GOVERNMENT RELATIONS UPDATE

The following report is derived from a presentation by the Joint Government Relations Office of The Society of Nuclear Medicine and the American College of Nuclear Physicians at the SNM Annual Meeting in June.

REIMBURSEMENT FOR HEALTH CARE

SPECT Project. The SPECT Project raised $305,000 to support research through 1993 to evaluate the clinical utility of SPECT. The goal of the project is to facilitate the establishment of a national policy for SPECT reimbursement. The physicians and industry representatives directing the SPECT Project have chosen to fund five studies: 1) Insurer Information Package on SPECT, a data collection proposal by Project HOPE. 2) SPECT Utilization Data Collection, proposed by Technology Marketing Group. 3) RVU and Practice Expense Evaluation (yet to beawarded). 4) Literature Review for Bone SPECT, a clinical analysis proposal by Benjamin Littenberg, MD, assistant professor of medicine at Dartmouth-Hitchcock Medical Center. 5) Evidence Table for Myocardial Perfusion Imaging, a clinical analysis proposal by the SNM Office of Health Care Policy.

PET. The Food and Drug Administration held a hearing on March 5, 1993 to review the regulation of PET radiopharmaceuticals (see *Newsline,* April 1993, p. 26N). The FDA's decision regarding PET radiopharmaceutical regulation has delayed the Office of Health Technology Assessment ruling on medicare reimbursement for almost three years.

Assuming OHTA assesses PET positively, current policy seems to require a PET facility to secure an NDA to be eligible for reimbursement from Medicare, unless the facility purchases tracers from a centralized radiopharmacy that has an NDA.

Medicare Reimbursement. Of the seven PET codes and six SPECT codes submitted to the CPT-4-Editorial Panel in April, the following gained approval and will appear in the 1994 CPT book:

78606—Brain imaging, positron emission tomography (PET); metabolic evaluation
78609—perfusion evaluation
78807—Radionuclide localization of abscess; SPECT

The panel withheld approval of codes for myocardial perfusion imaging and whole body tumor imaging with PET, citing the need for more clinical studies.

HEALTH CARE POLICY

Bans on Self-Referral. Representative Pete Stark (D-CA), long an opponent of physician self-referral, has proposed new legislation against self-referral to a facility in which a physician has proprietary interest. The measure would save the government approximately $350 million next year. Nuclear medicine and radiology advocate that the bill be extended to "internal referral" where a primary care giver also performs specialty services such as diagnostic imaging. Since such a proposal has not been proven to save money, the Congressional Budget Office will not "score" any savings from a ban on this type of self-referral and policy makers refuse to acknowledge internal referral legislation as a significant savings.

PPRC on SPECT. The Physician Payment Review Commission has contracted with Project HOPE to evaluate the clinical acceptance of SPECT as an "emerging technology." The PPRC is developing a system to track new technologies and each year interviews experts in different medical fields. The professional opinions are entered into a data base and certain modalities are selected for further evaluation.

Health Care Reform. President Clinton's popularity with Congress has suffered and key representatives required to pass a sweeping health care proposal have become openly critical. Early estimates put the cost of the proposal at $100-$150 billion a year–a difficult pill for the nation to swallow on the heels of deficit-reduction taxes. Financing the plan could require unprecedented tax increases, global budgeting, employer mandates, and a number of other cost containment measures. If the debate on reform is resolved, the plan may still be at risk of failure over the debate of funding.

The odds are against any legislation passing this year. Reform is more likely to pass in 1994 after budget cuts have been realized. Most politicians find it difficult to justify any tax increase–even for health care–if there is no proof of budgetary responsibility in government. Since 1994 is an election year members will be particularly sensitive to public perception which may make passage even more complicated.

State-Level Reform. The President has indicated that his plan will include an "opt out" provision for state plans. Approximately 20 state legislatures are in the process of debating or at least considering developing a local health care plan. States are focused on universal coverage with managed competition being the basis for most. Tracking activity at the local level is very important since state plans could comprise the bulk of the national system. Of particular concern to nuclear medicine would be the implementation of radiology, anesthe-

siology, and pathology (RAP) diagnosis-related groups (DRGs) in state plans.

NUCLEAR REGULATORY COMMISSION

Congressional Inquiries. At a hearing held May 6 by the Senate Governmental Affairs Committee, Chairman John Glenn of Ohio, questioned the adequacy of regulation of medical devices to protect patients and health care workers from radiation exposure. Nuclear Regulatory Commission Chairman Ivan Selin and the four other commissioners testified, as did Bruce Burlington, MD, of the Food and Drug Administration and Aubrey V. Godwin of the Conference of Radiation Control Program Directors. Senator Glenn expressed concern about the apparent lack of central coordination of the regulation of radiation producing devices used in medicine. The senator gave the NRC until August 6, 1993, to report back to the committee with recommendations for how the regulation of radiation medicine should be coordinated by the government.

Agreement States. The House Governmental Operations Committee, chaired by Representative Mike Synar of Oklahoma, intends to hold a hearing on the NRC's agreement state program this summer to evaluate how agreement states are held accountable for compliance with NRC standards. Rep. Synar released a study by the General Accounting Office in May pointing out deficiencies in radiation control programs in as many as two thirds of the Agreement States.

The congressman's committee is planning to review the effectiveness of NRC enforcement measures such as fines and press releases. Committee staff have expressed concern that NRC renews licenses with too little review.

Budget Scrutiny. NRC has submitted a request for $547.7 million in fiscal 1994, of which $83.9 million is slated for nuclear materials regulatory programs. Testifying on the NRC budget before the House Energy and Water Appropriations Subcommittee, ACNP and SNM asked the committee to examine the medical applications program budget in greater detail. Because the NRC is funded through user fees, ACNP and SNM are concerned that the agency's budget escapes the rigorous scrutiny applied to federal programs funded by taxpayers. The NRC has yet to give a final answer to the ACNP and SNM petition for a revised user fee schedule, but a decision is expected soon. The NRC has published two additional rulemakings on the user fee structure. The first notice is a result of a U.S. Court of Appeals ruling in which the NRC must publish a request for public comment on the methodology used to collect fees from licensees. The second notice is a request for comments on proposed amendments for the collection of user fees in the upcoming year. In response to both proposals, ACNP and SNM will press for the same measures sought in the petition: exemptions for medical licensees, greater input in NRC decisions, uniform exemption criteria for all licensees, and a sliding fee scale for small entities based on the total revenue of the institution.

Radiopharmacy Regulations. The NRC is proposing to extend until December 31, 1994, the expiration date of the interim final rule on preparation and use of radiopharmaceuticals. The proposed action would maintain the status quo until the NRC completes a broader rule on preparation, transfer, and use of reactor byproduct material in medicine, which is expected to include many of the changes requested in a petition submitted by ACNP and SNM in 1989.

ACMUI. The May meeting of the Advisory Committee on the Medical Use of Isotopes was the last for four retiring members: Capt. William Briner (U.S. Public Health Service, retired), Steve Collins, Gerald Pohost, MD, and Edward Webster, PhD. Daniel Berman, MD, and Dennis Swanson RPh, MS, representing nuclear medicine and nuclear pharmacy respectively, will be joining the committee at the next meeting. One of the retiring positions will not be filled and the remaining seat has yet to be named.

Pregnancy Rule. The NRC is conducting cost studies and evaluating the effect on licensees of proposed new requirements for patients who are pregnant or nursing their infants. The studies will include a review of precautions taken by medical groups using non-radioactive drugs as part of their practice. The NRC staff reported to the ACMUI in May that a proposed rule can be expected at the end of the year.

Patient Release Criteria. NRC is reviewing regulations for the release of patients who have received diagnostic nuclear medicine procedures. The review follows the filing of petitions by the American College of Nuclear Medicine and, separately, by Carol S. Marcus, MD, PhD, requesting revised criteria for the release of patients who may expose members of the public to more than 100 mrem. The NRC expects to propose a final rule by December, 1993, and plans to publish a regulatory guide to accompany the rule. Possible actions include a mandate that physicians provide written guidelines on how to reduce the exposure rate to members of the public and a requirement that physicians keep records for five years on patients released under the revised criteria.

Enforcement Actions. In April the NRC published a new policy, effectively immediately, that increases penalties for medical misadministrations by modifying severity levels. Previously, misadministrations would trigger a Level II or III violation and result in civil penalties consistent with the severity of the incident. Under the new policy, these severity levels apply to any misadministration regardless of the dose. Programmatic

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problems may also be enough to result in a Level II or III violation and subsequent civil penalties.

Since this new policy will put nuclear medicine licensees at a greater risk of penalty, ACNP and SNM will challenge NRC's procedural decision to make such a significant change in policy without prior public notice and comment.

DEPARTMENT OF ENERGY

Isotope Supply. A follow-up to last year's oversight hearing on isotope production and distribution is planned by Rep. Synar of the House Governmental Operations Committee, but no date has been set. The National Electrical Manufacturers Association has taken an interest in this issue and has retained a consultant to gather data on isotope needs in the United States for presentation to Rep. Synar's committee. The search for a reliable domestic source of Mo-99 continues with the future of the Omega West Reactor at Los Alamos National Laboratory uncertain following detection of a coolant leak and other problems (see *Newsline,* April 1993, p. 20N). Meanwhile, as pressure mounts on national labs to diversify into "peace time" initiatives, other opportunities have arisen. Sandia National Laboratory claims to have a facility capable of producing ^{99}Mo and many other isotopes needed by the nuclear medicine community. Babcock & Wilcox, a contractor has developed a reactor design that promises to be remarkably cost effective and is trying to interest investors in building a reactor facility dedicated to medical radioisotope production.

New Research Director. Martha Krebs, a former staff member of the House Committee on Science and Technology, will replace William Happer, Jr., PhD, as director of the DOE Office of Energy Research. Ms. Krebs most recently worked at Lawrence Berkeley Laboratory and her experience could suit her well to understanding nuclear medicine research funding and isotope availability concerns.

ENVIRONMENTAL PROTECTION AGENCY

Clean Air Act. Are hospitals and radiopharmacies required to comply with the Environmental Protection Agency's National Emission Standards for Hazardous Air Pollutants (NESHAPs)? The question alludes an easy answer. Medical, academic and research centers in 1990 obtained a two-year stay from compliance with the Environmental Protection Agency's National Emission Standards for Hazardous Air Pollutants (NESHAPs), during which time the EPA evaluated whether NRC material licensees operate under an adequate margin of safety under NRC requirements. The EPA concluded that 98% of all facilities are in compliance under existing NRC regulations. But the stay on NESHAPs expired on November 15, 1992–prior to the EPA formally exempting NRC material licensees. When a federal appeals court ruled earlier this year in favor of environmental groups that had challenged the EPA's authority to waive compliance with the Clean Air Act, it appeared that medical licensees would be held responsible for documenting compliance with NESHAPs. But in a recent meeting with ACNP and SNM staff, EPA officials said they plan to finish drafting a rule by August 1993 that would officially exempt medical licensees.

When asked how EPA plans to treat NRC licensees for the four-month gap period, officials responded that EPA inspectors are not being trained to review material licensees for compliance with NESHAP regulations. ACNP and SNM interprets this to mean that NRC medical licensees will not be held accountable to NESHAPs.

LOW-LEVEL RADIOACTIVE WASTE

California. The California State Court of Appeals in Sacramento ruled in May in favor of the ACNP and SNM in a law suit challenging the state's mandate to hold adjudicatory hearings. The decision stated that adjudicatory hearings are not necessary to address safety and liability issues posed by the Ward Valley LLRW disposal facility. Governor Pete Wilson ordered the Department of Health Services to decide within 30 days if a license should be granted to U.S. Ecology for development of the Ward Valley site. Two obstacles still remain before construction of the Ward Valley site can commence. State authorities await the transfer of land from the federal government to the state of California. Interior Secretary Bruce Babbitt, handling the situation with extreme caution, has neither approved nor opposed the land transfer. The other obstacle is a suit filed in San Francisco that would bar development of the waste repository until it is proven that the proposed site does not impinge on the habitat of the desert tortoise, which is protected under the Endangered Species Act. The federal government has yet to designate a critical habitat for the tortoise.

Congressional Action. ACNP and SNM met with several congressional staffers to discuss the possibility of amending, again, the Low-Level Radioactive Waste Policy Act to revamp the current siting process. Lawmakers appear content to leave the issue in the hands of the states. Several members of Congress, including Senators Joseph Lieberman and Christopher Dodd of Connecticut, and Representative Synar of Oklahoma, have asked the GAO to evaluate the siting process for LLRW facilities under the current system. This report will be issued in the near future.

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