ACNP/SNM Government Relations Office Summary of Activities June–September 1997

The ACNP/SNM Government Relations Office was kept busy through the summer monitoring legislation in Congress and keeping watch over agencies such as the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA). The following summary highlights recent Office activities. For a more detailed and up-to-date description of government relations activities, members are encouraged to visit the Government Relations page on the SNM Web site at www.snm.org.

Nuclear Regulatory Commission

NRC REFORM (10 CFR 35)

The NRC has begun reviewing the existing 10 CFR 35 to identify and discuss specific sections for either revision or elimination.

There are currently three levels of staff working on this project. The first is the writing group, which consists of one or two NRC staff members and consultants assigned to specific areas of Part 35. The writing group reports to the working group, which is composed of NRC staff, agreement-state representatives and NRC consultants. The working group has been charged with reviewing the structure of the new Part 35 and suggesting alternative regulatory language for each section. The working group will present its suggestions to a steering group made up of NRC managers.

The working group has developed a modality-based approach, breaking out regulations for diagnostic nuclear medicine, therapeutic nuclear medicine and various radiation oncology modalities. This structure allows for both general sections whose regulations would apply to all modalities and more specific areas of regulation for each modality. The working group has also been studying six specific areas: the 1979 medical policy statement, the quality management program, radiation safety committee requirements, training and experience requirements, patient notification requirements, and related definitions of reportable events. These six areas have been under staff consideration for development of alternatives to the existing regulations and new draft regulatory language.

These actions were presented to the NRC's Advisory Committee on the Medical Uses of Isotopes September 24-25, and they are scheduled to be discussed at two public workshops, October 28-30 in Philadelphia, and November 12-14 in Chicago. ACNP/SNM will participate in both workshops and is also putting together a briefing booklet in preparation for a detailed meeting with NRC staff in late November to emphasize its position on many of these issues.

RADIOPHARMACY RULE GUIDANCE

ACNP/SNM submitted a detailed letter to the NRC expressing its concern with DG-0006, which deals with the procedures for nuclear pharmacies. This regulatory guide is associated with the radiopharmacy rule. In the comments, ACNP president Martin L. Nusynowitz, MD, and SNM president H. William Strauss, MD, questioned some of the NRC's statements about required usage and criticized several points in the draft guide that appear to be imposing restrictions far more excessive than the actual regulations. In closing, Nusynowitz and Strauss claimed that this draft guide far exceeded its intent and boundaries. They said that they could not support any regulatory guide that does more than assist the applicant in comprehending the regulations. A final version of the regulatory guide is expected by the end of the year.

Food and Drug Administration

FDA REFORM

The House and Senate have almost completed action on the FDA reform bills that have been under consideration for several years. During consideration of these bills, there have been three issues that directly affect nuclear medicine.

The first is the radiopharmaceutical approval process. This legislation, developed by the Council on Radionuclides and Radiopharmaceuticals and supported by ACNP/SNM, would require the FDA to establish proposed regulations governing the approval of radiopharmaceuticals designed for the diagnosis and monitoring of diseases and conditions. The regulations would include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical and the estimated absorbed radiation dose of the radiopharmaceutical. These proposed regulations are due within 180 days of passage of the bill. This provision is in both the House and Senate bills.

The second relates to the regulation of PET radiopharmaceuticals. This section of the legislation, which has been supported by the Institute for Clinical PET and received considerable support from Senator Ted Stevens (R-AK), was included in both the House and Senate bills. It would allow PET radiopharmaceuticals to be compounded in accordance with USP guidelines. The legislation also requires the FDA to develop appropriate procedures for the approval of PET, taking into account the differences between academic and commercial applications. Also, the FDA would not require new drug applications or abbreviated new drug applications for 4 years or up to 2 years after the development of guidelines for the approval process. Finally, the legislation would withdraw the notice on the guidance from the public workshop published in February 1995, the guidance for industry on current good manufacturing practices (CGMP) published in April 1997 and the final rule on CGMPs published in April 1997.

The third issue, compounding language, has been perhaps the most contentious for nuclear medicine. The original language,

supported by ACNP/SNM because of the relief provided for PET, would have allowed compounding under state medicine and pharmacy law. However, during negotiations between FDA and Senate staff, a compromise was developed that granted the FDA the power to limit compounding in certain situations. This acknowledgment of FDA authority in scenarios such as drug product sources and advertising would be detrimental to radiopharmaceuticals. To ease the burden on nuclear medicine physicians, ACNP/SNM moved to exclude radiopharmaceuticals from the compounding provisions and seek additional legislative history that would have used the 1984 FDA nuclear pharmacy guidelines as a model for appropriate regulation. This provision, without the legislative history, was inserted into the Senate bill but was excluded from the House provision. It is now up to House and Senate conferees to work out the differences between the two pieces of legislation. At that point, ACNP/SNM will again try to insert additional legislative history.

SYNCOR v. SHALALA

ACNP/SNM, in conjunction with the American Pharmaceutical Association, joined Syncor in an appeal of the October 1996 decision in *Syncor v. Shalala* in favor of the FDA regarding the regulations affecting PET. The appeal challenged the district court judgment that upheld the FDA's regulation of PET as published in notice in February 1995. The case was appealed in the U.S. Court of Appeals for the D.C. Circuit, and oral arguments, presented by Alvin J. Lorman of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, PC, were held on September 11, 1997. A decision on the case is expected early in 1998.

Department of Energy

ISOTOPE PRODUCTION

The Department of Energy (DOE) faced budget-cutting appropriators once again during discussions over the fiscal year 1998 budget. Of the $21.7 million it requested, DOE received $17.5 million in the Senate bill and only $11.3 million in the House bill. For research production of isotopes, DOE requires $10.7 million to operate the four laboratories currently designated for research isotope production and to carry out specific projects related to medical research. The four laboratories, Oak Ridge, Pacific Northwest, Brookhaven and Los Alamos, cost over $6 million to operate. The latest figures from the House and Senate conference designate $6 million for research isotope production with the remaining amount going toward the development of ^{99}Mo production capability.

ACNP/SNM is working toward report language that would earmark the $10.7 million necessary for research production, allotting the remaining amount toward ^{99}Mo production. House and Senate members were expected to finish meeting and pass a final bill to President Clinton by the end of the congressional session.

Technologist Section

ALLIED HEALTH APPROPRIATIONS

The House and Senate are still debating allied health funding for fiscal year 1998, as part of a larger Department of Labor/Department of Health and Human Services appropriations bill. The House figure for funding is $306 million for health professions, with $3.9 million for allied health, an increase of $100,000. The Senate figure is much lower, with only $220 million for health professions and $3 million for allied health. The SNM-TS is working to raise the Senate figure to match the House amount of $3.9 million. Of that $3.9 million, grant money goes to approximately 10 programs that provide training for nuclear medicine technologists.

Also still under consideration by Congress is the combining of several health professions into funding clusters. This would get the Appropriations Committee away from approving individual line items like allied health and shift much of the discretion for funding to the Bureau of Health Professions. Currently under consideration is a cluster that would combine allied health, rural care and geriatrics. This proposal will likely be carried over into the next session of Congress and move through the House Commerce Committee in 1998.

NATIONAL LICENSURE

At the SNM-TS National Council meeting, the council advocated moving forward with national licensure. The Government Relations Office has been investigating partnering with the ASRT effort and also working with the NRC to develop training and experience criteria. However, this process is still in the early stages, and a strategy as to which avenue creates the best scenario for the SNM-TS has not yet been decided on.

Note: For more information on any of these topics contact either David Nichols or Amanda Sullivan at (703) 708-9773.

—David Nichols is the director of the ACNP/SNM government relations office.