Regulatory and Legislative Issues: SNMMI at Work

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Over the past 2 decades, nuclear medicine has seen the introduction and clinical implementation of multiple new modalities, techniques, and radiopharmaceutical agents for diagnosis and therapy. Compounding the challenges that come with rapid technologic change has been the accelerated growth of regulatory and legislative oversight affecting all aspects of the field. Our continued success—and the welfare of our patients—depends on our ability to meet changing regulatory demands while proactively influencing those demands. This process involves not only maintaining open and goal-directed communication with regulatory and legislative bodies but also gathering and delivering the most relevant scientific information for evidence-based regulatory decisions. SNMMI leaders work closely with society members and those of affiliated professional societies to track proposed actions affecting the field, to anticipate and be prepared for changes, to collaborate with federal and other agencies on regulatory actions that can positively impact the field, and to serve as an expert resource on the economic and social impact of nuclear medicine. I have personally been involved in a number of these activities and know first-hand the degree of dedicated and highly specialized effort required from SNMMI staff, leadership, and member volunteers in these activities. A few highlights of our recent collaborative projects provide insight into the complexities of these efforts.

SNMMI has worked successfully to advance nuclear medicine at the national level, with a goal of increasing the availability of the field's most promising innovations. On August 21, the U.S. Food and Drug Administration (FDA) approved a New Drug Application (NDA) for ^{68}Ga-DOTATOC injection for PET imaging in localization of somatostatin receptor–positive neuroendocrine tumors (NETs) in adult and pediatric patients. The University of Iowa PET Imaging Center is the holder of the approved NDA. SNMMI coordinated closely with the FDA in the effort to secure orphan drug designation for the agent. The University of Iowa plans to relinquish exclusivity of its ^{68}Ga-DOTATOC NDA so that other institutions can pursue Abbreviated NDAs with the FDA.

In 2018, SNMMI, with input from members, petitioned the FDA to add arginine and lysine to its 503B bulks list or move them to the 503B Category 1 list. The FDA responded on March 4 this year by adding these to the categories of bulk drug substances under its interim policy under section 503B of the Federal Food, Drug, and Cosmetic Act. This will ultimately make it easier for manufacturers to compound and make available an arginine/lysine–only solution, which will help patients with gastroenteropancreatic NETs to better tolerate and thereby benefit from ^{177}Lu-DOTATATE therapy.

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The SNMMI leadership, staff, and volunteer team is at its most impressive when pooling expertise to advance nuclear medicine initiatives with legislators at the national level. On July 17, SNMMI cohosted a briefing on Capitol Hill with clinicians, patients, and industry representatives to discuss the importance of nuclear medicine and diagnostic radiopharmaceuticals and to highlight H.R. 3772 (Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019). The bill was introduced on the previous day by Reps. Scott Peters (CA-52), Bobby Rush (IL-01), and George Holding (NC-02). The bill calls for all diagnostic radiopharmaceuticals that reach a cost of more than $500 per day to be paid separately in the Hospital Outpatient Prospective Payment System. The change in reimbursement would correct the current flawed payment policy, under which many hospitals cannot afford to offer these procedures. Successful enactment of the bill would be significant for patients, helping ensure the most appropriate care possible. SNMMI representatives met with more than 40 Congressional offices and have launched a vigorous grassroots letter-writing and lobbying campaign to support the bill as it advances toward potential passage.

Many achievements in support of nuclear medicine are the result of years of coordination, fact finding, collaboration, and evidence gathering. In 2016 SNMMI developed a white paper with recommendations on public standards for compounded sterile radiopharmaceuticals that recommended that that the U.S. Pharmacopeia (USP) create a separate general chapter for radiopharmaceutical preparation, compounding, and dispensing. Using elements of the white paper as a basis for discussion, the USP held a stakeholders workshop on radiopharmaceutical compounding, resulting in USP agreement to create the new General Chapter <825> dedicated to radiopharmaceuticals. The chapter, published on June 1, provides uniform minimum standards to provide, in the words of the USP, "a reasonable and rational basis for the protection of patients from unsafe practices."

Multiple similar efforts to represent nuclear medicine are underway right now at SNMMI, with the pace of new regulatory and legislative challenges and opportunities matching those of innovations in the field. The resulting achievements do not happen in a vacuum or outside the reach of individual participation—they require the widest representation from the entire spectrum of the nuclear medicine and molecular imaging community. SNMMI members can be involved by joining an SNMMI council; by staying up to date through the SNMMI website (http://www.snmmi.org/GRNews); and by working directly with the society on emerging issues that call for grassroots or volunteer response. Some of the most wide-reaching efforts with which SNMMI has been involved have begun with anecdotal reports of local regulatory, legal, or guidance challenges. Members are urged to let the society know about relevant activities in their communities as SNMMI continues to speak out on decision making that will affect the field for years to come.

LETTER TO THE EDITOR

^{68}Ga-PSMA Ligand as Potential ^{99m}Tc-DMSA Alternative

To the Newsline Editor: I read with great interest the paper by Lim et al. (*1*) that was published in the August issue of *JNM* Newsline. The article highlighted the importance of ^{99m}Tc-dimercaptosuccinic acid (^{99m}Tc-DMSA) scans in pyelonephritis and other renal cortical diseases and the implications of current shortages of ^{99m}Tc DMSA in the United States. We have recently published ^{68}Ga–prostate-specific membrane antigen (^{68}Ga-PSMA) ligand PET/CT images of the kidneys that show a high degree of uptake and excellent distribution of this radiotracer in the renal cortex and demonstrate renal parenchymal defects caused by various sizes of renal cysts (*2,3*). ^{68}Ga-PSMA ligand renal images appear to be superior to those acquired with ^{99m}Tc-DMSA (*2,3*).

The main limitations of DMSA scanning include the relatively long waiting time after radiotracer injection, long acquisition time, high radiation dose (particularly important in repeated studies in children), and limited spatial resolution with gamma cameras. ^{68}Ga has a shorter half-life (68 min) than ^{99m}Tc (6 h). Effective and kidney radiation doses with the ^{68}Ga-PSMA ligand appear to be comparable to those with ^{99m}Tc-DMSA, but this should be further studied (*4–6*). The CT component of PET/CT imaging further increases radiation dose, but CT images may not be needed because non–attenuation-corrected PET also provides good quality images of the kidneys as a result of high renal cortical uptake. This is particularly important when used in pediatric patients (*2,3*). Waiting time after radiotracer injection and image acquisition time is less with ^{68}Ga-PSMA ligand PET (30–60 min and 2–6 min, respectively) than for the DMSA scan (2–3 h and 15–30 min, respectively). PET scanners offer higher efficiency for detecting gamma photons and higher spatial resolution than gamma cameras (*7*).

Although the ^{68}Ga-PSMA ligand is more expensive than ^{99m}Tc-DMSA and not available at every institute, it would be worthwhile to directly compare PSMA PET to DMSA scanning in renal diseases to better understand whether this PET radiotracer could be used to image the renal cortex and serve as an alternative to DMSA scanning, particularly in countries with shortages of ^{99m}Tc-DMSA. We have recently received institutional approval for a prospective research project for such a comparison in adult patients with pyelonephritis, and the study will begin soon.

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