Government Relations Update

ACNP/SNM Government Relations Office Midyear Report: January–May 1998

The American College of Nuclear Physicians/Society of Nuclear Medicine (ACNP/SNM) Government Relations Office has been active on both the regulatory and legislative fronts this year. This report highlights the Office's activities, which include involvement with the Nuclear Regulatory Commission's (NRC's) revision of 10 CFR 35, Food and Drug Administration (FDA) workshops on approval of conventional and PET radiopharmaceuticals, Department of Energy (DOE) isotope production issues and national licensure legislation for the SNM Technologist Section (SNM-TS).

During the SNM Mid-Winter Meeting in Las Vegas, NV, in January, the Government Relations Committee selected four goals to assist in priority setting within the Office:

1. To continue to work with the NRC and Congress to eliminate unnecessary regulations affecting diagnostic and therapeutic nuclear medicine during the ongoing rewrite of 10 CFR 35.
2. To work with the FDA to implement the portions of the Food and Drug Modernization Act of 1997 affecting nuclear medicine.
3. To increase funding available for the production of research isotopes through the DOE.
4. To continue to monitor and disseminate information on issues pertinent to nuclear medicine.

Nuclear Regulatory Commission

10 CFR 35 REVISIONS

The NRC is in the final stages of preparing a proposed rule on 10 CFR 35 for public comment. This rule would involve significant changes to the NRC's regulatory position on nuclear medicine. The NRC has addressed such issues as training and experience, patient notification, misadministrations/medical events and the reporting of precursor events. ACNP/SNM has provided detailed comments to the NRC on risk assessment and has gone over specific sections of the draft rulemaking to highlight concerns. The risk assessment document clearly identified diagnostic nuclear medicine as a low-risk procedure. It is important to convey this point to the NRC, as its mandate for the revision of Part 35 is to look first at high-risk procedures.

The most contentious issue that the NRC is dealing with is the training and experience requirements for authorized users. A number of organizations, including the ACNP and SNM have expressed opinions on this issue. The draft NRC proposal, based on comments from two public meetings in 1997, reduced the total number of hours required for diagnostic procedures down from 1200 to 120. This 120 hours would include 80 hours of classroom training and 40 hours of practical, hands-on experience. There would also be a requirement that physicians pass an examination demonstrating competence in the classroom principles. Medical boards that met these criteria would likely be granted deemed status by the NRC.

The SNM position on this issue looked at waiving the specific number of hours, instead favoring an approach that established a core curriculum in radiation sciences for the classroom as well as certain procedures necessary to understand at the practical level. SNM felt that a specific number of hours was not relevant and often only created situations in which competence was based on the number of hours spent sitting in a classroom. Instead, reliance was placed on a comprehensive examination as well as requiring that practical training take place in an Accreditation Council for Graduate Medical Education-approved course or a graduate-level course at an accredited institution. It is important to note that both SNM and the NRC removed requirements for clinical training, choosing to focus only on radiation safety.

The ACNP took a different position. In deliberations at its January meeting in Las Vegas, the ACNP determined that the 1200-hour requirement set by the NRC was adequate and should not be changed. The ACNP emphasized the importance of both radiation safety and clinical competence to ensure that patient, worker and public safety not be jeopardized.

A proposed rule is expected in July, and additional public meetings have been scheduled in August and September 1998. A final rule will go into effect by June 1999.

ATOMIC ENERGY ACT AMENDMENTS

SNM has also moved toward taking advantage of pushing a more aggressive position with Congress on reform of the NRC. The House and Senate currently are considering a bill that would reauthorize the charge of the NRC for the next year. SNM is meeting with congressional staff to discuss the possibility of an amendment to this reauthorization bill that would recognize the low risk of diagnostic medical procedures and significantly reduce regulation of this area of medicine.

Food and Drug Administration

RADIOPHARMACEUTICAL APPROVAL PROCESS

The FDA, complying with the FDA reform bill passed in 1997, held a workshop in February on the approval process for radiopharmaceuticals. There were four questions posed by the FDA:

1. How should the proposed use of a radiopharmaceutical in the practice of medicine determine the nature and extent of safety and effectiveness evaluations?
2. What general characteristics should be considered in the preclinical and clinical pharmacological and toxicological evaluations of a radiopharmaceutical (including the

radionuclide as well as the ligand and carrier components; i.e., nonradioactive components)?

3. How should the estimated absorbed dose in humans be determined and considered?
4. Under what circumstances might an approved indication for marketing refer to manifestations of disease (biochemical, physiological, anatomic or pathological processes) common to, or present in, one or more disease states?

Representatives of several organizations, including the Council on Radionuclides and Radiopharmaceuticals (CORAR), the American College of Radiology, the ACNP and SNM, made presentations addressing these questions. The workshop discussions led to tentative agreements with the FDA regarding the approval of radiopharmaceuticals. The following are the major agreements attained regarding regulation of diagnostic radiopharmaceuticals:

- The FDA agreed to acknowledge the concept of "Class 1 radiopharmaceuticals" (i.e., tracers) and, further, that flexible safety requirements would apply.
- The FDA agreed to further define "Class 1 radiopharmaceuticals" in the preamble to the forthcoming regulation and in a guidance document to accompany the regulation.
- The FDA assured workshop participants that a guidance document would be proposed soon after the regulation (approximately May 20, 1998).
- The FDA agreed to include language in the preamble of the regulation making it clear that the NRC's occupational radiation limits (5 rem) are not an appropriate benchmark for establishing the radiation dose of a radiopharmaceutical.
- The FDA stated that the proposed regulation language would be similar to the position taken by CORAR and ACNP/SNM regarding both indications for diagnostic radiopharmaceuticals (multiple indications) and the evaluation of effectiveness.
- The FDA also agreed to the concept of granting early meetings with sponsors both before and during the preclinical phase of a trial to determine the level of safety studies required.

ACNP/SNM and CORAR achieved major gains in the FDA's approach to the regulation of radiopharmaceuticals. While the outcome of the process will not be determined until the release of the proposed rule, ACNP/SNM representatives feel confident about the content of the rule. ACNP/SNM and CORAR will comment on the proposed rule when it is published this summer.

PET RADIOPHARMACEUTICALS

The ACNP and SNM, in conjunction with a working group formed under the Institute of Clinical PET (ICP) and chaired by Jorge Barrio, PhD, are working to develop a firm position on the future of PET regulation through the FDA. The FDA Modernization Act of 1997 brought the FDA to the negotiating table to work out an agreement with the regulated community. The ACNP and SNM are working closely with the ICP task force developing the position paper on PET, and both groups will be discussing the issue at the SNM Annual Meeting in Toronto, Ontario, Canada, in June.

Department of Energy

The ACNP and SNM have taken the lead in pushing for more funds for research isotope production through the DOE's national laboratories. Mounting frustration over the DOE's failure to make research production a priority led the ACNP and SNM to work to identify additional funds. These funds would go to producing isotopes at four national laboratories: Sandia (Albuquerque, NM), Los Alamos (Los Alamos, NM), Brookhaven (Brookhaven, NY) and Pacific Northwest (Richland, WA).

Funds requested in the fiscal year 1999 Energy and Water Appropriations bill include $2 million for target development at Los Alamos in conjunction with the construction of an isotope production beam spur; $2 million for chemistry separation work for the production of ^{193}Pt at Los Alamos; $2 million for ^{127}Xe production at TRIUMF, with processing completed at Los Alamos and Brookhaven; $2 million for Sandia to investigate the production of research isotopes along with the planned production of ^{99}Mo; and $2 million for Pacific Northwest for work on therapy isotopes, including generator development of ^{213}Bi and separation technology of ^{227}Ac and ^{228}Th.

The ACNP and SNM also recognize the importance of peer review for many of the projects involving isotope production. This includes evaluating which isotopes should be produced and which facilities should produce them. To meet this goal for fiscal year 2000, the ACNP and SNM have advocated the creation of a standing federal advisory committee that would oversee the isotope production programs as well as look at opportunities for privatizing existing national laboratory programs. The two groups also endorsed a program put forward by the DOE called the "Advanced Nuclear Medicine Initiative." This program would serve as a focal point for appropriations and administer the review and production of research isotopes by evaluating the entire program and its capabilities instead of looking at each facility on an individual and isolated basis.

Technologist Section

The SNM-TS has maintained a working relationship with the American Society of Radiologic Technologists (ASRT) regarding their national licensure bill. In accordance with a 1997 directive from the National Council, the SNM-TS continues to push for national licensure legislation. The ASRT has developed such legislation and has shared it with the SNM-TS for review. Although concern has risen about the inclusion of sonographers in the legislation, the ASRT attempted to attach its language to the Mammography Quality Standards Reauthorization Act. This initially has been rejected by congressional staff handling the bill, but the ASRT still is seeking support for the legislation. This issue will be discussed by the SNM-TS at the SNM Annual Meeting in June, and further information will be provided as it becomes available.

Note: For more information on any of these topics, contact David Nichols or Amanda Sullivan at (703) 708-9773 or visit the Government Relations web page at www.snm.org.

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