Government Relations Update

ACNP/SNM Government Relations Activities 1998 Yearend Report

The Government Relations Office has been very active on both the regulatory and legislative fronts this year. This report highlights these activities, including matters concerning the U.S. Nuclear Regulatory Commission (NRC), the Food and Drug Administration (FDA), the Department of Energy (DOE), and national licensure for the Technologist Section.

At the Mid-Winter Meeting in Las Vegas, January, 1998, the ACNP/SNM Government Relations Committee selected four goals to assist the Government Relations Office in setting its priorities: 1) To continue to work with the NRC and the Congress to eliminate unnecessary regulations as part of the rewrite of the NRC's Medical Use Program (10 CFR 35); 2) to work with the FDA in implementing of provisions affecting nuclear medicine in the Food and Drug Modernization act of 1997; 3) to increase funding available for DOE production of research isotopes; and 4) to continue to monitor other issues important to nuclear medicine and to discuss these issues with members of the Government Relations Committee. At the SNM Annual Meeting held last June, the Government Relations Committee reviewed the Government Relations Office's success at meeting these goals and once again reiterated the importance of following the stated priorities.

U.S. NUCLEAR REGULATORY COMMISSION

Commissioner Nominations: One of the Society's chief complaints to the NRC in the past is that the commissioners are unfamiliar with nuclear medicine or are unwilling to listen to the concerns of the nuclear medicine community. This year, SNM had the opportunity to alter this course slightly with the nomination of Jeff Merrifield, who has served as congressional staff member on several important committees, such as Senate Environment and Public Works.

In the past, Merrifield has used his position to remove duplicate regulations facing nuclear medicine practitioners, and SNM felt that he would be someone willing to listen to the nuclear medicine community's concerns. The Government Relations Office wrote to Senators John H. Chafee and Max Baucus and to President Clinton urging them to endorse Merrifield's nomination. Before the close of the 105th Congress, the Senate accepted Merrifield's nomination, and he now serves as an NRC commissioner. The ACNP and SNM also supported the renomination and confirmation of Commissioner Greta Joy Dicus, who has served on the commission for five years and was previously Arkansas director of radiation protection.

10 CFR 35 Revisions to the Medical Use Program: The NRC spent the last year working on a proposed rule to revise 10 CFR 35 that would involve significant changes to the regulatory position of the NRC as it applies to nuclear medicine. The NRC has addressed such issues as training and experience, patient notification, misadministrations/medical events, and the reporting of precursor events. From the beginning, ACNP and SNM have been a part of this process, offering detailed comments to the NRC on risk assessment as well as addressing specific sections of the draft rulemaking to highlight concerns. The risk assessment document clearly identified diagnostic nuclear medicine as a low-risk procedure. This point is important to communicate to the NRC, as their mandate from the commissioners for this revision was to look first at high-risk procedures. One of the most contentious issues dealt with by the NRC was the "Training and Experience" requirement for authorized users. The draft NRC proposal, based on commentary from two public meetings in 1997, reduced the total number of training/experience hours required for diagnostic procedures from 1200 to 120, including 80 hours of classroom training and 40 hours of practical hands-on experience. There would also be a requirement that physicians pass an exam demonstrating competence in the classroom principles. Medical boards that meet this criterion would likely be deemed as acceptable substitutes by the NRC.

The SNM had recommended that the NRC waive the specific number of training hours, to be replaced with a required core curriculum in radiation sciences for the classroom and a laboratory practical segment to test certain procedures required to maintain safety. SNM believed that specifying a certain number of hours was not a relevant way to assess knowledge. The NRC should rely instead on a comprehensive examination and practical training to take place within the context of an ACGME approved course or an accredited graduate-level course. It is also important to note that both the NRC and the SNM removed requirements for clinical training, choosing to focus only on radiation safety. The ACNP, in deliberations at its meeting in Washington, DC, in September 1998, felt that the current requirements set by the NRC requiring 1200 hours were adequate and should not be changed. The college emphasized the importance of both radiation safety and clinical competence to assure that patient, worker, and public safety were not jeopardized.

Once the proposed rule was published, the NRC held three public workshops nationwide. ACNP/SNM leaders attended all of these and were active participants at each. The NRC commissioners said they were interested in the competency exam suggested by SNM,

but they needed input on how it should be put into effect. SNM, ACR and other organizations immediately began constructing an overview of the benefits of such an exam and the best way to enact it. Robert Carretta, MD, presented the strategy to the NRC at the second workshop in Kansas City.

By the third and final workshop, October 21 and 22, in Rockville, MD, SNM and ACNP participants agreed that the proposed rule was no better, and in some instances was in fact worse, than the one it was replacing. ACNP and SNM were represented by Carol Marcus, MD, and James Fletcher, MD. Marcus presented a talk on the absence of a risk-informed analysis in the revisions to Part 35. By the end of the first day, participants from the medical community reached an agreement on two points. They decided that the NRC should extend the comment period on the revision for at least a year, and they decided the NRC should conduct a risk-based analysis to justify the need for these regulations.

Along with other organizations, the SNM and ACNP wrote to the NRC formally requesting these provisions. Additionally, David Nichols, Director of Government Relations at ACNP/SNM, and representatives from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) met with the NRC commission staff in an attempt to further explain the nuclear medicine community's overall safety record and its desire for a competent risk analysis study. The nuclear medicine representatives reminded the NRC staff that when the revision process for Part 35 began, the commissioners' directive was to revise Part 35 on a risk-informed basis.

An extension was agreed to, but a subsequent letter sent from the commissioners compelled the NRC staff to discuss the need for a risk analysis during the presentation of the proposed final rule. The comment period was extended to 30 days, during which ACNP/SNM drafted its position paper and submitted it to the NRC.

While the position paper clearly states that the nuclear medicine community believes the proposed final rule is flawed due to the lack of risk analysis, it also points out—issue by issue and part by part—the corrections needed to make this rule adequate, if not acceptable. The final comment focuses on eliminating regulations for diagnostic nuclear medicine and changing the regulations for therapeutic nuclear medicine.

The final rule is expected in June 1999, but a congressional hearing is anticipated before then. Government Relations has also initiated two grassroots campaigns. In one instance, members from Florida and Missouri are contacting Senators Bob Graham (D-FL) and Christopher Bond (R-MO) asking them to write to Chairman Jackson. In the action alert letter, the Senators are given three questions to ask Jackson: "1. What information on risk did the Commission consider when it revised the regulations for diagnostic medicine? 2. Why did the Commission disregard the NAS-IOM report? 3. How can the Commission claim the document is risk informed when it dismissed the NAS-IOM report?"

In a second grassroots campaign, ACNP and SNM members are urged to write to the NRC stating that they agree with the ACNP/SNM position on the revisions. Letters have been sent out to SNM leadership and delegates as well as the technologist leadership and committee chairs. An action alert letter, which includes contact information, is available on the government relations portion of the web site (www.snm.org).

FOOD AND DRUG ADMINISTRATION

Commissioner Nomination: Jane E. Henney is the new FDA commissioner, making her the first woman to hold that position. Henney was vice-president of health sciences at the University of New Mexico and previously worked at FDA as a deputy under Commissioner Kessler.

Radiopharmaceutical Approval Process: The FDA, complying with the FDA reform bill passed by Congress last year, held a workshop on the approval process for radiopharmaceuticals, February 27, 1998. The workshop was moderated by George Mills, MD, of the office of biologics at FDA, and the staff panel was headed by Pat Love, MD, Jane Axelrad, MD, and David Lee, MD. Four questions were posed by the FDA: a) How should the proposed use of a radiopharmaceutical in the practice of medicine determine the nature and extent of safety and effectiveness evaluations? b) What general characteristics of a radiopharmaceutical 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)? c) How should the estimated absorbed radiation dose in humans be determined and considered? d) 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? Presentations were made by representatives from CORAR and SNM/ACNP. The workshop discussions ultimately led to the following tentative agreements with the FDA about the approval of diagnostic radiopharmaceuticals.

- FDA agreed to acknowledge the concept of "Class 1 radiopharmaceuticals" (tracers) and that flexible safety requirements would apply to these radiopharmaceuticals.
- FDA agreed to further define "Class 1 radiopharmaceuticals" in the preamble to the upcoming regulation and in a guidance document to accompany the regulation.
- FDA assured ACNP/SNM that a guidance document would be proposed soon after the proposed regulation (approximately May 20, 1998).
- FDA agreed to include language in the regulation's preamble that clarifies that NRC's occupational radiation limits (5 rem) are not an appropriate benchmark for establishing the radiation dose of a radiopharmaceutical.
- FDA stated that its proposed regulation language would reflect the position taken by CORAR and ACNP/SNM on both indications for diagnostic radiopharmaceuticals (multiple indications) and evaluation of effectiveness.
- FDA also agreed to the concept of

granting early meetings with sponsors both before and during the preclinical phase to determine the level of safety studies required.

ACNP/SNM and CORAR have been working together with the FDA to assure the outcome of these agreements. It appears the nuclear medicine community has achieved major gains in the FDA's approach to the regulation of radiopharmaceuticals. A proposed rule for in vivo radiopharmaceuticals used in diagnosis and monitoring was published in July and the Government Relations Office submitted comments on behalf of ACNP and SNM. That comment letter said that this was one of the most interactive endeavors undertaken by the FDA and applauded the agency's recognition that radiopharmaceuticals should be categorized based on defined risk characteristics for purposes of safety evaluation. This shift from the traditional method of reviewing drugs by the agency reflects the inherent safety of radiopharmaceuticals. However, ACNP/SNM strongly supported the specific points of contention raised by CORAR and urged the FDA to implement the suggested changes prior to proceeding with a final rule. One example cited was that the FDA should use pre-existing available information for consideration not only of previously approved radiopharmaceuticals but also for radiopharmaceuticals not yet approved.

PET: On September 27, 1998, the FDA held a hearing on chemical manufacturing and control issues. FDA Associate Director of Policy Jane Axelrad and her staff presided over the meeting. ACNP, SNM and Institute for Clinical PET representatives submitted to the FDA a proposed framework for PET radiopharmaceuticals. The intent behind this document was to propose a coherent, reasonable and achievable approach to the production of PET drugs, which will protect the interests of patients and not impose unnecessary and potentially harmful requirements on nonprofit institutes. A follow-up meeting to discuss the review of indications was held on November 17 at FDA. The FDA is still gathering information and a proposed rule is expected in fall 1999.

DEPARTMENT OF ENERGY

NERAC Nominations: Three of the four candidates nominated for the Nuclear Energy Research Advisory Committee by the Government Relations Office have been accepted. They are Richard C. Reba, MD, Linda Knight, PhD , and Daniel C. Sullivan, MD.The committee will advise the DOE's Office of Nuclear Energy on many issues, including isotope production.

Fiscal Year 1999 Energy and Water Appropriations: The Government Relations Office took a proactive approach in the push for more funds for research isotope production through the DOE's national laboratories, believing that identification of additional funds is vital. The funds support isotope production at Sandia, Los Alamos, Brookhaven, and Pacific Northwest national laboratories. The Senate budget appropriated $9 million for molybdenum-99 production, $7.5 million for operational funds for national laboratories, and $6 million for construction of a beam spur at LANL. Additionally, the Senate supported an Advanced Nuclear Medicine Initiative (ANMI), which is intended to augment important research and technology within the field. ANMI would work as a peer-reviewed research program, modeled after the Nuclear Energy Research Initiative. SNM was a key supporter of this initiative. While the House and Senate were reconciling their varying appropriations, however, a battle ensued in the FY '99 appropriations process over holding funding at these appropriated levels. (The House appropriated much lower funding than the Senate.) During reconciliation sessions, the Government Relations Office lobbied intensively, both in person and through letters, to inform Congress about the importance of the isotope program. The strategy was successful in that the Government Relations Office was able to increase funding for isotope support from the $14 million dollar amount appropriated in the House to almost $22 million in the final bill. This funding will allow the DOE to produce isotopes vital to nuclear medicine research in the fight against cancer, heart disease, and Alzheimer's. Additionally, at least $6 million of that amount has been designated specifically for beam spur construction at Los Alamos National Laboratory. Without this facility, a valuable supplier of isotopes would have been lost to the medical research community.

Nordion Strike: Last May, the United Steel Workers at AECL Chalk River Laboratories went on strike. Since the Chalk River facility is the primary U.S. producer of molybdenum-99, the strike had the potential to severely affect the nation's supply of radiopharmaceuticals and adversely affect health care for thousands of patients. In response, the Government Relations Office wrote to members of the Canadian government and to the Steelworkers Union urging them to end the strike as soon as possible. Newsbriefs and updates were placed on the web site, allowing SNM members to keep abreast of the situation, and SNM encouraged members to copy the action alert letter on the web site and send it to Canadian Officials. By the end of the month, union workers and AECL had come to an agreement and production of the radiopharmaceutical was once again under way.

TECHNOLOGIST SECTION

National Licensure: The SNM-TS has maintained a working relationship with the American Society of Radiologic Technologists (ASRT) regarding the latter's National Licensure bill. In accordance with a directive from the National Council in 1997, the Technologists Section continues to push for National Licensure legislation. The ASRT and SNM-TS have developed such legislation and are preparing it to be introduced in the 106th Congress.

To support its initiative, the SNM-TS and ASRT have formed the Alliance for Quality Medical Imaging and Radiation Therapy with other like-minded organizations. The alliance's goals are to—

- Ensure the quality of patient care by pursuing standards for the certification and education of medical imaging and radiation therapy professionals
- Educate patients about medical imaging and radiation therapy procedures and personnel who perform them
- Encourage lawmakers at the state and