GOVERNMENT RELATIONS UPDATE

The Joint Office of Government Relations of The Society of Nuclear Medicine and the American College of Nuclear Physicians presents the following report on regulatory developments, radioisotope supply, radioactive waste disposal, and other national issues affecting nuclear medicine:

NUCLEAR REGULATORY COMMISSION

Quality Management Rule

Following a U.S. Court of Appeals ruling that upheld the NRC's quality management rule, the SNM and ACNP hold the option of asking Congress to limit the agency's mandate to regulate the medical use of isotopes. Citing NRC's "broad statutory mandate" to "minimize" danger to life and property, the court said the NRC is not bound by limitations such as economic impact or regulatory burden and was therefore unable to overturn the QM rule for procedural reasons. The merit of the SNM and ACNP case against the QM rule is supported by the Office of Management and Budget, which stated flatly that the burden imposed by the regulations is not justified (see sidebar on p. 34N).

The NRC appears to be making an effort to re-evaluate its medical uses division internally. The Commission called a special meeting of the Advisory Committee for the Medical Uses of Isotopes (ACMUI) on July 29 and 30. The ACNP and SNM will analyze NRC's administrative agenda, and then reconsider whether a legislative fix is still necessary.

Meanwhile, the NRC is in the process of training inspectors for the QM program. Inspections should begin shortly. The NRC has also made an effort to clarify the rule guidance. The staff has developed a single-page check list to be completed for each patient receiving a therapy dose or a dose greater than 30 mCi.

The ACNP/SNM appropriated $15,000 each for fiscal 1992 (a total of $30,000) for legal fees associated with the QM lawsuit. The case was concluded with expenditures of approximately $7,500 by each association. The SNM supported the initial phases of the petition, but these costs were off-set by $4,000 in pledges from the AMA and the USCEA Committee on Radionuclides and Radiopharmaceuticals.

Testing for Pregnancy

The NRC is developing the first addition to the QM program. Within the coming months, the Commission will publish a proposed rule on the pregnancy and lactation testing of women prior to the administration of a radiopharmaceutical. The rule is expected to require that the status of the woman be verified with one of several methods. While the ACMUI supported the intent of the rule, it opposed the initial draft and the commissioners themselves challenged the draft during a June 1 briefing.

Medical Use Program

The NRC Medical Use Division in June presented the status of its "Five-Point Program" for improving the regulation of the medical uses of radioisotopes. In contrast to previous NRC staff reports, the commissioners were remarkably prepared to debate the issues of concern to nuclear medicine. Appearing conciliatory, the commissioners urged staff to develop a common denominator of risk assessment when identifying the need for regulation and requested that the ACMUI work directly with the commissioners, as the reactor advisory committees do.

Licensing Fee

The SNM and ACNP petitioned the NRC to reduce licensing fees, which the societies say unfairly burden medical licensees. The NRC published the petition for rule making in the *Federal Register* on May 12, 1992. Since releasing its dramatically increased fee schedule, the NRC has made several changes to its fee regulations, including a decrease in the billing intervals for some license fees and a reduction in the amount of annual fees assessed to certain small entities. The revised fee structure, effective on May 18, 1992, includes a lower-tier, small-entity annual fee of $400 for small businesses and nonprofit organizations with annual gross receipts of less than $250,000 and small governmental jurisdictions with a population of less than 20,000. Maximum annual fees for all other small entities remain at $1,800.

Through licensing, inspection, and annual fees charged to licensees, the NRC must recover $492.5 million for fiscal year 1992. Some 2,000 licensees have requested that their licenses be terminated since adoption of the final rule in 1991.

The ACNP and SNM petition proposes fees based on a sliding scale, and calls for not-for-profit and teaching medical centers to be exempt from fees. The medical societies say that fee hikes to medical licensees should require the approval of the Department of Health and Human Services and be reflected by an increase in Medicare fee schedule reimbursements for nuclear medicine.

Investigator General Probe

The NRC Office of the Investigator General has initiated a probe of the NRC Medical Uses staff. Stephen D. Potts, Director of the U.S. Office of Government Ethics, was asked in a letter sent by a physician to investigate "grave ethical breaches" and examples of how NRC regulation has interfered

with the practice of medicine. Mr. Potts was unable to review the NRC since the NRC is an independent agency, but he conveyed the letter to the NRC Investigator General and requested to personally receive the results of the inquiry.

Radiation Protection

The NRC postponed until January 1, 1994 the deadline when licensees are required to implement the revised standards for protection against radiation (10CFR 20. 1001-20.2401). The NRC needed more time to develop regulatory guides and to ensure that resources are available to meet the regulatory requirements. The postponement also provides a uniform implementation date for NRC licensees and Agreement States.

FOOD AND DRUG ADMINISTRATION

Positron Emission Tomography

An advisory committee to the Food and Drug Administration in May recommended approval of a drug master file for fluorine-18 fluorodeoxy glucose (FDG) submitted by the Institute for Clinical PET (see story on p. 24N). In testimony to the Medical Imaging Drugs Advisory Committee (MIDAC), the ACNP and SNM urged FDA to approve the DMF based on its scientific merit and called for expediency so that HCFA could develop a policy for PET reimbursement—an issue of great importance to Medicare patients and nuclear medicine professionals. Primary purpose of the SNM and ACNP testimony, however, was to advance the position that the compounding and local intrastate distribution of FDG is rightfully controlled by state laws governing the practices of medicine and pharmacy. The societies maintain that drug approval by the FDA is necessary only for a manufacturers who introduce PET tracers into interstate commerce.

MIBG Brain Imaging

MIDAC also recommended approval for I-131-meta-iodobenzylguanidine (MIBG) as a tracer for determining specific sites of pheochromocytomas and neuroblastomas in adults and children. CIS-US, Inc. is sponsoring the New Drug Approval for MIBG.

Orphan Drug Coalition

The ACNP has joined the Coalition for Orphan Drug Research in an effort to prevent Congress from weakening the Orphan Drug Act. The Senate Labor and Human Resources committee has already held two hearings this year on the future of the law, which gives drug companies a patent-like protection for the first seven years that an orphan drug is on the market. The act rewards companies who develop promising compounds for treatment of rare diseases by granting exclusive rights to market the drug. The proposed change would strip companies of their market exclusivity once an arbitrary sales cap has been reached. SNM and ACNP believe that this attempt to manipulate the marketplace would have a chilling effect on future research and development of other orphan drugs.

ENVIRONMENTAL PROTECTION AGENCY

National Emission Standards

The EPA completed its study of radionuclide air emissions from NRC and Agreement State licensees and has indicated that medical licensees are meeting EPA dose limits. The agency is expected to publish soon the results of their survey and is likely to exempt nuclear medicine facilities from National Emission Standards for Hazardous Air Pollutants (NESHAPs). NRC is expected to present to the EPA their proposal to monitor radionuclide air emissions generated by NRC licensees. Several options have already been discussed by the NRC and EPA and include re-surveying medical licensees. The EPA previously stayed the NESHAPs for NRC and Agreement State medical licensees until November 1992.

Mixed Waste Petition

The Utility Solid Waste Activities Group (USWAG) petitioned the EPA to rewrite its guidelines for regulating hazardous waste that is mixed with radioactive waste. The petition proposes a mechanism for resolving dual and conflicting EPA and NRC regulation of this waste by allowing generators to reclassify it as low-level radioactive waste or store it on site. The EPA has put off a decision on the petition until a joint EPA-NRC survey of mixed waste generators yields information on how much and what type of waste they produce. The survey was set for completion in July. The ACNP and SNM submitted comments to the EPA supporting the concept behind the USWAG petition, but pointed out that on-site storage is only a temporary solution to the larger hazardous and radioactive waste problems.

DEPARTMENT OF ENERGY

National Biomedical Tracer Facility

The Office of Government Relations enlisted the help of Society and College members in a letter writing campaign seeking support from lawmakers for the construction of a dedicated high-energy accelerator for medical and research radioisotope production. The House and Senate Energy and Water Appropriations Subcommittees were asked to urge the DOE to authorize emergency funding of $2 million, which would be split among the most promising proposals for developing the National Biomedical Tracer Facility. At least seven institutions, either national labs or universities, have expressed interest in the NBTF. According to the plan developed by the SNM's NBTF task force, site selection would be based

on a competitive scientific review of the proposals, then the Administration would be asked in fiscal 1993 to appropriate funds for construction, which would take at least four years. Although the DOE has not made the NBTF a priority, some 40 members of Congress have responded to the letter-writing campaign by calling the Joint Office of Government Relations.

LOW-LEVEL RADIOACTIVE WASTE

Repository Closures

The South Carolina State Legislature voted in June to let the Barnwell low-level waste repository remain in business until 1996. The site is scheduled to remain open to waste from states outside the Southeast Compact only until July 1, 1994. And starting in 1993, surcharges on out-of-compact waste shipped to Barnwell will increase to $160 per cubic foot—an increase of $40 per cubic foot. Starting January 1, 1993, the Beatty, Nevada low-level waste site will close and the Richland, Washington facility will accept only waste from states in the Rocky Mountain Compact and the Northwest Compact.

Waste Network

The U. S. Council for Energy Awareness, the public relations organization of the nuclear power industry, is developing a low-level radioactive waste network with representatives from all the major rad waste producers. This network, which includes the ACNP and SNM, will be used to provide resources to various organizations and institutions about the benefits of proper burial of LLRW and the important uses of radioactivity. The SNM and ACNP government relations office has served as a liaison between USCEA and the nuclear medicine community.

REIMBURSEMENT FOR HEALTH CARE

Medicare Fee Schedule

Government relations staff continue efforts to convince the Health Care Financing Administration (HCFA) to acknowledge that nuclear medicine services are undervalued in the final Medicare Fee Schedule published in November 1991. A special task force met during the ACNP annual meeting last February to formulate a response to HCFA.

Comments submitted in March 1992 on behalf of SNM and ACNP called for a general correction in the fee schedule for a series of nuclear medicine codes and corrections to the interim relative value units, or RVUs, which determine payment rates for specific physician services. The inequity of the current RVU system for nuclear medicine was illustrated through the analysis of payment for pulmonary perfusion imaging. A two-phase process for developing a radiopharmaceutical price resource was presented.

Government relations staff supplied phase one results to HCFA, including background information on radiopharmaceuticals and the factors influencing the costs to physicians furnishing radiopharmaceuticals, a listing of FDA-approved radiopharmaceuticals, and a description of the approach to determine radiopharmaceutical acquisition costs. The comments also requested that HCFA clarify its policy on payment

Presidential Budget Office Lambastes NRC's Quality Management Rule

The U.S. Office of Management and Budget in June resoundingly disapproved of the record-keeping requirements of the Nuclear Regulatory Commission's medical quality management program.

While the NRC can overturn the decision, the OMB's rejection of the record-keeping requirements bolsters claims by physicians that the NRC regulations will drain resources without improving safety. The OMB is an office under the President charged with assessing the burden of new Federal regulations.

After reviewing the requirements of the QM program, which became effective in January 1992, OMB officials found scant evidence that the regulations would prevent misadministrations and concluded that the NRC had not justified the burdens imposed on nuclear medicine.

The Society of Nuclear Medicine and the American College of Nuclear Physicians unsuccessfully petitioned a Federal court to void the QM program, which the two associations claimed was an unnecessary and costly intrusion into the practice of medicine. The case was decided in favor of the NRC in May 1992 (see *Newsline* July, 1992, p. 19N).

The head of OMB's Office of Information and Regulatory Affairs, James B. MacRae, Jr., said in a letter to the NRC, dated June 26, 1992, that "the reporting and record keeping requirements will have little if any practical utility furthering the goal of reducing injuries from misadministrations. Therefore, any significant burden is unreasonable, whether that burden amounts to 20,000 hours (as the NRC estimates) or 200,000 hours (as the professional association estimates)."

"The OMB decision confirms that the medical community is justified," says Kristen D.W. Morris, director of government relations for the SNM and ACNP. She says that the decision carries "enormous political clout" should the SNM and ACNP decide to seek help from Congress or the White House to limit the NRC's regulation of medicine.

The immediate effect of OMB's disapproval was to suspend the record-keeping requirements of the QM program, including misadministration reports. According to an internal memo, NRC lawyers have determined that agency is prohibited from enforcing the information collection requirements after June 26, 1992. All of the rule's other measures are still in effect, however, and licensees will be held accountable for reporting misadministrations and other required information from January 27, 1992 to June 26, 1992. The suspension will be lifted if the Commission decides to overrule the disapproval, which Ms. Morris says is likely.

"Although the NRC has the authority to overturn the OMB disapproval," says Stanley J. Goldsmith, MD, chairman of government relations for SNM, "it certainly should give the commissioners reason to pause and consider again the merits of the regulation before they vote to overturn the OMB."

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for stressing agents and in- and out-patient hospital services. Phase II, the creation of the price listing, will be conducted under the supervision of an independent contractor.

Office of Payment Policy

On May 20, ACNP and SNM representatives met with HCFA's of Office of Payment Policy for feedback on the groups' comments on the Medicare fee schedule. HCFA stated that ACNP and SNM requests would require the agency to deviate from the radiology fee schedule. HCFA maintains that the radiology fee schedule was established through legislation, which prohibits the agency from modifying nuclear medicine RVUs. This interpretation denies nuclear medicine the due process for revising RVUs that is granted to other medical specialties. It is doubtful that lawmakers intended this interpretation, but HCFA awaits clarification from Congress. In the meantime, HCFA has begun to re-evaluate the nuclear medicine RVUs.

AMA Update Committee

If HCFA does not agree to revise nuclear medicine RVUs, the SNM and ACNP could propose revisions to the AMA's RVU Update Committee, an interspecialty advisory body to HCFA that evaluates proposed RVU revisions by secret ballot. Some 23 specialty organizations hold seats on the panel. The SNM and ACNP jointly hold a two-year rotating seat.

PPRC Report to Congress

In its 1992 annual report to Congress, the Physician Payment Review Commission recommended changes to the Resource Based Relative Value Scale (RBRVS) for the medicare fee schedule. The PPRC, a congressional advisory body on Medicare, said that the fee schedule should be refined to assure equitable payment to physicians. The report favored changes to correct problems with the relative value scale rather than modifications of transitional rules or exceptions in the fee schedule for specific types of physicians. The PPRC also said that refinements should be made openly and with the involvement of public and private payers, practitioners, and consumers.

The PPRC report carried several sobering messages. The document stated that the number of physicians exceeds, or will soon exceed, that required to meet national health care needs and called for limits on physician incomes. Since Medicare began in 1965, the report noted that physician income has grown by 13% each year and that radiologists (including nuclear medicine physicians) earn the second highest average income of all specialists, about $200,000 per year. Since Medicare accounts for almost a quarter of all fees collected by physicians, the PPRC argued that Medicare reform should play a significant role in containing these costs.

SPECT

The SNM Board of Trustees in June endorsed an industry-sponsored project to advocate equitable reimbursement for clinical single photon emission computed tomography. Managed by the Joint Office of Government Relations, the SPECT project is intended to promote the diagnostic and prognostic capabilities of SPECT imaging and to improve, through education, the clinical and research utilization of SPECT to produce new insights into maladies such as breast cancer, Alzheimer's disease, and heart disease. The ACNP, SNM, and industry are each represented on the steering committee of the project. Selected proposals for research, data collection, analysis, and methodology development will be passed to the steering committee for implementation. The SNM Office of Health Care Policy is expected to play a significant role in the project due to its expertise and overlap of its mission. The SPECT Project has been joined by nine paying members and has established liaisons with the American College of Radiology and the National Electrical Manufacturers Association.

LEGISLATIVE ACTIONS

Bans on Self-Referral

Pending congressional action on legislation that would prohibit physician referral to a facility in which the doctor has any ownership interest, several states have approved or are considering legislation that would restrict self-referral activity.

On April 8, 1992, Florida Governor Lawton Chiles signed into law legislation that will prohibit physicians from referring patients to facilities in which they have a financial interest, including diagnostic imaging centers, radiation therapy centers, clinical laboratory centers, physical therapy centers, and facilities that provide comprehensive rehabilitative services. The referral prohibition is effective October 1, 1995, for facilities that were in existence on May 1, 1992. The legislation includes a provision to retroactively include radiation therapy centers opened before April 1, 1991.

The Maryland legislature considered a similar self-referral bill. The state senate failed to take up the legislation prior to the session's adjournment but a similar bill is expected to be introduced next year.

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