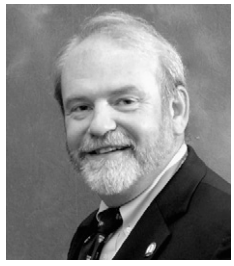
Ensuring the Future of Nuclear Medicine and Molecular Imaging

The dramatic success the world has witnessed in the diagnosis and treatment of human disease during the opening years of the 21st century are based to a great extent on the basic nuclear medicine research of the past 2 to 3 decades—research that had been continuously funded by the U.S. Congress since 1954. By contrast, the past few years have seen drastic cuts in federal funding that were only recently and partially restored after tireless effort on the part of SNM and our colleagues in other professional societies.

In light of these and other challenges that threaten the development and distribution of new and better imaging agents and tools, SNM has taken bold steps to develop strategies and collaborations that confront issues surrounding reimbursement, regulatory affairs, research, and radioisotope availability. We believe the following actions are necessary to ensure a sound future for nuclear medicine and molecular imaging.

Reimbursement. As we develop new imaging and therapeutic agents and tools that can better inform us about physiologic, metabolic, and other functional activity in the body or its pathology, we need to guarantee that these agents and tools will be adequately reimbursed in order to be effectively utilized. To achieve that purpose, SNM members are crafting clinical trials that will convince referring physicians and the Centers for Medicare & Medicaid Services (CMS) of their value and partnering with industry to see that these procedures are reimbursed at a level that will not be punitive to the imagers or the patients being imaged. SNM continues to press the case that: radiopharmaceuticals (including radioimmunotherapy agents such as Bexxar and Zevalin) should be recognized and treated as drugs rather than supplies, CMS should continue to reimburse radiopharmaceuticals at charges reduced to cost in 2008 and work with nuclear medicine pharmacies and manufacturers to develop standard payment methodology based on the average radiopharmaceutical invoice price at the distributor or nuclear pharmacy level (which is the model for traditional drugs), radiopharmaceuticals should qualify for the same threshold as other traditional drugs, and CMS should use external data sources to identify and appropriately reimburse radiopharmaceuticals—as they do for all other drugs.

Regulatory Affairs. As with therapeutic drugs, imaging agents must undergo extensive testing to demonstrate their safety and effectiveness in order to be approved by the Food and Drug Administration (FDA). SNM is currently in discussions with the FDA to create a process for the efficient development and distribution of radiopharmaceuticals. Toward that end, our 2 organizations will hold a workshop in conjunction with the National Institutes of Health (NIH) with the goal of outlining major scientific, translational, and logistic gaps in developing investigational PET and SPECT radiopharmaceuticals and coming to consensus on bridging those gaps. SNM has also had some success in identifying and proposing candidates who would review requests for radiopharmaceutical development and usher these through the regulatory process.



Robert W. Atcher, PhD, MBA

Research. In addition to successfully achieving restoration of funding in the Department of Energy (DOE) budget earlier this year for research and development of new instrumentation and radiochemistry for nuclear medicine, SNM was instrumental in persuading Congress to override a presidential veto of the Medicare Improvements for Patients and Providers Act of 2008. This action not only reversed the 10% cut in Medicare fees to physicians but also made possible an 18-mo extension of the 2007 reimbursement rates for radioimmunotherapies used in the treatment of cancer, neurologic disease, and many other debilitating illnesses. In the meantime, DOE has completed its review of grant applications and is in the process of awarding funds for nuclear medicine and molecular imaging research trials. We also continue to work with other imaging societies, such as the American College of Radiology, the Radiological Society of North America, and the Academy of Radiology Research, to increase funding for imaging research at NIH.

Radioisotope Availability. An SNM task group has been working for several months to put together a draft report of possible ^{99}Mo suppliers for the domestic market. Initiation of this project—with its mission to research alternative means for isotope production within the United States—began with the shutdown late last year by the Atomic Energy of Canada Limited of the aging National Research Universal reactor. At that time, it was noted that the capacity for domestic medical radioisotope production in support of nuclear medicine had declined sharply over the past 10 y. Currently, no facilities in the United States are dedicated to manufacturing ^{99}Mo for ^{99}Mo /^{99m}Tc generators. This, coupled with recent efforts to

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currently limited to about 50 tours annually. Beginning in March 2009, individuals and families will be able to tour at least 3 d/wk through October 2009 by presenting identification at the Hanford Site. The DOE plan sets a timetable for more permanent decisions about the future preservation of B Reactor. Five of Hanford's 9 plutonium production reactors have been dismantled and "cocooned" as part of a closure contract covering cleanup of Hanford's Columbia River Corridor, and the B Reactor could have undergone this process as early as 2009. In March 2008, DOE announced a policy directive to support preservation of the B Reactor that required the reactor to be maintained in a state that preserves its historical significance.

U.S. Department of the Interior
U.S. Department of Energy

Tatum Named Associate Director of CIP

The National Cancer Institute (NCI) announced on August 1 that James L. Tatum, MD, has been selected for the position of associate director of its Cancer Imaging Program (CIP). He joined CIP in 1998 as a special assistant to the associate director and since that time has assumed increasing responsibilities. In 2006, he became the head of CIP's Molecular Imaging Branch. Since July 2007, he has used his expertise in the areas of molecular imaging and imaging drug development to guide CIP as its acting associate director.

Tatum serves as chair of the imaging drug group of the Joint Development Committee, where he plays a vital role in overseeing imaging agents in the NCI drug pipeline. He represents imaging from the NCI viewpoint on the steering committee for the Nanotechnology Characterization Laboratory (NCL), a joint effort of NCI, the Food and Drug Administration, and the National Institute of Standards and Technology. He is also a member of the NCL review panel and serves on the steering committee of the Small Animal Imaging Program at NCI–Frederick.

Early in his research career, Tatum focused on imaging alterations in the pulmonary capillary membrane associated with acute respiratory distress syndrome and the application of imaging techniques to evaluate drug interventions. Later, his research shifted to studies of myocardial ischemia, including acute coronary syndrome, with a focus that continues in his research today on the use of imaging in medical decision making.

Tatum received his undergraduate degree in biology from the College of William and Mary (Williamsburg, VA) and his MD from the Medical College of Virginia (MCV; Richmond). He completed his residency in medicine and radiology at MCV Hospitals, followed by a nuclear medicine fellowship at Duke University (Durham, NC). He is board certified in diagnostic radiology, nuclear medicine, and nuclear cardiology. In 1978, he joined the faculty of Virginia Commonwealth University (VCU), where he was later appointed professor of both radiology and medicine. During his tenure at VCU, he served as chair of the division of nuclear medicine, director of nuclear cardiology, chair of the department of radiology, associate vice president for health sciences, and director of the Molecular Imaging Center.

National Cancer Institute

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Mollura, MD, Johns Hopkins University; Karen Gulenchyn, MD, McMaster University (Ottawa, Canada); Wim Oyen, MD, PhD, Radboud University (Nijmegan Medical Center, The Netherlands); Matthias Benz, MD, University of California, Los Angeles; Andreas Buck, MD, The Children's Hospital of Philadelphia (PA); and Wengen Chen, MD, PhD, also from The Children's Hospital of Philadelphia.

"We are truly thrilled to offer these awards and deeply appreciative of the support of the donors who make this ground-breaking research a reality," said VanBrocklin.

Application deadlines for the 2009 SNM Research Grants will be in late winter 2009. More information about the awards, along with application forms, is available at www.snm.org/grants.

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curtail the use of highly enriched uranium in radioisotope production as a nonproliferation strategy and to deter terrorism, now poses a significant threat to ^{99}Mo availability within the United States. The subsequent cancellation in May 2008 of the MAPLE reactors at the Chalk River Laboratories has made the need for an alternative domestic source for ^{99}Mo production more acute. We will keep SNM members apprised of this developing situation.

There has been a tremendous amount of activity during the first 3 mo of my presidency. In addition to developments in the issues reviewed above, we will report on a major new thrust for SNM in the coming months. As I have noted to many audiences, many of SNM's activities are now multiyear projects that require teamwork and commitment to common goals. We are fortunate that Alexander McEwan, MD, immediate past president of SNM, established a solid framework and that Michael Graham, PhD, MD, president-elect, and Dominique Delbeke, MD, PhD, vice president-elect, have agreed to sustain many of these longer range activities.

Robert W. Atcher, PhD, MBA
SNM President