Priorities Over the Next Year: Achieving Our Strategic Vision Together

Over the past several years, SNM has undertaken significant efforts to advance the field and the profession of nuclear medicine. These efforts have served as the framework for the society's strategic plan, while positively impacting all aspects of our activities at the chapter level as well as nationally.

As we enter the fourth year of a 5-y campaign to elevate awareness of the benefits and value of molecular imaging, we are looking ahead to build on the significant progress that we have made to date. SNM is on track to raise $5 million to support these goals. In only a short period of time, the Molecular Imaging Center of Excellence (MICoE) has become an established presence within the society and, more critically, with external audiences.

Many priorities that are part of the MICoE's strategic plan have been integrated into SNM's overall activities. In fact, many individuals have already taken advantage of enhanced opportunities to expand nuclear medicine practice into molecular imaging. For the second consecutive year, molecular imaging had its own research track at SNM's Annual Meeting. Going forward, molecular imaging will become part of all research tracks, since it is an integral part of how we practice medicine today. In addition, molecular imaging has become part of the standard curriculum. SNM's Education Department now offers continuing education credits and competencies focused on molecular imaging. Working with MICoE leadership and other experts in the field, we are offering the most up-to-date information and best practices for practicing physicians, technologists, researchers, and clinicians.

SNM's Health Policy & Regulatory Affairs team continues to advocate for legislation and policies that protect and support molecular imaging research, funding, and reimbursement. SNM will continue to focus its efforts on Capitol Hill, working with local, regional, and national policymakers. As SNM's influence on legislative affairs grows, the society is expanding its presence with international policymakers and influencers, especially concerning the ongoing isotope shortage and regulatory processes related to clinical trials and the development of new radiopharmaceuticals. Molecular imaging has become a vital component of the policies for which we advocate on behalf of our members. Because the regulatory environment is constantly changing, it is critical that we proactively stay out in front of policymakers and other influencers who shape the environment for the medical imaging community. In the year ahead, we will continue to invest in advocacy, which will remain a top priority for the society.

Virginia Pappas

In August, SNM and MICoE leadership met with representatives from the Bench-to-Bedside Campaign Advisory Board, which provides strategic direction and advice for the society's major activities to advance molecular imaging and therapy. In addition to advocacy, our priorities over the next year will include public relations, outreach, PET utilization, and comparative effectiveness. SNM will continue to devote time and resources to other major areas, such as education, which have already become integrated into the society's overall operations.

Through public relations efforts, SNM will continue to draw attention to its research, advocacy activities, and members, both from trade press that cover the imaging community and health care and from influential national and international news media. Over the past year, we have established ourselves as a recognizable and sought-after source among journalists, who turn to SNM for expert opinions and leadership. SNM will continue to raise its profile among media, foster awareness of research and activities that are leading the field, and seed the environment for advocacy, development, and other initiatives that advance molecular imaging. In addition to working with journalists, public relations activities will include briefings with think tank analysts, outreach to bloggers, and expanding our presence on social networking sites and other Web 2.0 channels.

In the year ahead, SNM will also turn its attention to outreach. Over the past year, SNM has worked with leadership of national patient advocacy groups to raise awareness of the vital role of molecular imaging in diagnosing and treating many prevalent cancers, cardiovascular conditions, and neurologic disorders. In addition to holding individual meetings, SNM will develop resources to demonstrate the essential role of molecular imaging in today's medical practice. By making these patient organizations more aware of the value of molecular imaging, we can help patients benefit from the best treatments available today as well as advancements coming down the road tomorrow.

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CDRH currently receives most mandatory medical device adverse event reports on paper, which requires reports to be manually entered into the center's adverse event database, called the Manufacturer and User Facility Device Experience (MAUDE) database, for further analysis. Not only is this step costly, but it hinders CDRH's ability to quickly review safety data and to uncover potential public health problems. The proposed regulation for medical devices would require manufacturers, importers, and user facilities to submit reports to the FDA in electronic format, which will be loaded into the MAUDE database.

The electronic medical device reporting system, known as eMDR, provides a choice of 2 electronic options for reporting postmarket safety information. Small manufacturers with a limited number of reports may prefer an application known as eSub, which runs on free software available from the FDA. Large manufacturers may prefer to use a batch submission protocol based on a widely recognized informatics standard.

The FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) currently receive adverse event reports on paper forms or electronically. Safety reporting data submitted on paper forms must be manually entered into the FDA's Adverse Event Reporting System before these data can be evaluated. Since 2000, CDER and CBER have allowed manufacturers (through a pilot program and FDA guidance) to submit adverse event reports electronically. This pilot program has enabled FDA staff to more rapidly review postmarketing safety data and identify emerging safety problems. Safety reports in electronic format can currently be submitted to the FDA either through the FDA's Electronic Submission Gateway or on CD-ROM, digital tape, or floppy disk. International Conference on Harmonization (ICH) standards for data elements and technical specifications are used for these electronic submissions.

The proposed rule for medical devices does not apply to reports submitted on a voluntary basis Manufacturers submitting reports under either rule would be required to obtain an electronic certificate to use the FDA Electronic Submissions Gateway. Information on how to prepare and send postmarket safety reports for devices and for drugs and biologics is contained in draft guidance documents. Draft guidance for device reports is available at: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.

U.S. Food and Drug Administration

Ilse Zolle (1931–2009)

Newsline was notified in August of the death of Professor Ilse Zolle on April 8 in Vienna, Austria, at the age of 77. She was credited with being the first radiopharmacist in Austria. Born and raised in Klagenfurt, Austria, she moved to Vienna in 1950 to pursue pharmacology studies at Vienna University. In 1970, after working as a pharmacist in Zülpich, Germany, she earned an MS in pharmacology at the John Hopkins University in Baltimore, MD. She returned to Austria, where she worked as a pharmacologist at the Medizinische Universitätsklinik Department of Nuclear Medicine. She received her doctorate from Vienna University in 1987.

Dr. Zolle played a key role in building up the first nuclear medicine department at the Vienna Universitätsklinink under Professor Rudolf Höfer. She was a pioneer in the field of ^{99m}Tc-human serum albumin microspheres. Working as a lecturer at Vienna University she actively supported many students. Even after retirement in the late 1990s she was deeply committed to the field of radiopharmacy, editing *Technetium-99m Pharmaceuticals: Preparation and Quality Control in Nuclear Medicine* (Berlin, Germany: Springer-Verlag; 2007) and securing a U.S. patent on radiolabeled phenylethylimidazole carboxylic acid ester derivates in 2005. Dr. Zolle will be remembered not only for her significant contributions to Austrian nuclear medicine but also for her participation in conferences and her lively and stimulating discussions.

European Association of Nuclear Medicine

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This year, SNM's PET Center of Excellence established a PET Utilization Task Force. The task force, cochaired by George Segall, MD, and Homer Macapinlac, MD, has been researching and compiling data to prove the effectiveness of PET. Given the vast array of data and critical need for our community, this will remain an ongoing priority for the society. Significant progress has been made to date; the task force is developing resource materials for distribution to referring physicians nationwide.

Finally, comparative effectiveness has become an important topic on the national agenda for health care reform. SNM President Michael Graham, MD, PhD, is chairing these efforts for the society. Along with colleagues, he has been working tirelessly to ensure that molecular imaging and nuclear medicine are recognized as examples of the best and most effective in medical care. These efforts are closely connected to our advocacy efforts to protect reimbursement and ensure adequate funding for nuclear medicine research.

These priorities all support SNM's strategic plan to raise awareness of molecular imaging and therapy, advocate for the profession, and position molecular imaging as the standard of patient care. As with many successes, ongoing commitment and support are critical to advancing our achievements to date. Together, we will ensure that molecular imaging is driving health care and contributing to patient care worldwide.

Virginia Pappas CAE
SNM Chief Executive Officer