of anti-amyloid therapy, and monitoring the effectiveness of such therapy. This latter application is an example of the use of an MI biomarker in drug development, as was reviewed by Mozley. Data were shown demonstrating the superiority of  $^{11}\text{C}$ -PIB over  $^{18}\text{F}$ -FDG in the detection of AD and its utility in the differential diagnosis of dementia. Clinical trials with  $^{11}\text{C}$ -PIB are now being carried out in numerous international sites.

In "Monitoring Gene Therapy in Parkinson's Disease," Krystof Bankiewicz, MD, presented several aspects of using

imaging to assess local drug delivery in the brain and an elegant example of imaging to monitor the expression of a therapeutic gene. Parkinson's disease (PD) is characterized by the loss of dopaminergic neurons that project to the striatum. The gene replacement strategy involves the striatal delivery of the genes for amino acid decarboxylase (AADC) in an adeno-associated virus vector. The expression of AADC is visualized with  $^{18}\text{F}$ -fluoro-m-tyrosine or  $^{18}\text{F}$ -fluoro-L-DOPA. This gene therapy has been extensively evaluated in primate models of PD, where it was found that gene expression was sustained for many years and the PD symptoms were reduced. A phase I study of this therapy in humans with concomitant  $^{18}\text{F}$ -fluoro-m-tyrosine imaging is underway.

The development and application of MI probes will be critical to understanding the pathophysiology of neuropsychiatric diseases and to developing and monitoring better therapies. Labeled agonists, antagonists, and substrates for components of neurotransmitter systems have been applied to assess neuroreceptor density and metabolic processes associated with a variety of neuropsychiatric diseases. MI agents are increasingly being used to monitor drug delivery, dose response, drug metabolism, and drug interactions, all key components of the drug development paradigm. Although this symposium presented examples that involved PET or SPECT probes, MR also has an important role in MI applications in the brain. It is clear that molecular neuroimaging will play a pivotal role in the future of patient management and care.

*Henry VanBrocklin, PhD*

*University of California, San Francisco*

*Peter Herscovitch, MD*

*National Institutes of Health*

*Bethesda, MD*