Government Relations Update

Government Relations Office

Annual Report 1997

The ACNP/SNM Government Relations Program reports one of its most successful years in recent memory. Because of the dedication of volunteers on the Government Relations Committee and the time and direction given by the leadership, ACNP and SNM have had a positive influence on both the legislative and regulatory fronts. This report captures the highlights of the past year. For more detail on any of these issues, please consult the government relations web page at www.snm.org, or feel free to contact the Government Relations Office at (703) 708-9773.

LEGISLATION

P.L. 105-115 (Food and Drug Administration Modernization Act of 1997)

One of the major accomplishments of the year has to be ACNP/SNM's impact on the FDA reform legislation. Working independently as well as in conjunction with ICP, CORAR, and APhA, nuclear medicine had several sections pertaining to its field within the bill. This type of legislative activity is rare, and ACNP and SNM were well positioned to work with other organizations and congressional staff to influence the outcome.

There are three provisions in the FDA bill that pertain to nuclear medicine: the provision on PET, the approval process for radiopharmaceuticals and, finally, the application of federal law to the practice of compounding. President Clinton signed the bill on November 21, 1997.

For more detail on this topic, refer to last month's *Newsline*. Copies of the actual text of all three provisions as well as the conference report language that becomes part of the legislative history can be found on the government relations web page. (The description of the Act in last month's *Newsline* is only a summary, and all interpretation of the provisions should be based solely upon the official statutory language.)

P.L. 105-78 (Labor, HHS and Education Appropriations Bill for FY 1998)

The SNM Technologist Section (TS), in conjunction with other members of the Allied Health Roundtable, were successful in increasing the appropriation for allied health funding under Title VII. Overall, health professions training received an increase from FY 97 of $13,695,000 to a total in FY 98 of $306,513,000. Within that budget amount, the Allied Health Special Project was increased from FY 97 by $13,000 to a total of $3,845,000 for FY 98. This money is used in part to support training programs for nuclear medicine technologists. Approximately 6 to 8 programs receiving money from Title VII involve such training.

P.L. 105-62 (Energy and Water Development Appropriations Bill for FY 1998)

The Energy and Water Development Appropriations bill covers all isotope production appropriations through the Department of Energy (DOE). The isotope production program received $7 million for operations at four facilities: Los Alamos National Laboratory, Brookhaven National Laboratory, Pacific Northwest National Laboratory, and Oak Ridge National Laboratory. This was almost $4 million less than the DOE recommended and is expected to impair the ability for many research and development initiatives to continue at these labs. In addition, the DOE received $9 million for its ^{99}Mo project at Sandia, as well as reprogramming another $3.7 million, bringing the total up to $12.7 million.

REGULATIONS

10 CFR 35 (NRC's Medical Use Program)

The NRC has been undergoing a review of its medical program regulations contained in 10 CFR 35 for approximately 6 months. Following the end of one phase of their strategic assessment, the Commission directed the staff to engage in a process that would bring about a revision to 10 CFR 35. The agency has conducted two public workshops in Philadelphia and Chicago as well as a meeting with the agreement states in California. ACNP and SNM member physicians, pharmacists and technologists attended these workshops.

Based on Commission direction, the agency is adopting a multiple-modality approach, with regulations different for nuclear medicine compared to regulations for radiation oncology. The NRC staff have offered a two-tiered approach for nuclear medicine, with the first tier as diagnostic nuclear medicine (considered by many to be low-risk) and the second tier as therapeutic nuclear medicine, which NRC believes to have a higher associated risk.

ACNP and SNM over the past year have sought out a fair and open process that involves comments and dialogue with all stakeholders. In response to a request by ACNP and SNM, the Commission structured the two workshops, extended its comment period and used the internet to receive and display comments and dialogue in an open process that can be directly attributed to the work of ACNP and SNM. In addition to the public process, NRC has expressed an interest in working with the specialty societies to gather information, and several meetings between the leadership of ACNP and SNM and key NRC staff and commissioners have already taken place. Meetings and discussions among the membership will be key to providing comments to the NRC in the coming year as text of the proposed rule becomes available. Key issues revolve around (1) training and experience for physicians; (2) the Quality Management Program; (3) the role of the radiation safety committee; and (4) the criteria for reporting events to the NRC. A draft proposed rule is expected to be disseminated at the end of January, with an official proposed rule and more public workshops during the summer of 1998.

Patient Release Rulemaking (10 CFR Part 35)

The NRC issued a Final Rule in 1997 regarding the release of patients to whom radioactive material has been administered, with a shift of focus to the potential dose to individuals who may come in contact with the patient. The rule is consistent with recommendations of the National Coun-

cil on Radiation Protection and Measurements (NCRP) and the ICRP. The following are the provisions of that rulemaking.

1. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
2. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem), assuming there were no interruption of breast feeding, the instructions shall also include (a) guidance on the interruption or discontinuation of breast-feeding, and (b) information on the consequences of failure to follow the guidance.
3. The licensee shall maintain a record of the basis for authorizing the release of an individual for 3 years after the date of release, if the total effective dose equivalent is calculated by (a) using the retained activity rather than the activity administered, (b) using an occupancy factor less than 0.25 at 1 m, (c) using the biological or effective half-life, or (d) considering the shielding by tissue.
4. The licensee shall maintain a record for 3 years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

Unauthorized Usage Rule - Nuclear Regulatory Commission (10 CFR Part 20)

On February 20, 1997 the NRC staff forwarded to the Commission a final draft. The rulemaking, which would have created additional regulations and notification requirements upon the discovery of an unauthorized usage of byproduct material, was presented along with three additional options for the Commission to consider. These included (1) finalizing the rule as drafted, (2) renoticing the rule and soliciting public comment, and (3) terminating rulemaking.

The Commission decided to terminate the rulemaking. This is consistent with the comments provided to the Commission from ACNP and SNM.

Exempt Distribution of a Radioactive Drug Containing One Microcurie of C-14 Urea - Nuclear Regulatory Commission (10 CFR Parts 30 & 32)

In December 1997, the NRC amended its regulations to permit NRC licensees to distribute a radiopharmaceutical containing one microcurie of carbon-14 urea to any person for in vivo diagnostic use. The NRC has determined that the radioactive component of such a drug in capsule form presents an insignificant radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This amendment makes the drug more widely available and reduces costs to patients, insurers and the health care industry.

LEGAL ISSUES

Successful Appeal of FDA Regulations on PET

SNM, Syncor International, ACNP and the APhA were successful in their appeal of an original decision by the U.S. District Court. The case brought by SNM and others questioned FDA's 1995 regulation that required NDAs and ANDAs for PET drugs. The U.S. District Court ruled in favor of FDA, claiming that the policy change was consistent with the Administrative Procedure Act. The professional and industry groups, represented by Alvin J. Lorman of Mintz, Levin, Cohn, Ferris, Glovsky, & Popeo, appealed, and the U.S. District Court decision was overturned 3–0 by the U.S. Court of Appeals.

In reversing the district court decision in *Syncor v. Shalala*, the appeals court held that FDA should have engaged in notice-and-comment rulemaking to adopt the challenged regulation. FDA had argued that it was simply issuing a policy statement or an interpretive rule, rather than imposing substantive new requirements — an argument the court rejected.

The court decision now requires FDA to enter an official notice and comment period should it desire a change to any of the regulations governing PET. This case also sets a precedent that could potentially require an official notice and comment period pertaining to any changes involving radiopharmaceuticals.

While the victory was substantial in reversing the tide of overregulation by FDA, it is overshadowed by the requirements advocated by ACNP, SNM and ICP in the FDA reform bill passed by the Congress.

In response to this decision, the Justice Department filed a motion to vacate the ruling on the grounds that the passage of the PET provision in the FDA Modernization Act renders the case moot. ACNP and SNM, along with APhA and Syncor, filed in opposition to the government's motion, and the court agreed and denied the government's motion. This led to a completion of all matters on this action.

The decision by the court on the motion to vacate validates the actions of PET facilities not complying with FDA's policy statements and final rules from 1995 to 1997. Removal of the appeals court decision would have made those actions illegal and subject to potential liability lawsuits or action by FDA (which was unlikely, however).

The decision also indirectly protects the nuclear medicine community from facing internal change to the 1984 nuclear pharmacy guideline by FDA without appropriate notice and comment. This is the guiding document for FDA jurisdiction over radiopharmaceutical compounding.

OTHER ISSUES

Health Professions Network

The Government Relations Office continues to work with the Health Professions Network (HPN), which is sponsored in part by the SNM–Technologist Section. This federation of allied health organizations provides an opportunity for different allied health disciplines to meet on a regular basis to discuss the promotion and dissemination of information highlighting the importance of the allied health field. As part of this effort, the network is working with the Bureau of Health Professions under the Department of Health and Human Services to produce a workshop to instruct emerging leaders on the work-

ings of government. This 5-day forum, to be held in April 1998, is being coordinated by the SNM-TS as part of HPN's commitment to this project.

Outreach to Chapter Meetings

The Government Relations Office conducted several chapter visits by Robert Carretta, MD, chairman of the Government Relations Committee, in an effort to expand the visibility of the ACNP and SNM's government relations efforts. Chapter visits included those to the Pacific Northwest, Greater New York, Missouri Valley, and Northern and Southern California meetings. Chapters interested in arranging for a government relations speaker at their upcoming meetings should contact David Nichols, Director of Government Relations, at (703) 708-9773.

Political Action Committee

SNM, through the Government Relations Office, is moving forward with the establishment of a political action committee (PAC) by April 1998. This PAC will allow the Society to become more visible in the Congress and assist those members who are legislative friends of nuclear medicine in their reelection campaigns.

Legislative Network

The SNM-TS continues to operate a very successful legislative network. With more than 50 members in the legislative network, spread out among all the chapters of the SNM, the network enables members to keep informed on legislative issues and contact their members of Congress prior to key votes on Capitol Hill. If you are interested in participating in this legislative network or being included as a key contact in our nuclear medicine database, please contact Amanda Sullivan in the Government Relations Office at (703) 708-9773.

For more information on any of these topics, members are encouraged to routinely check the government relations page on the web at www.snm.org or to contact the Government Relations Office at (703) 708-9773.

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

Alpha Particle Therapy

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parent of ^{229}Th, which is the parent of ^{225}Ac, which is the parent of ^{213}Bi. The DOE is currently working out plans to use U.S. uranium stockpiles for the production of alpha emitters and other medical isotopes. "This is a swords-to-plowshares story about using bomb-grade materials directly toward the treatment of cancer," said Robert E. Schenter, PhD, deputy site manager for the isotope program at PNNL. Scientists at PNNL are currently producing the beta emitter ^{90}Y and the alpha emitters ^{213}Bi, ^{225}Ac and ^{223}Ra from stored nuclear materials.

Still a Long Way to Go

As promising as alpha emitters seem as a potential treatment for cancer, researchers remain reserved in their enthusiasm. They remember the initial excitement over monoclonal antibodies and the resulting disappointment when that treatment failed to work against solid tumors. While acknowledging that they have made tremendous strides in alpha research over the past decade, researchers know they still have a long way to go.

—Deborah Kotz

Antibody Pretargeted Radiography

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recently initiated to evaluate tumor delivery of ^{212}Pb/^{212}Bi in the pretargeting system.

Initial studies used the gamma-emitting isotopes ^{203}Pb and ^{205}Bi for study of DOTA-biotin stability and pretargeting. The complexes were found to be stable, and pretargeting tumor and normal organ values were similar to those with ^{111}In and ^{90}Y. Then, ^{212}Pb and ^{212}Bi DOTA-biotin were prepared and evaluated. As expected from the results of Mirzadeh et al., about 35% of the biotin binding was lost for the ^{212}Bi from decay of the ^{212}Pb. However, when applied in the pretargeting context with NR-LU-10-SA, both the ^{212}Pb and ^{212}Bi values in tissue resulted in over 20% ID/g in tumor in 15 min, rising to 30% ID/g after 1 hr. Blood values were below 5% ID/g by 15 min, resulting in high tumor-to-blood AUC values. The kidney ^{212}Bi values were increased over the first 3 hr, then diminished, indicating that ^{212}Bi released from circulating forms localized in the kidney, but tumor-targeted radioactivity remained, even following escape from the DOTA chelator.

The preliminary studies of the alpha emitters briefly described establish potential in an efficient targeting system for radionuclides with short half-lives. The pretargeting system provides a means to evaluate the potential of targeted alpha radiotherapy in small and large xenograft tumors as well as metastatic tumor models. Issues for alpha emitters in pretargeting to be addressed in future research include toxicity to normal tissues and efficacy with respect to applicability in micrometastases relevant to adjuvant tumor treatment and the potential for treating established solid tumors.

Note: Pretargeting of ^{212}Pb supported by PHS Grant CA71221.

—Alan R. Fritzberg, PhD, is chief scientist and chairman of the scientific advisory board, NeoRx Corporation, Seattle, WA.