

## The Washington Office: New Agenda, Big Plans

With the anti-regulatory fervor in Congress, the Society of Nuclear Medicine (SNM) has decided to strike while the iron is hot: The Washington Office recently changed management hands and is now being headed by the lobbying firm, Marc Associates. The office will be more aggressive in trying to persuade Congress to loosen government agencies' regulation of nuclear medicine. In conjunction with SNM's government relations committee, the new Washington staff has developed this agenda and list of priorities for 1995.

### Breaking Free from the Nuclear Regulatory Commission

The Nuclear Regulatory Commission (NRC), and its predecessor agency the Atomic Energy Commission, has regulated the medical use of reactor-produced radionuclides for over 40 years. The current NRC Commissioners—especially outgoing Chairman Ivan Selin, PhD—favor ending NRC's medical program which SNM and ACNP leaders have been advocating for years, said Randolph Fenninger, vice-president of Marc Associates.

Although Selin wants to deregulate nuclear medicine, NRC policy wonks have written stricter rules regarding the medical use of radionuclides in recent years. Fenninger said more and more regulatory requirements have been established which deprive patients of appropriate procedures, increase the cost of medical care, and limit physicians' and pharmacists' professional judgment.

In nuclear medicine, the cost of ever increasing regulatory requirements is about \$1 billion a year, or about \$100 per scan, said Robert Atcher, PhD, a member of SNM's government relations committee. Atcher testified in March before the House Appropriations Committee on SNM's behalf asking for an end to the medical regulation program at the NRC.

The Society is pushing to get the NRC out of the regulation of nuclear medicine and transfer the functions to the states. Since the states now regulate 75% of ioniz-

ing radiation medicine, they can easily absorb the remaining 25%, Fenninger said. Amendments to the Atomic Energy Act for nuclear medicine have already been developed and Congressional sponsors are now being sought. NRC issues are all being tackled in a similar way: petitions are being filed and meetings are underway with Congressmen, government officials and agency leaders.

### Warding Off Regulation of PET Drugs

PET centers and the FDA have been haggling over the regulation of PET radiopharmaceuticals for 8 years. Given their ultra-short half-lives, PET drugs simply do not fit the definition of traditional drugs, thus they should not be treated differently by the FDA, Fenninger said.

Unfortunately, the FDA disagrees and has proposed new rules that will regulate all PET drugs. One way the Washington Office is planning to counteract these new regulations is through lobbying for legislation to limit the FDA's authority over pharmacy practice. A major target is the Brewster Bill, which applies to pharmacy. This bill protects pharmacies from certain areas of federal regulation that are already regulated by the states. When the bill was first crafted, radiopharmacy was not considered and therefore not included.

"This is the heart of the PET issue. SNM is supporting legislation to clarify the limits of the FDA's authority over the practice of pharmacy," Fenninger said. Legislative language will hopefully be added to the bill later this summer to include radiopharmacy. To date, there are 56 supporters of the bill and the Nuclear Pharmacists of America have already filed their support.

Members of the SNM and the American College of Radiology met with FDA staff on May 8th to discuss the regulation of PET radiopharmaceuticals and to address questions relating to new drug approvals.

### Cutting Away Overlapping Regulations

Marc Associates is currently sorting through the regulatory burdens of nuclear medicine that exist due to overlapping regulations imposed by various government agencies. For instance, the NRC and the Environmental Protection Agency (EPA) each have rules regarding radiation safety which often conflict with each other.

One suggestion already presented to Congress is to have an independent science body review and make recommendations on the regulation of radioactive substances, ensuring that a conflict of interest does not exist. SNM and ACNP both recommended the National Academy of Sciences. The Washington Office has asked the House Appropriations Committee to direct the EPA to initiate such a review. "Congress today is concerned about unnecessary regulation which provides a good window of opportunity to alter the dual-regulation sector. They are willing to look at overlapping regulation, which did not exist with the Democratic Congress prior to the November election," said Joseph Karpinski, director of the Washington Office.

### Supporting the Department of Energy

Since Congress has already slashed the Department of Energy's (DOE) budget, legislators will probably call on the DOE to reduce spending in the area of research grants. Marc Associates is working to prevent much needed funding from being taken away from nuclear medicine research.

SNM and ACNP leaders are extremely supportive of the isotope program department and have met with DOE officials to ensure that a domestic source of isotopes is available for nuclear medicine. They have also filed letters and testified in support of the DOE to Congress.

The ongoing reimbursement, research, drug control, radiation safety and technologist issues remain in constant sight of SNM's ultimate goal to get nuclear medicine's needs implemented as laws.

## Recent Actions from the Board of Directors

Board Members, SNM staff and invited guests gathered April 8th in Reston, VA to attend the Board of Directors' (formerly known as the Executive Committee) Spring Meeting to discuss a wide range of agenda items pertaining to both the Society and the nuclear medicine industry.

### RADIOPHARMACEUTICAL TASK FORCE: MEETING OF THE MINDS

The Radiopharmaceutical Task Force addressed two key topics: the regulation of all radiopharmaceuticals and recent regulatory actions directed at PET radiopharmaceuticals.

- **Regulation of Radiopharmaceuticals:** The biggest problem facing radiopharmaceutical suppliers is the possibility of tighter regulations from the FDA. The Task Force predicts that the FDA will slow the approval of radiopharmaceutical and add restrictions to drug labels.

- **Solution:** The Task Force agreed that while the FDA should continue to define and set rules for the drug review process, actual drug reviews should be performed outside of the FDA. The group decided that a realistic determination of who should write the standards for drug review should be created by a group of "true experts" assembled from sources such as the United States Pharmacopoeia and medical societies as well as the FDA.

- **PET Regulation:** A proposed rule by the FDA would basically put all manufacturers of PET drugs on the same regulatory footing as the general pharmaceutical industry. In essence, PET centers would not be able to manufacture drugs that do not have FDA approval without filing a new drug application. Although a legal challenge to this rule is being considered, meeting participants judged it to be a last option with a low likelihood of a successful outcome.

- **Solution:** Lobby for the inclusion of PET radiopharmaceuticals in the Brewster Bill (pharmacy legislation) and encourage PET drug manufacturers to develop their own proposal of reasonable Current Good Manufacturing Practice guidelines.

### PUBLIC RELATIONS PILOT PROGRAM LAUNCHES OFF

Referring physicians' lack of awareness of nuclear medicine procedures has long been an issue recognized by the SNM. The SNM's Public Relations Committee is taking a new tack: go straight to the patient's themselves. At the weekend Board meeting, representatives of the public relations committee formed a study group with SNM leaders, industry representatives and technologists to create an action plan for reaching the most patients in the least expensive and most efficient way.

They outlined a public relations pilot program geared to acquiring press coverage for nuclear medicine—most notably in the women's magazine market. The pilot program is currently focusing on "hot topics" of nuclear medicine as they relate to women's health issues such as coronary artery disease, ovarian and breast cancer, bone pain and osteoporosis.

The program will consist of a limited media outreach effort to 37 publications. The department plans to contact the magazines through press kits, various mailings and follow-up phone calls in an effort to reach approximately 50 million readers.

An example of how media pick-up could aid nuclear medicine is: A woman is admitted to the hospital with chest pain. She has read in *Good Housekeeping* that the standard EKG stress test has a low predictive value in women and that nuclear imaging tests are more reliable. She asks her doctor for this test.

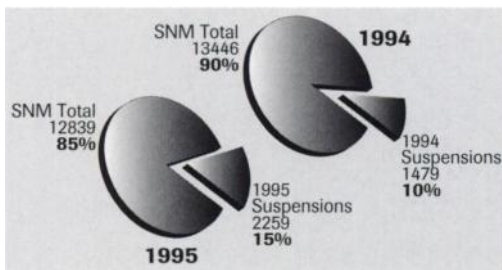
An estimated \$6000, already in the current SNM budget, will be earmarked for this effort. "The aim of this meeting was to get the study group focused on immediate and future nuclear medicine goals in order to begin development on a comprehensive public relations program," said Kristin Ludwig, SNM marketing and public relations manager. Much of the discussion centered on identifying the obstacles facing nuclear medicine today and identifying target audiences, messages and outreach strategies for the remainder of 1995 through 1996.

Based on its success, the long-term goal is to develop a program to further publicize the value and benefits of nuclear medicine. A full status report of the pilot program will be presented to the leadership at the upcoming Annual Meeting in Minneapolis.

—Compiled by Stacey Silver

### A NEW LOOK AT DECLINING MEMBERSHIP

The \$50 dues increase (a rise of 4%) implemented in January reflects a decline in membership over the past few years.



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In an effort to retain members, the membership department decided the first step is to evaluate why membership is declining. Within the

next few months, a survey will be mailed out to those who withdrew their membership and will include a personalized letter asking for reasons why they did not renew. The survey results should supply the SNM with solid data on the diminishing membership and help identify the marketing and recruitment tactics necessary for future growth.

In 1995, about 2300 members did not renew their membership, a 50% increase from 1994 (see chart above). Technologist attrition accounted for 64% of the members who chose not to renew.

"I think the main reason for the decline in membership is due to hardship in the [nuclear medicine] field, particularly for technologists. People are losing their jobs," said Lori Tremmel, director of membership services.