

Advocating for Our Field

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One of the more important but perhaps less visible arenas in which SNMMI is active is advocacy—for the field of nuclear medicine, for our members, and for our patients. Our work, from radiochemistry laboratories to patient care, is impacted by the regulatory policies of a number of federal agencies, ranging from regulation of radionuclides by the Nuclear Regulatory Commission (NRC) to approval of radiopharmaceuticals by the Food and Drug Administration (FDA) to decisions regarding reimbursement by the Centers for Medicare and Medicaid Services (CMS). It is also affected by the actions of legislatures, both federal and state; state government agencies; and insurance companies.

One ongoing issue is CMS's decision to bundle the cost of radiopharmaceuticals with the cost of the imaging procedure in the hospital outpatient setting. In many cases, reimbursement for the bundle is much less than the actual cost of the drug, which means that an imaging department loses money whenever it carries out an imaging procedure with these agents. This has, in some cases, led to departments not performing studies with these agents. In an effort to address this problem, SNMMI and its coalition partners worked to encourage the introduction of H.R. 3772 in July 2019—a bill that would require separate payment for high-value radiopharmaceuticals—with broad bipartisan support during the last Congressional term. Recently, however, after meeting with the House of Representative's Energy and Commerce Committee, the coalition was encouraged to once again explore a regulatory solution with CMS, and SNMMI and its partners are communicating with the new CMS administration to urge the agency to reverse its decision to bundle diagnostic radiopharmaceuticals. If this effort is not successful, SNMMI and its partners will reintroduce the bill, and SNMMI is asking other imaging societies to consider supporting this legislation. Shortly after the new bill is introduced, SNMMI plans to initiate a new letter-writing campaign and will explore options for an in-person or virtual fly-in event to show support for the bill on Capitol Hill.

In another CMS-related issue, after many discussions with CMS over the last year, SNMMI was successful in getting the national noncoverage decision removed for use of ^{18}F -FDG PET for infection/inflammation imaging. Coverage determinations for these indications will now be made by local Medicare Administrative Contractors. Our long-range goal is to achieve CMS coverage for all FDA-approved PET indications, and this is a significant first step.

SNMMI continues to work with CMS's National Correct Coding Initiative to correct procedure-to-procedure codes. The strategy is working, as many of these codes have been corrected.

To address the challenge of providing in-person learning experiences during the COVID-19 pandemic, SNMMI successfully advocated for exemptions to in-person training and experience requirements from the NRC. Rather than mandating hands-on experience, this one-time modification allowed authorized users to participate in virtual training for imaging and localization studies. In a separate NRC issue, SNMMI responded to an NRC petition for rulemaking that would require that extravasations/infiltrations of radiopharmaceuticals be reported to the NRC as adverse medical events. SNMMI issued a statement expressing its belief that no additional rulemaking is required and is working with other imaging societies to address this issue. The Society will continue to monitor these and other NRC issues.

SNMMI also regularly monitors the work of the FDA to stay informed about changes that impact nuclear medicine and molecular imaging, and the Society has created a dedicated FDA PET Drug Manufacturing Q&A section on the SNMMI website (<http://www.snmmi.org/IssuesAdvocacy/FDAQandA.aspx?navItemNumber=34424>). In 2021, SNMMI and the FDA plan to cohost workshops focused on newly introduced radiopharmaceuticals.

In the commercial payer realm, in August 2020 Humana issued a policy decision denying coverage for PET/CT and SPECT/CT for several common indications. In response, SNMMI wrote 2 letters to Humana protesting this decision: 1 focused on cardiac indications and 1 on oncologic and neurologic PET/CT and SPECT/CT. The Society will continue to work with Humana to reverse this decision and will continue to oppose similar determinations by other third-party payers.

On the state level, SNMMI has been monitoring licensing legislation and regulatory developments in key states, such as Pennsylvania and Georgia, and bills that were not passed in 2020 will be reintroduced in these states this year. The SNMMI Technologist Section recently conducted a survey of technologist licensing requirements across the United States. The results are available on SNMMI's website (www.snmmi.org/stateinfo) and have been very helpful for



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The pooled sensitivity and specificity for diagnosing disease recurrence were 81% and 83%, respectively, for ^{18}F -FDG PET/CT and 59% and 96%, respectively, for contrast-enhanced CT. The authors concluded that although both ^{18}F -FDG PET/CT and contrast-enhanced CT were highly useful for diagnosing recurrent gastric cancer, “these techniques cannot be used to exclude or confirm the presence of lymph node metastases or recurrent gastric cancer tumors but can be used for the confirmation of distal metastasis.”

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Reviews

Review articles provide an important way to stay up to date on the latest topics and approaches through valuable summaries of pertinent literature. The Newslane editor recommends several general reviews accessioned into the PubMed database in December, January, and February. Murray and Du, from the Royal Marsden NHS Foundation Trust and Institute of Cancer Research (Sutton, UK), provided an overview of “Systemic radiotherapy of bone

metastases with radionuclides” in the February issue of *Clinical Oncology (Royal College of Radiology)* (2021;33:98–105). In an article in the December issue of *Translational Andrology and Urology* (2020;9:2908–2919), Kim, from the National Cancer Center (Goyangsi, Korea), reviewed the “Role of PET/CT in muscle-invasive bladder cancer.” The “Role of nuclear imaging to understand the neural substrates of brain disorders in laboratory animals: Current status and future prospect” was outlined by D’Elia et al. from the National Research Council of Italy and University “Roma Tre” (both in Rome, Italy) in the December 11 issue of *Frontiers in Behavioral Neuroscience* (2020;14:594509). Dev et al. from the Massachusetts General Hospital/Harvard Medical School (Boston, MA) published “Neuroimaging in frontotemporal lobar degeneration: Research and clinical utility” in *Advances in Experimental Medicine and Biology* (2021;1281:93–112). In the January 1 issue of *Nanotheranostics* (2021;5:90–112), Abousaway et al. from the Dana-Farber Cancer Institute/Harvard Medical School and Brigham and Women’s Hospital/Harvard Medical School (Boston, MA)

reported on “Noninvasive imaging of cancer immunotherapy.” Sier et al. from the Leiden University Medical Center, the University of Twente (Enschede), UniQure (Amsterdam), and Percuros BV Leiden (all in The Netherlands), University Medicine Center Göttingen/Max-Planck-Institute for Experimental Medicine (Germany), and the University of Sheffield (UK) offered perspective on “Cell-based tracers as Trojan horses for image-guided surgery” in the January 13 issue of the *International Journal of Molecular Sciences* (2021;22:E755). In an article published on January 13 in *Diagnostics (Basel)* (2021;11:E117), Luining et al. from the Amsterdam University Medical Center (The Netherlands) reviewed “Nuclear imaging for bone metastases in prostate cancer: The emergence of modern techniques using novel radiotracers.” Ha et al. from Korea University (Sejong, South Korea) reported on “Inhibitors of prostate-specific membrane antigen in the diagnosis and therapy of metastatic prostate cancer: A review of patent literature” on January 17 ahead of print in *Expert Opinion on Therapeutic Patents*.

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technologists who have questions about what they can and cannot do in their states.

All of SNMMI’s advocacy work this year took place against the backdrop of COVID-19, and SNMMI led multiple discussions on the impact on nuclear medicine and molecular imaging. The Society participated in letter-writing campaigns with coalition partners to address hero’s pay,

personal protective equipment shortages, and regulatory relief requests. Finally, SNMMI acted to ensure that nuclear medicine technologists were included in initial vaccine phases.

SNMMI has taken many positive steps in achieving its advocacy goals in the past year, and we look forward to carrying on this important work in the coming year.