also announced plans to use his share of the prize for charitable purposes.

The Vienna symposium on radiopharmaceuticals was the nuclear medicine highlight of the IAEA year. It was attended by more than 220 basic scientists and clinicians from 70 countries, including North America, many countries in Europe, and more than 50 developing countries. Invited to speak at the opening ceremony were the representatives from the European Association of Nuclear Medicine (EANM; Dr. Ignasi Carrio), the Singapore Radiological Society, the World Federation of Nuclear Medicine and Biology (WFNMB; Dr. C. Lee), and the SNM (myself). I was glad to represent SNM as its immediate past president, not only because I was able to share with leading world radiopharmaceutical scientists and physicians some of the SNM activities to promote nuclear medicine in developing countries, but also because in my absence there would have been a void for SNM on the podium at the traditional European-type of formal opening ceremony in which other prominent biomedical organizations, such as EANM and WFNMB participated. Thanks to SNM for partially covering my travel expenses.

Scientifically, the symposium was a very good one. The topics ranged from novel diagnostic agents in oncology, neurology, and cardiology to therapeutic applications in oncology to rheumatoid arthritis. The topics also included production of radionuclides using cyclotrons and using low-, medium-, and high-neutron flux reactors. In issues related to federal regulations, restrictions associated with highly enriched uranium targets were discussed, and it was noted that certain developing countries with access to high-flux reactors are planning to use low-energy uranium targets, with some even going back to bombarding $^{98}$Mo and developing $^{99}$Mo/$^{99m}$Tc generators using "gel" columns onto which a relatively large quantity of molybdenum can be loaded.

It was also interesting to note that developing countries are eager to have cyclotrons, PET, and PET/CT scanners installed in rapidly increasing numbers. One speaker from Europe stated in his presentation that the fate of $^{99m}$Tc may be "short lived" when cyclotrons and PET scanners are increasing in numbers so rapidly.

I was also impressed by the ways in which radiopharmacists and nuclear medicine experts who hail from different parts of the world work at IAEA throughout the year to promote nuclear medicine and the peaceful applications of nuclear energy in developing countries. Their creative ways of utilizing the relatively small amount of funds for education and research to promote capacity building in local production and utilization of radiopharmaceuticals for nuclear medicine applications in developing countries is inspiring. This not only properly serves the IAEA mission but also helps enormously the many deserving investigators in developing countries.

In brief, for me it was a scientifically rich, socially enjoyable, and professionally beneficial gathering. I am glad that, on behalf of SNM, I was able to participate in the meeting, which conveyed successfully SNM's contribution in promoting nuclear medicine in developing countries and our symbolic support for IAEA activities. These efforts may lead SNM to a closer partnership with the IAEA.

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# Council on Radionuclides and Radiopharmaceuticals

### The Energy Policy Act of 2005

Congress passed the Energy Policy Act of 2005, and President Bush signed it into law on August 8, 2005. The bill contained 2 important sections for nuclear medicine. First, the bill assured a continued supply of high-enriched uranium (HEU) that is used to produce the isotopes $^{99}$Mo and $^{131}$I that are so important to nuclear medicine. The Council on Radionuclides and Radiopharmaceuticals (CORAR) supported this language with tremendous help from SNM and many people in the nuclear medicine community through letters to their congressmen and senators. The language in the bill will assure a continued supply of HEU until low-enriched uranium (LEU) technology is fully developed and commercially viable. The industry is currently developing LEU targets and alternate reactor technologies utilizing LEU. The act also gave the Nuclear Regulatory Commission (NRC) authority over specific nuclear materials.

### NRC Jurisdiction Over ARM

The Energy Policy Act of 2005 broadened the definition of byproduct material to include accelerator-produced

radioactive materials (ARM). Before passage of the act, ARM was regulated by the individual states. The NRC will now have jurisdiction over all radioactive material produced in accelerators, including but not limited to $^{201}$Tl, $^{111}$In, $^{67}$Ga, $^{123}$I, and $^{82}$Sr/$^{82}$Rb, as well as all PET radionuclides. The NRC has been seeking input from CORAR, SNM, and the entire nuclear medicine community in their development of implementing regulations. CORAR and SNM also participated in an NRC-sponsored public meeting on this topic. NRC has already sent a draft rulemaking to the states for their review, and is expected to publish the proposed rulemaking on this subject in early 2006. This rulemaking process will need the continued involvement of the nuclear medicine community in 2006.

### Food and Drug Administration Current Good Manufacturing Practices

On September 20, 2005, the U.S. Food and Drug Administration (FDA) published a Proposed Rule in the *Federal Register* on Current Good Manufacturing Practices (CGMPs) for PET drugs. On the same day, the FDA announced the availability of draft guidance on PET drug CGMPs. CORAR and SNM have been providing FDA feedback on their PET CGMP rulemaking and guidance for the last few years, and CORAR again submitted comments on the most recent proposed rule and guidance. As a general matter, the proposed PET drug CGMP requirements are a more simplified version of the CGMP requirements set forth in 21 CFR Part 211. However, the FDA has afforded smaller PET centers some flexibility in the application of CGMP.

### FDA Critical Path Initiative

In 2004, the FDA introduced its Critical Path Initiative designed to reduce barriers to the development of new drug therapies. The agency is encouraging the development, qualification, and use of biomarkers, including imaging biomarkers, for a variety of functions, including screening promising drug candidates, enriching investigational study populations, evaluating the effectiveness of therapies during development, and serving as surrogate endpoints for approval purposes. During 2005, CORAR met with the FDA to discuss imaging biomarkers and the possible sharing of data between imaging and therapeutic drug manufacturers. In 2006, CORAR intends to work more closely with SNM, the American College of Radiology, and the National Electrical Manufacturers Association on the Critical Path Initiative and to continue to communicate with FDA on imaging biomarkers.

### Reestablishment of the Medical Imaging Drugs Advisory Committee

The FDA terminated the Medical Imaging Drugs Advisory Committee (MIDAC) in November 2002. Since then, in letters and discussions with the FDA, CORAR has advocated the reestablishment of the committee. CORAR has also communicated with FDA to seek improvements in the agency's current procedures for obtaining expert advice on imaging products and issues, which is to appoint medical imaging experts as ad hoc voting members to existing standing advisory committees.

### Hospital Outpatient Prospective Payment System (HOPPS)

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) requires the Center for Medicare & Medicaid Services (CMS) to determine payment for specified covered outpatient drugs in 2006 based on average acquisition costs. In the 2006 HOPPS proposed rule, CMS indicated that they would use average sales price data as a proxy for the average acquisition cost rather than rely on data from a study compiled by the Government Accountability Office. CORAR provided detailed comments to CMS regarding cost-to-charge ratio (CCR) payment methodology and drug handling costs for radiopharmaceuticals. CMS adopted many CORAR recommendations in the November 10, 2005, final HOPPS rule for 2006, including CORAR's recommendations to use the overall hospital (not department-specific) CCR as the basis for determining radiopharmaceutical payment. Also, over the past 5 years, CORAR and its manufacturer members have submitted numerous requests for additional and more accurate Healthcare Common Procedure Coding System (HCPCS) codes for various radiopharmaceutical products. Throughout this period, the HCPCS National Panel has established a wide variety of new HCPCS billing codes including temporary C-codes, Q-codes, and permanent A-codes to describe radiopharmaceuticals.

CORAR appreciates the continued support from SNM staff, SNM members, and SNM leadership.

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