

Board of Trustees Endorses New Standing Committee on Efficacy

SNM INITIATES EFFICACY STUDY OF RIA TESTS AND TAKES ACTION ON PET REIMBURSEMENT

One of the most sensitive and specific radionuclide procedures is being threatened by newer laboratory tests, while one of the newest technologies in nuclear medicine faces tough obstacles in its transition from a research to a clinical tool. The Society of Nuclear Medicine (SNM), however, has taken action to enlighten the medical community and government agencies about radioimmunoassay (RIA) and posi-

tron emission tomography (PET).

Howard J. Dworkin, MD, who took office as president of the SNM on June 22, has created a new special committee to study the efficacy and cost-effectiveness of RIAs. "I thought it was time to review this situation and look at how competitive RIAs are compared to other types of biochemical assays," Dr. Dworkin told the SNM Board of Trustees during its meeting on June 21, 1986, in Wash-

ington, DC. The committee has been directed to issue its report within the next year.

"From the calculations that I've done at my institution, I strongly feel that RIA is competitive and has many advantages over other existing technologies, although this opinion may not be reflected in the literature. I think this issue should be aired in public," said Dr. Dworkin.

About 15-20% of the nuclear med-

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um-111-labeled platelets to detect peripheral as well as pulmonary thrombi (Abstract No. 285).

Dr. P. Frey, *et al.* of the University Hospital of Geneva in Switzerland, with investigators in the United Kingdom from the Royal Marsden Hospital, Manchester University, and the University of Oxford, used the positron emitter iodine-124 to generate striking thyroid images (Abstract No. 135).

At the University of California at Davis, Robert C. Stadalnik, MD, and his group continue to develop models for assessing liver mass by means of receptor-binding radiotracers, using technetium-99m neogalactose albumin (NGA) for liver imaging (Abstract No. 196).

Bone Densitometry

Dual-photon absorptiometry remains an area of rapid growth in nuclear medicine. Malcolm R. Powell, MD, *et al.* of Nuclear Medicine Consultants in San Francisco,

presented a study that shows the importance of monitoring bone density to help direct patients to a particular therapy (Abstract No. 41).

The scintillation camera can also be used for bone density measurements, reported Masao Fukunaga, MD, *et al.* of the Kawasaki Medical School and colleagues from Hamamatsu Phototonics and Kyoto University in Japan (Abstract No. 450). A nuclear medicine department that is phasing out the imaging uses of one of its gamma cameras could use that piece of equipment for bone density studies.

Infectious Diseases of AIDS

For the detection of *pneumocystis carinii* pneumonia in patients with acquired immunodeficiency syndrome (AIDS), Dr. J. Rosso, and colleagues at the Universite Paris XII in Creteil, France, presented results of a comparison of technetium-99m diethylenetriamine pentaacetic acid (DTPA) aerosol and gallium-67 scans (Abstract No. 303). One of the

manifestations of pulmonary infection is accelerated clearance of inhaled chelate aerosols.

In some cases, treatment of patients with antibiotics decreased the gallium-67 accumulation, but the technetium-99m DTPA clearance did not return to normal. The aerosol clearance, therefore, was more sensitive in diagnosing pulmonary infection than gallium-67 accumulation, although gallium has proved very helpful in the detection of pneumocystis disease in AIDS patients.

Link Between Structure & Function

In summary, the most significant development that has emerged during this year's SNM Annual Meeting is the progress with technetium-99m compounds—in particular, HMPAO for brain blood flow and the isonitriles for myocardial studies.

The main theme of nuclear medicine remains its role in using chemistry and physics to relate anatomic structure and function.

Henry N. Wagner, Jr., MD

icine community is involved with RIA, and Dr. Dworkin has invited anyone interested in the study to contact the chairman of the RIA Cost-Effectiveness Committee, Oscar M. (Jay) Powell, Jr., MD, of the Division of Nuclear Medicine at Allegheny General Hospital in Pittsburgh, PA.

As a step toward encouraging Medicare and other third-party payers in the United States to reimburse for PET studies, Raymond Marty, MD, chairman of the Socio-Economic Affairs Committee, introduced a resolution directing that the PET Reimbursement Subcommittee work with PET centers to prepare package inserts detailing the use of the major PET radiopharmaceuticals.

"Health care delivery with PET is based on the local production of radiopharmaceuticals," said Dr. Marty. "Standardization and recognition by the US Food and Drug Administration (FDA) are required for PET to be included in nation-wide reimbursement schemes—otherwise reimbursement will remain a local issue," he added.

Michael D. Loberg, PhD, a researcher at E.R. Squibb & Sons, Inc., a radiopharmaceutical manufacturer in New Brunswick, NJ, further explained the purpose of the resolution, which was passed by the Board.

"These package inserts may become part of the PET submission to the Office of Health Technology Assessment (OHTA) and made available to the FDA Radiopharmaceutical Drugs Advisory Committee (RDAC) to aid in the discussion of how to obtain FDA recognition for these procedures," said Dr. Loberg, who is a member of the PET Reimbursement Subcommittee.

[The OHTA is the branch of the US Department of Health and Human Services that reviews medical technology for the Health Care Financing Administration (HCFA), which establishes Medicare reimbursement policies. The RDAC is a nongovern-

mental group of nuclear medicine experts who advise the FDA on radiopharmaceuticals. Since PET radiopharmaceuticals are produced and distributed locally, there are no new drug applications (NDAs) filed with the FDA, which is the usual mechanism for obtaining FDA approval.]

Efficacy Evaluation Committee

To provide a permanent mechanism for the SNM to deal with efficacy issues for all nuclear medicine procedures, Michael L. Goris, MD, PhD, of the Division of Nuclear Medicine at Stanford University in California, introduced a resolution to create a standing Committee on Efficacy Evaluation.

"The committee would review the efficacy of scintigraphic procedures on the basis of data and analysis published in peer-reviewed journals," said Dr. Goris. Officers of the SNM are frequently called upon to defend particular nuclear medicine procedures to regulatory agencies, third-party payers, and providers of research grants, explained Dr. Goris, "and the new committee would help the SNM leadership to render informed opinions supported by scientific evidence."

The Board passed the resolution and the SNM president disbanded the previous Subcommittee on Efficacy. The Bylaws Committee will develop language for the Committee on Efficacy Evaluation. If approved at the next Board meeting, the bylaws change will be presented to the membership in the next election ballot.

Dr. Dworkin also created another new special committee to conduct a human resource survey of nuclear medicine physicians and scientists. The Manpower Committee, chaired by Richard A. Holmes, MD, who began his term last June as vice president of the SNM for 1986-87, will compile demographic data and issue a report within the next two-to-three years.

President's Report

Stanley J. Goldsmith, MD, president of the SNM, reported that the Ad Hoc Inter-Society Commission on Radiopharmaceuticals met last spring to discuss possible solutions to the problem of delays in the FDA approval process. The Commission, including representatives of the SNM, the American College of Nuclear Physicians (ACNP), and the American College of Radiology (ACR), has arranged a meeting with FDA Commissioner Frank E. Young, MD, to discuss the issue.

Amendment of Mission Statement

A motion came from the Executive Committee to amend the mission statement of the SNM to include a "proactive role in government relations and socioeconomic issues." B. Leonard Holman, MD, secretary of the SNM, explained the current objectives of the Society are: "to maintain an organization of physicians and scientists of high standing with a common interest in the scientific and clinical disciplines concerned with the diagnostic, therapeutic, and investigational use of radionuclides;" to foster scientific meetings, to disseminate nuclear medicine information in professional journals, and "to strive to better the welfare of mankind."

Dr. Holman also explained that a proactive, as opposed to a reactive, role indicates that the SNM would try to "look ahead and prepare for impending problems instead of looking behind and trying to patch up a situation."

Dr. Goldsmith explained that the addition to the mission statement would not increase the socioeconomic and political activities of the SNM, but rather would make the organization's objectives describe more accurately its current role. "Just as we promote the 'welfare of mankind,' the SNM should also promote the welfare of nuclear medicine," he said.

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The Board passed the resolution and referred it to the Bylaws Committee.

Government Relations Report

Robert H. Wilbur, director of government relations at the SNM/ACNP Conjoint Washington Office, reported on several issues.

The regulations proposed by the US Nuclear Regulatory Commission (NRC) for changing the education and training requirements for licensure for cardiologists and other physicians using radiopharmaceuticals are being prepared for submission to the NRC commissioners by late summer. If accepted by the Commission, they would subsequently be published in the *Federal Register* for public comment.

Drs. Goldsmith and Dworkin recently testified in Congress on the value of nuclear medicine research funding from the US Department of Energy (DOE). The Subcommittee on Research and the Environment of the House Committee on Science and Technology has recommended a \$1.2 million increase, which would maintain this funding at this year's level, over the Reagan Administration's budget request for the next fiscal year.

Concerning Medicare reimbursement for dual-photon absorptiometry (DPA), the presidents of the SNM and ACNP recently sent letters to HCFA. The OHTA has completed its study of DPA, but HCFA has said it would delay its decision until the OHTA completes a companion study on single-photon absorptiometry.

HCFA is also questioning the value of a more effective diagnostic test for osteoporosis if it does not change patient management. Several SNM members are compiling data to respond to this concern.

The presidents of the SNM and ACNP also sent letters to HCFA on the issue of reimbursement for PET procedures, requesting that HCFA initiate its review procedure for eval-

uating a new medical technology.

Last year, the SNM and ACNP responded negatively to a proposal that the FDA charge user fees for reviewing NDAs. Although Congress voted to prohibit the FDA from charging these applications fees, the Reagan Administration has revived the proposal in the federal budget for fiscal year 1987. The new proposal provides that the funds be used to improve the FDA review process, and the Pharmaceutical Manufacturers Association recently gave it a qualified endorsement. Congress is now waiting for the FDA to submit a legislative proposal, reported Mr. Wilbur.

Last year, the SNM and ACNP also responded to the NRC's proposed new rules on Human Uses of Byproduct Material (10 CFR 35) by recommending that two requirements—for reporting diagnostic misadministrations and for limiting the usage of radiopharmaceuticals to the routes of administration listed on the package insert—be dropped.

"Initially, we were not terribly optimistic that the NRC staff would accept these major changes, but it did," said Mr. Wilbur, and the proposed revision now goes to the commissioners for their review. If they approve the changes, the rules will become final.

The NRC is also working on a revision of its Standards for Protection Against Radiation (10 CFR 19 and 20). The deadline for the comment period has been extended to September 12. "We have received some conflicting views from members as to whether, for example, the proposed *de minimis* levels are too low or the costs of changing procedures might outweigh the benefits," reported Mr. Wilbur.

SNM in Canada

Following up on an action item passed by the Board last March, Steven M. Pinsky, MD, of the Bylaws Committee, introduced a bylaws change

that establishes the SNM in Canada (see *Newsline*, May 1986, p. 589). The group will not be a chapter, a council, nor a section, but a new type of SNM subgroup; it will have one voting member on the Board of Trustees.

There are two Canadian SNM chapters, and two chapters with members from both Canada and the United States. "In the past, depending on the results of chapter elections, there have been up to four Canadians on the Board of Trustees," said Albert A. Driedger, MD, of the Ad Hoc Committee on Canadian Membership.

Since the Board's agenda deals heavily with US issues, the binational chapters should be represented by a US member, and only one Canadian is needed on the Board to provide a liaison with the SNM in Canada, explained Dr. Driedger. The new group could also encourage more Canadians to join the SNM, he added. The Board passed the resolution, and the membership will vote on the bylaws change next year.

In response to an invitation from the Canadian Association of Nuclear Medicine to hold the 1990 SNM Annual Meeting in Montreal in conjunction with the Fifth World Congress

SNM 1986 ELECTION RESULTS

President-Elect	B. Leonard Holman, MD
Vice President-Elect	Paul M. Weber, MD
Secretary	Naomi Alazraki, MD
Historian	Frank H. DeLand, MD
Trustees	Daniel S. Berman, MD Leon S. Malmud, MD Michael M. Graham, MD, PhD

Members Taking Office for the 1986-1987 Term

President	Howard J. Dworkin, MD
Vice President	Richard A. Holmes, MD

of Nuclear Medicine and Biology (if the World Federation selects Montreal as the site), the SNM leadership has decided not to withdraw from signed contracts for the Annual Meeting to be held in Washington, DC. The SNM is neutral on the site selection for the next World Congress.

[A few hours after the Board meeting, Dr. Goldsmith and several members of the SNM leadership met with at-large SNM members, who are members residing outside the United States and Canada, to discuss their concerns with how the Society serves and represents them. SNM members from Europe, Asia, India, and South America attended, and Dr. Dworkin said he plans to hold a similar meeting next year. Thomas P. Haynie, MD, editor of *The Journal of Nuclear Medicine*, also addressed the group about the journal's international scope.]

Budget Report

The Board spent almost two hours of the five-hour meeting discussing the SNM budget. "Your Society is fiscally sound," said Edward V. Staab, MD, treasurer of the SNM. "For the most part, revenues meet expenses," he said, although there was a deficit in the 1985-1986 budget, and a deficit is projected for 1986-1987. The SNM annual budget is about \$3.7 million.

Dr. Staab gave three reasons for the recent trend: (1) Advertising revenues have dropped over the past few years as companies have merged, gone out of business, or faced their own budget cut-backs which affected their marketing programs. (2) The relocation of the Central Office resulted in a payment of up-front dollars for renovation, and the rental and utility expenses have increased. As the Board reviewed the relocation decision, it was pointed out that the lease for the previous space expired last year, and the rent increase would have been more than the current rent for the new space. (3) The number of SNM programs has gradually expanded.

Martin L. Nusynowitz, MD, chairman of the Finance and Budget Committee, also explained that the project to computerize the office is reaching the implementation stage, and those expenses are included in the 1986-1987 budget. Dr. Nusynowitz presented a resolution from his committee to raise the dues for full members by \$10, and for all other members by \$5, excluding technologists. Several trustees, however, said that the SNM should focus on cost containment rather than a dues increase, and the resolution was not approved.

Student Fellowships Restored

The Finance Committee did not include its usual \$10,000 grant to the SNM Education and Research (E&R) Foundation in the 1986-1987 budget, but the Board voted to restore it. Dr. Nusynowitz explained that when the Foundation was established four years ago, the SNM decided to fund it for a limited period of time until it developed its own sources of contributions. Walter Wolf, PhD, president of the Foundation, said that he would prepare a report for the Board on the success of the student fellowship program. The E&R Foundation provides stipends of \$2,000 to medical students for summer fellowships in nuclear medicine research.

"I'm disturbed that this is the one item in the budget that was identified as dispensable, and I think we should critically look at the SNM's philosophy on supporting student fellowships," said Heidi S. Weissmann, MD, of the Education and Training Committee. "Even if Dr. Wolf's report shows that many fellowship students do not choose a career in nuclear medicine, those students will have a very different and positive outlook towards nuclear medicine as they practice in other specialties," said Dr. Weissmann. "We should be increasing our support to medical student education—not decreasing it," she added.

Dr. Goris recommended that the

Board establish more concrete priorities before the budget process. He suggested that the Board divide the SNM program into three categories: activities that must be done at any cost, those that should be done if affordable, and those that should be done only if they generate revenue.

Violations of SNM Rules

Richard C. Reba, MD, chairman of the General Program Committee, reported that several participants in this year's Annual Meeting have ignored or been unaware of certain rules.

For example, it has been suspected that "duplicate or even triplicate submissions of the same data" have occurred. To examine this complaint, Dr. Reba announced that all abstracts submitted for the 1986 meeting will be entered into a computer and analyzed. "I will then write to authors of duplicate abstracts and ask them to be more critical with future submissions," he said.

With respect to nuclear medicine activities scheduled during the SNM Annual Meeting, Dr. Reba noted that all educational, scientific, committee, or users' group meetings (whether sponsored by the SNM or outside groups) should be coordinated through the SNM Central Office. Users' group meetings are not allowed to conflict with educational sessions, and must be held after 3:30 pm.

Dr. Reba also reminded the Board that the SNM recently established a committee to review and approve proposals for SNM cosponsorship of meetings (including those held during the Annual Meeting and others held throughout the year). These requests should be submitted to the SNM vice president, who chairs that committee.

[Additional information on the SNM organizational structure, committee appointments, council reports, and the budget is available from the SNM Central Office.]

Linda E. Ketchum